The Federal Physician Payments Sunshine Act: Rules and Impact on Life Sciences Manufacturers, Physicians, and Teaching Hospitals

By Kelly N. Reeves, Brian A. Bohnenkamp, Caitlyn J. Ozier

¶21,580 Introduction

The federal Physician Payments Sunshine Act (Sunshine Act) requires certain pharmaceutical, biologic, and medical device manufacturers to annually report to CMS information about certain payments or other transfers of value they furnish to physicians and teaching hospitals (deemed "covered recipients").* The law also requires certain manufacturers and group purchasing organizations (GPOs) to annually report information about ownership or investment interests in their organizations held by physicians and their immediate family members.[1] CMS is required to aggregate the information manufacturers and GPOs submit and make it publicly available through a searchable website.[2]

The Sunshine Act was enacted on March 23, 2010, as part of the Patient Protection and Affordable Care Act (ACA).[3] CMS published the final rule to implement the requirements on February 8, 2013, and amended the regulations in a subsequent final rule published in November 2014.[4]

This chapter provides an overview of the Sunshine Act and the regulations adopted in the final rule and describes the obligations that the rule imposes on life sciences manufacturers and GPOs.

¶21,585 Compliance Dates

Life sciences manufacturers that are subject to the federal Physician Payments Sunshine Act (Sunshine Act) requirements were required to begin collecting data regarding payments and other transfers of value provided to covered recipients in accordance with the final rule starting August 1, 2013.[5] Applicable manufacturers and group purchasing organizations (GPOs) also were required to begin tracking ownership or investment interests held by physicians as of August 1, 2013.[6]

Disclosure reports providing information about interactions that occurred during the previous calendar year or reportable ownership/investment interests held during the previous year must be submitted by the 90th day of the calendar year (around March 31).[7] CMS must post submitted information on its public website annually by June 30.

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[1] Social Security Act § 1128G(a)(2).

[2] Social Security Act § 1128G(c)(1)(C).

[3] Patient Protection and Affordable Care Act (P.L. 111-148) § 6002, codified at Social Security Act § 1128G.

[4] Final rule, 78 FR 9458, February 8, 2013; Final rule, 79 FR 67548, 67758-67761, November 13, 2014.

[5] Final rule, 78 FR 9458, 9460, February 8, 2013.

[6] Id.

[7] 42 C.F.R. § 403.908(a).

The Sunshine Act requires CMS to submit annual reports to the states and Congress about the information submitted by applicable manufacturers and applicable GPOs.[8] For purposes of annual reporting to states, CMS clarified that states should utilize the data tools that CMS posts on its website to aggregate and filter data by state, as well as create state-specific data visualizations.[9] CMS submits annual reports to Congress regarding its implementation of the requirements by April 1 each year.[10]

¶21,590 Key Definitions

CMS defined and interpreted key terms, including, "applicable manufacturer," "covered product," and "covered recipients." in the final rule implementing the provisions of the federal Physician Payments Sunshine Act (Sunshine Act).[11]

Definition of "Applicable Manufacturer"

Under the adopted regulations, entities deemed "applicable manufacturers" are required to submit to CMS annual reports of payments or other transfers of value they provide to covered recipients.[12] The final rule defines "applicable manufacturer" as an entity that (a) has a physical location in the United States or otherwise conducts activities in the United States, whether directly or indirectly through contracted agents, (which the final rule defines as "operating in the United States") and (b) falls into one of two categories:

1. An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply ("covered products"), but not if such covered product 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 that do not hold title to any covered product.
2. An entity under common ownership with an entity in paragraph (1) that provides a service that is necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product.[13]

Regarding wholesalers and distributors, CMS states in the preamble to the final rule that it believes wholesalers and distributors "that hold the title to a [covered product] meet the definition of an applicable manufacturer for the purpose of this rule" and a manufacturer that "has product(s) with titles held by distributors does not need to report payments or other transfers of value made by the distributor[s] or wholesaler[s] to covered recipients, since these will be reported by the distributor or wholesaler."[14]

Importantly, as a general matter, if an entity is deemed an applicable manufacturer, it must report "all payments or transfers of value to covered recipients rather than only payments related to [covered products] . . . ."[15] The final rule, however, provides for more limited reporting by certain applicable manufacturers that have limited activities that relate to covered products. For instance, applicable manufacturers under paragraph 2 of the definition are only required to report payments or other transfers of value that are related to a covered product for which they provided assistance or support to an applicable manufacturer under paragraph 1.[16] In addition, applicable manufacturers with gross revenues from covered products that constitute less than 10 percent of total gross revenue for a fiscal year preceding a reporting year are only required to report payments or other transfers of value that relate to covered products.[17] Also, applicable manufacturers that have divisions that do not manufacture any covered products (e.g., an animal health division) are only required to report payments or other trans-

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[8] Social Security Act § 1128G(d)(1), (2).

[9] Reports to States, CMS Open Payments, https://www.cms.gov/OpenPayments/Explore-the-Data/Reports-to-states.html.

[10] Annual Report to Congress on the Open Payments Program For Fiscal Year 2014, https://www.cms.gov/OpenPayments/Downloads/Open-Payments-April-2015-Report-to-Congress.pdf.

[11] Final rule, 78 FR 9458, 9460, February 8, 2013.

[12] 42 C.F.R. § 403.904(a).

[13] 42 C.F.R. § 403.902.

[14] Final rule, 78 FR 9458, 9462, February 8, 2013.

[15] Id.

[16] 42 C.F.R. § 403.904(b)(2).

[17] 42 C.F.R. § 403.904(b)(1).

fers of value incurred by those divisions that relate to covered products.[18]

In addition, separate and aside from the scope of the requirements, the final rule provides that applicable manufacturers that are under common ownership with one another may, but are not required to, file consolidated disclosure reports.[19] When manufacturers opt to use consolidated reporting, the applicable manufacturer that files the consolidated report must identify which manufacturer was responsible for each payment. The applicable manufacturer that files the consolidated report also is liable for civil money penalties that might be imposed on each of the applicable manufacturers included within the consolidated report.[20]

Tip: A company should thoughtfully determine which entities and affiliates are subject to the Sunshine Act reporting requirements as "applicable manufacturers," and should consider consulting legal counsel when making these determinations. For those entities and affiliates the company determines are "applicable manufacturers," the company should:

- implement systems to track and record interactions with covered recipients;
- implement systems and processes to report those interactions to CMS in the manner required;
- train sales representatives and other employees who might make payments or transfers of value to covered recipients on the systems and processes for recording these payments or transfers of value and the importance of recording the information completely, accurately, and timely; and
- educate covered recipients on how the organization approaches compliance with the requirements.

Definition of "Covered Products"

CMS generally interprets "covered products" as those for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, either separately or as part of a bundled payment (regardless of whether the product is actually reimbursed in any particular situations through one or more of these federal programs).[21] For drugs and biologics, the definition is limited to those that, by law, require a prescription to be dispensed. For medical devices (or medical supplies that are medical devices), the definition is limited to those that require Food and Drug Administration (FDA) premarket approval or notification. Under this regulatory framework, entities that manufacture exclusively over-the-counter drugs and/or certain Class I or Class II medical devices (those that do not require premarket approval or notification under the 510(k) process, as determined by FDA) would not be subject to the Sunshine Act reporting requirements and, therefore, their interactions with covered recipients would not be publicly disclosed.

Definition of "Covered Recipients"

Applicable manufacturers must submit to CMS annual reports of direct and indirect payments or other transfers of value they provide to "covered recipients," or entities or individuals at the request of, or designated on behalf of, "covered recipients."[22] "Covered recipients" are defined in the final rule to include "physicians" and "teaching hospitals."[23]

The regulations define "physician" in accordance with the definition of "physician" provided in the Social Security Act, which includes licensed doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors.[24] The final rule specifically excludes as covered recipients those physicians who are employees of the applicable manufacturer that would report the payment (e.g., an employed medical director).[25] In addition, CMS noted in the preamble to the final rule that "residents (including residents in medicine, osteopathy,

[18] 42 C.F.R. § 403.904(b)(3).
[19] 42 C.F.R. § 403.908(d)(1).
[20] Id.
[21] 42 C.F.R. § 403.902.
[22] 42 C.F.R. § 403.904(a).
[23] 42 C.F.R. § 403.902.
[24] Id (citing Social Security Act § 1861(r)).
[25] 42 C.F.R. § 403.902.

dentistry, podiatry, optometry, and chiropractic) will not be required to be reported."[26]

The regulations define "teaching hospitals" as institutions that receive direct or indirect graduate medical education (GME or IME) payments from CMS during the last calendar year for which the information is available.[27] CMS notes that it will publish a list of teaching hospitals annually "at least 90 days in advance before the beginning of the reporting year, or for the first reporting year, at least 90 days prior to the start of data collection."[28]

Notably, in October 2018, President Trump signed into law the "SUPPORT for Patients and Communities Act" (P.L. 115-271) that, among other things, expanded the list of covered recipients under the Sunshine Act beyond physicians and teaching hospitals to also include: (1) physician assistants; (2) nurse practitioners; (3) clinical nurse specialists; (4) certified nurse anesthetists; and (5) certified nurse-midwives.[29] The expanded list of covered recipients will apply "with respect to information required to be submitted under §1128G of the Social Security Act [the Sunshine Act] on or after January 1, 2022."[30]

Tip: A company should thoughtfully determine which individuals and entities it interacts with are considered "covered recipients" under the Sunshine Act.

¶21,595 Payments or Other Transfers of Value

Under the federal Physician Payments Sunshine Act (Sunshine Act) regulations, applicable manufacturers must report direct and indirect "payments or other transfers of value" they furnish to covered recipients. Applicable manufacturers also must report payments or other transfers of value furnished to entities or individuals at the request of, or designated on behalf of, covered recipients.[31]

Definition of "Value"

The regulations define "payments or other transfers of value" as "a transfer of anything of value."[32] In the preamble, CMS states that it interprets "value" to mean "discernible economic value on the open market in the United States" and believes that "applicable manufacturers should be allowed flexibility to determine value."[33]

Indirect Payments

The regulations expressly define "indirect payments or other transfers of value," as payments or other transfers of value made to a covered recipient through a third party when the applicable manufacturer "requires, instructs, directs, or otherwise causes" the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient.[34] The preamble of the final rule includes the following examples of payments that CMS would consider indirect payments:

1. "If an applicable manufacturer gave money to a medical professional society earmarked for the purpose of funding awards or grants for physicians, the awards or grants would constitute indirect payments to covered recipients and would be subject to the reporting requirements."[35]
2. "[A]n applicable manufacturer may provide a general payment to a clinic for one of its employed physicians to review materials. In this case, the applicable manufacturer directed that the payment be provided to a physician covered recipient, so it would constitute an indirect payment and would be a reportable indirect payment or other transfer of value."[36]

Under the regulations, an indirect payment is not reportable if provided to a covered recipient and the applicable manufacturer "does not know . . . the identity of the covered recipient during the reporting year or by the end of the second quarter of the

[26] Final rule, 78 FR 9458, 9467, February 8, 2013.
[27] 42 C.F.R. §403.902.
[28] Final rule, 78 FR 9458, 9470, February 8, 2013.
[29] SUPPORT for Patients and Communities Act (P.L. 115-271), §6111, October 24, 2018.
[30] Id.
[31] 42 C.F.R. §403.904(a).
[32] 42 C.F.R. §403.902.
[33] Final rule, 78 FR 9458, 9470, February 8, 2013.
[34] 42 C.F.R. §403.902.
[35] Final rule, 78 FR 9458, 9490, February 8, 2013.
[36] Id.

following reporting year."[37] CMS defined "know" broadly as having "actual knowledge of the information," acting "in deliberate ignorance of the truth or falsity of the information," or acting "in reckless disregard of the truth or falsity of the information."[38] In the final rule, however, CMS clarified that when a manufacturer makes a payment or other transfer of value through a third party so that the identity of the covered recipient remains anonymous, CMS will not consider the applicable manufacturer to be acting in deliberate ignorance or reckless disregard of a covered recipient's identity. CMS provided the example of double-blinded market research to illustrate this point.[39]

Tip: A company should understand how institutional interactions with industry might implicate the Sunshine Act requirements (e.g., research agreements, educational grants, etc.).

¶ 21,600 Payments or Other Transfers of Value Not Subject to Reporting

The federal Physician Payments Sunshine Act (Sunshine Act) regulations identify certain payments or other transfers of value that are excluded from the reporting requirements.

Exclusions from Reporting

The regulations require applicable manufacturers to report direct and indirect "payments or other transfers of value" they furnish to covered recipients or entities or individuals at the request of, or designated on behalf of, covered recipients.[40] The final rule expressly excludes 14 types of payments, items, and other benefits from the reporting requirements. These exclusions include:

- indirect payments or other transfers of value where applicable manufacturer does not "know" the identity of the covered recipient during the reporting year or by the end of the first half of the following reporting year;[41]
- transfers of value that are under $10, when the total value of all payments or transfers of value made to a single covered recipient do not exceed $100 during the reporting year;[42]
- product samples (including coupons and vouchers) that are not intended to be sold and are intended for patient use;[43]
- educational materials that directly benefit patients or are intended for patient use, which CMS interprets to includes things like "anatomical models" and "wall charts," but not "medical textbooks" or "journal reprints;"[44]
- the loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days or a quantity of 90 days of average daily use, to permit evaluation of the device or medical supply by the covered recipient;[45]
- items or services provided under a contractual warranty (including service or maintenance agreements), whether or not the warranty period has expired, including the replacement of a covered device, when the terms of the warranty are set forth in the purchase or lease agreement for the covered device;[46]
- payments or other transfers of value when the physician covered recipient is a patient, research subject, or participant in data collection for research and not acting in the professional capacity of a covered recipient;[47]
- discounts and rebates;[48]

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[37] 42 C.F.R. § 403.904(h)(1).

[38] 42 C.F.R. § 403.902.

[39] Final rule, 78 FR 9458, 9490, February 8, 2013.

[40] 42 C.F.R. § 403.904(a).

[41] 42 C.F.R. § 403.904(h)(1).

[42] 42 C.F.R. § 403.904(h)(2). The $10 and $100 thresholds are updated annually in accordance with any update to the consumer price index for urban consumers. For the 2019 program year, the de minimis thresholds are $10.79 and $107.91. Data Collection for Applicable Manufacturers and GPOs, Open Payments, https://www.cms.gov/OpenPayments/Program-Participants/Applicable-Manufacturers-and-GPOs/Data-Collection.html.

[43] 42 C.F.R. § 403.904(h)(3).

[44] 42 C.F.R. § 403.904(h)(4); Final rule, 78 FR 9458, 9486, February 8, 2013.

[45] 42 C.F.R. § 403.904(h)(5).

[46] 42 C.F.R. § 403.904(h)(6).

[47] 42 C.F.R. § 403.904(h)(7).

[48] 42 C.F.R. § 403.904(h)(8).

- in-kind items used in the provision of charity care;[49]
- a dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund;[50]
- in the case of an applicable manufacturer who offers a self-insured plan or directly reimburses for health care expenses, payments for the provision of health care to employees and their families;[51]
- payments or transfers to a physician covered recipient who is a licensed nonmedical professional, if the transfer is payment solely for the covered recipient's nonmedical professional services;[52]
- payments or transfers of value to a physician covered recipient if the transfer is payment solely for services related to an administrative proceeding, legal defense, prosecution, or settlement or judgment of a civil or criminal action and arbitration;[53] and
- payments or other transfers of value made solely in the context of personal, non-business-related relationships.[54]

Food and Incidental Items Provided at "Large-Scale" Events

The Sunshine Act regulations provide that applicable manufacturers are not required to report or track "buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a large-scale conference or similar large-scale event."[55] The preamble to the final rule additionally notes that "small incidental items that are under $10 (such as pens and note pads)" provided to covered recipients during similar large-scale events are also excluded from reporting.[56]

¶21,605 Food Provided to Covered Recipients

The federal Physician Payments Sunshine Act (Sunshine Act) regulations provide express instructions for how applicable manufacturers must allocate the cost of food and beverages provided to covered recipients in group settings when individual costs are not separately identifiable.[57] Specifically, the rule requires applicable manufacturers to calculate the value per person by dividing the entire cost of the food or beverage by the total number of individuals who partook in the meal (including both covered recipients and noncovered recipients, such as office staff). CMS noted in the preamble to the final rule that applicable manufacturers must only report on those covered recipients who partook in the food and beverages, and "does not require the reporting of meals eaten by office staff", however, there may be contexts when a meal provided to a member of a physician's office staff constitutes value to the physician covered recipient.[58]

In addition to the general reporting obligations for food and beverages provided to covered recipients, the Sunshine Act regulations provide a limited exclusion from reporting for "buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a large-scale conference or similar large-scale event."[59]

¶21,610 Contents of Disclosure Reports

The federal Physician Payments Sunshine Act (Sunshine Act) regulations require applicable manufacturers to report direct and indirect payments or other transfers of value they furnish to covered recipients or entities or individuals at the request of, or designated on behalf of, covered recipients.[60] For each direct or indirect payment or other transfer of value not excluded from reporting, the applicable manufacturer must report to CMS the following information:

- the name of the covered recipient;
- the "primary" business address of the covered recipient;

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[49] 42 C.F.R. §403.904(h)(9).
[50] 42 C.F.R. §403.904(h)(10).
[51] 42 C.F.R. §403.904(h)(11).
[52] 42 C.F.R. §403.904(h)(12).
[53] 42 C.F.R. §403.904(h)(13).
[54] 42 C.F.R. §403.904(h)(14).
[55] 42 C.F.R. §403.904(g)(2).
[56] Final rule, 78 FR 9458, 9485, February 8, 2013.
[57] 42 C.F.R. §403.904(g).
[58] Final rule, 78 FR 9458, 9479, February 8, 2013.
[59] 42 C.F.R. §403.904(g)(2).
[60] 42 C.F.R. §403.904(a).

- if the covered recipient is a physician, the National Provider Identifier (NPI), state license number, and specialty;
- the amount of the payment or other transfer of value;
- the date of each payment or other transfer of value;
- the form of the payment or other transfer of value, choosing one of six options: cash, in-kind items or services, stock, stock option, any other ownership interest, or dividend, profit or other return on investment;
- the nature of the payment or other transfer of value, choosing one of 17 options (e.g., consulting fee, food and beverage, education, research, royalty or license, etc.);
- the name(s) of the covered product(s) to which the payment or other transfer of value relates, if any;
- an indication as to whether the payment or other transfer of value is subject to delayed publication, which is available for certain types of research payments;
- if the payment or other transfer of value is made to an entity or individual at the request of (or designated on behalf of) a covered recipient, the name of the other entity or individual;
- an indication as to whether the payment or other transfer of value was provided to a physician who holds an ownership or investment interest in the applicable manufacturer; and
- if desired, a statement that provides additional context for the payment or other transfer of value.[61]

Tip: Manufacturers have some discretion to determine the best descriptor for each payment or other transfer of value. If there is no available nature descriptor that accurately describes a particular payment or other transfer of value, do not assume that the payment or other transfer of value is not reportable.

Tip: While manufacturers are allowed some flexibility in the manner in which payment dates are reported, the reporting method should be consistent within each nature of payment category.

Tip: In some cases, manufacturers may need to contact covered recipients to get the required information (e.g., NPI number).

¶ 21,615 Special Rules for Research Payments

The federal Physician Payments Sunshine Act (Sunshine Act) regulations generally require applicable manufacturers to report direct and indirect payments or other transfers of value they furnish to covered recipients, or to entities or individuals at the request of, or designated on behalf of, covered recipients.[62] The regulations also provide special requirements governing the information that must be reported for "research" payments that are subject to a written agreement or research protocol or both.[63] In addition, "research" is defined as "a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research."[64] In the preamble to the final rule, CMS interprets the definition of "research" to include "pre-clinical research and Food and Drug Administration (FDA) Phases I-IV research, as well as investigator-initiated investigations."[65]

Separate Reporting of Research Payments

Research payments that must be reported to CMS separately from other payments or other transfers of value, must include the following information:

- the name of the institution, individual or entity receiving the payment or other transfer of value;
- the total amount of the research payment, including all research related costs for activities outlined in a written agreement, research protocol, or both;
- the name of the research study;
- the names of any related covered products, if any;

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[61] 42 C.F.R. § 403.904(c)(1) - (12), (d).
[62] 42 C.F.R. § 403.904(a).
[63] 42 C.F.R. § 403.904(f).
[64] 42 C.F.R. § 403.902.
[65] Final rule, 78 FR 9458, 9482, February 8, 2013.

- the name, National Provider Identifier (NPI), state license number, specialty, and primary business address for each physician principal investigator;
- if desired, contextual information for the research; and
- if desired, the clinicaltrials.gov identifier.[66]

For pre-clinical studies that are conducted before any human studies have begun, applicable manufacturers are only required to report the following information:

- the name of the institution, individual, or entity receiving the payment or other transfer of value;
- the total amount of the research payment, including all research related costs for activities outlined in a written agreement, research protocol, or both; and
- the name, NPI, state license number, specialty, and primary business address for each physician principal investigator.[67]

In addition, the preamble to the final rule stated that the research payment amount reported "should include the aggregated amount of any payments for services included in the written agreement/research protocol," including "the costs associated with patient care, including diagnostics, exams, laboratory expenses, time spent by health care professionals treating the patient and managing the study, and the provision of study drugs, devices, biologicals, and medical supplies or other in-kind items."[68]

Delayed Publication of Certain Research Payments

The Sunshine Act regulations require CMS to delay publication of certain research payments or other transfers of value made under a product research or development agreement.[69] Specifically, publication of such research payments may be delayed if they relate to: (1) research on or development of a new (or a new application of an existing) drug, device, biological, or medical supply; or (2) clinical investigations regarding a new drug, device, biological, or medical supply.[70] For such publication to be delayed, the reporting applicable manufacturer must designate the research payments in question as being subject to the delay provisions.[71] Publication of such payments or other transfers of value is delayed until the first annual publication date after the earlier of: (1) the date of the approval, licensure, or clearance of the product by FDA; or (2) four calendar years after the date of the payment or other transfer of value.[72]

¶21,620 Physician Ownership and Investment Interests

In addition to requiring applicable manufacturers to report payments or other transfers of value provided to covered recipients, the federal Physician Payments Sunshine Act (Sunshine Act) requires each applicable manufacturer and applicable group purchasing organizations (GPOs)[73] to report certain information regarding any "ownership or investment interest" held by a physician (or his/her immediate family member, as defined in the final rule) in the reporting manufacturer or GPO.[74] Under the final rule, such interests held on or after August 1, 2013, must be annually reported CMS.

The regulations define "ownership or investment interest" as including, but not limited to, any direct or indirect: (1) stock or stock options (but not including those received as compensation, until they are exercised); (2) partnership shares; (3) limited liability company memberships; and (4) loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that

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[66] 42 C.F.R. § 403.904(f)(1).

[67] 42 C.F.R. § 403.904(f)(2).

[68] Final rule, 78 FR 9458, 9484, February 8, 2013.

[69] 42 C.F.R. § 403.910(a).

[70] Id.

[71] 42 C.F.R. § 403.910(d)(1).

[72] 42 C.F.R. § 403.910(c).

[73] Notably, the final rule broadly defines "applicable group purchasing organization" as an entity that has a physical location in the United States or otherwise conducts activities in the United States, which "purchases, arranges for or negotiates the purchase of [a covered product] for a group of individuals or entities, but not solely for use by the entity itself." CMS explains that this broad definition is expressly intended to include, among others, as many forms of physician owned distributor organizations as would be potentially captured by the statutory language of the Sunshine Act. See Final rule, 78 FR 9458, 9493, February 8, 2013.

[74] 42 C.F.R. § 403.906(a).

property or revenue.[75] It, however, would not include an ownership or investment interest in a publicly traded security or mutual fund, an interest that arises from a retirement plan through a physician's employment with an applicable manufacturer or applicable GPO, stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity, an unsecured loan subordinated to a credit facility, or an ownership or investment interest about which an applicable manufacturer or applicable GPO did not "know" (which is defined broadly to include actual knowledge of, or acting in deliberate ignorance or reckless disregard of, the information).[76]

Under the regulations, applicable manufacturers and applicable GPOs must report to CMS the following information for all ownership or investment interests that were held by a physician (or his/her immediate family member) during the preceding year:

- the name of the physician and whether the interest is held by an immediate family member;
- the primary business address of the physician;
- the physician's National Provider Identifier (NPI), state license number, and specialty (even if the interest is held by the physician's immediate family member);
- the dollar amount invested by the physician (or his/her immediate family member);
- the value and terms of the interest; and
- required information regarding any payment or other transfer of value provided to the physician holding the interest (in accordance with applicable requirements for reporting such payments or other transfers of value).[77]

¶21,625 Assumptions Documents

The federal Physician Payments Sunshine Act (Sunshine Act) regulations permit, but do not expressly require, applicable manufacturers to submit an assumptions document that describes the reasonable assumptions made and methodologies used when reporting payments or other transfers of value, including rationales for why particular "nature" descriptors were used to describe certain types of payments or other transfers of value.[78] These documents will not be made generally available to covered recipients, physician owners or investors, or the public.[79] CMS indicated in the preamble to the final rule that it intends to review assumptions documents submitted by applicable manufacturers to determine whether it needs to "publish more detailed guidance to assist applicable manufacturers in classifying the nature of payment categories, or other assumptions or methodologies included in the assumptions document."[80]

Notably, CMS also stated in the preamble to the final rule that it does "not intend to use the assumptions document for prosecution, but acknowledge[s] that the reporting based on the assumptions [whether produced to CMS or not] would be open to prosecution."[81] CMS further noted that other divisions with the Department of Health and Human Services, the Office of Inspector General, or the Department of Justice could "request access to the documents as part of an audit or investigation into an applicable manufacturer or applicable group purchasing organization (GPO)."[82]

In addition, in the event that a manufacturer's assumptions document would be requested under the Freedom Of Information Act (FOIA), CMS noted that it would follow its "predisclosure notification procedures at 45 C.F.R. §5.65(d) and seek the submitter's input on the applicability of FOIA Exemption 4, which protects trade secrets and commercial or financial information that is obtained from a person and is privileged or confidential."[83]

Tip: A company should consider consulting legal counsel when developing an assumptions document.

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[75] 42 C.F.R. §403.902.
[76] Id.
[77] 42 C.F.R. §403.906(b).
[78] 42 C.F.R. §403.908(f).
[79] Id.
[80] Final rule, 78 FR 9458, 9482, February 8, 2013.
[81] Id.
[82] Id.
[83] Id.

¶21,630 45-Day Review and Correction Period

The federal Physician Payments Sunshine Act (Sunshine Act) requires CMS to provide applicable manufacturers, applicable group purchasing organizations (GPOs), and covered recipients an opportunity to review and submit corrections to information submitted by applicable manufacturers and applicable GPOs for a period of not less than 45 days before CMS publicly posts the information.[84]

Process and Notification

To facilitate this review, CMS provides a secure website where each individual and entity, including covered recipients and physician owners or investors, may log-in and review information specific to it.[85] CMS also permits covered recipients to nominate one person in the system to review data on their behalf.[86] It will similarly notify applicable manufacturers and applicable GPOs that the information is ready for review through the points of contact identified for purposes of report filings.[87] CMS will notify physicians and teaching hospitals by using online posting and notifications on its listserves; however, covered recipients also may register with CMS to receive such a notification[88] Although registration is not mandatory for covered recipients to be able to review the data attributed to them, CMS strongly recommended that all covered recipients and physician owners or investors register and noted that they will be required to register so that CMS can appropriately match them to their data.[89] Upon review of the data, if a covered recipient agrees with the information, the covered recipient may certify electronically that the information is accurate.[90]

Disputes and Corrections

In the event a physician or teaching hospital disagrees with the information submitted by an applicable manufacturer or GPO, a dispute can be initiated directly with the applicable manufacturer or applicable GPO to resolve the issue.[91] If the dispute is not resolved within 15 days after the 45-day review period closes (i.e., 60 days after the 45-day review period begins), CMS will post the applicable manufacturer's or applicable GPO's version of the payment or other transfer of value and mark it as disputed.[92] Once any dispute is resolved, CMS will update the public website the next time that the website is refreshed. CMS will update the website at least once annually to make corrections of reporting errors.[93]

¶21,635 Public Availability of Reported Information

The federal Physician Payments Sunshine Act (Sunshine Act) requires CMS to publicly post information reported by applicable manufacturers and applicable group purchasing organizations (GPOs) following the covered recipient review and dispute period. CMS publishes the data on its Open Payments website.[94]

Tip: A company should consider how public disclosure of certain interactions will impact other institutional obligations, such as those associated with the receipt of National Institutes of Health (NIH) grant funding and applicable fraud and abuse laws (e.g., Anti-Kickback Statute and Stark law).

Tip: Health care professionals should consider how patients may react to public disclosure of payments or other transfers of value received from industry.

¶21,640 Penalties

Penalties for failing to timely, accurately, or completely report information as required by the federal Physician Payments Sunshine Act (Sunshine Act) regulations can be as high as $1,150,000 per applicable manufacturer or applicable group purchasing organization (GPO), per each annual

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[84] Social Security Act §1128G(c)(1)(D).

[85] 42 C.F.R. §403.908(g)(3).

[86] Review and Dispute for Physicians and Teaching Hospitals, CMS Open Payments, https://www.cms.gov/openpayments/program-participants/physicians-and-teaching-hospitals/review-and-dispute.html.

[87] 42 C.F.R. §403.908(g)(2).

[88] Id.

[89] Final rule, 78 FR 9458, 9499, February 8, 2013.

[90] 42 C.F.R. §403.908(g)(3)(iii).

[91] 42 C.F.R. §403.908(g)(3)(iv).

[92] 42 C.F.R. §403.908(g)(4).

[93] 42 C.F.R. §403.908(h)(2).

[94] CMS Open Payments Data, https://openpaymentsdata.cms.gov/.

submission.[95] Furthermore, in the event an applicable manufacturer or applicable GPO discovers an error or omission in its annual report, the applicable manufacturer or applicable GPO must submit corrected information to CMS "immediately upon confirmation of the error or omission."[96] Notably, in the preamble to the final rule, CMS stated that it does "not intend that errors corrected during the review and correction and dispute resolution periods will be subject to penalties for failure to report in instances when the original submission was made in good faith," but that "outside this period, any errors or omissions will be considered failures to report timely, accurate, or completely, and will be subject to penalties."[97]

Applicable manufacturers and applicable GPOs may be audited at any time for compliance to ensure the submission of timely, accurate, and complete reports.[98]

¶21,645 Document Retention Requirements

The federal Physician Payments Sunshine Act (Sunshine Act) regulations require applicable manufacturers and applicable group purchasing organizations (GPOs) to maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection by CMS, the Office of Inspector General, or their designees of the applicable manufacturer's or applicable GPO's compliance with the disclosure requirements.[99] Applicable manufacturers and GPOs must maintain the relevant documentation for a period of at least five years from the date the payment or other transfer of value is published on CMS' website.[100]

¶21,650 Preemption of State Laws

The federal Physician Payments and Sunshine Act (Sunshine Act) regulations expressly preempt any state statute or regulation that requires life sciences manufacturers to report the type of information required under the federal reporting requirements.[101] The Sunshine Act, however, neither preempts state law reporting requirements that require life sciences manufacturers to disclose the types of information excluded from federal reporting (e.g., certain educational materials) nor requirements to disclose payments to recipients on which manufacturers are not required to report under the federal obligations.

In recognition of the preemption provisions within the Sunshine Act, many states have acknowledged that they may not require manufacturers to report the same types of information that manufacturers are required to report to CMS. Many states, however, continue to collect data on other health care practitioners not covered by the Sunshine Act.

¶21,655 Subsequent Guidance and Materials from CMS

CMS has developed myriad resources for applicable manufacturers and group purchasing organizations (GPOs), covered recipients, and the public to understand the disclosure requirements and data published by CMS. For example, on its "OPEN PAYMENTS" website, CMS has posted and continues to update a growing list of frequently asked questions (FAQs) items and other implementation guidance documents and resources (e.g., fact sheets designed for applicable manufacturers, applicable GPOs, physicians, and teaching hospitals). CMS has also published an "Open Payments User Guide for Reporting Entities" that provides definitions, descriptions, screenshots, tools, and tips designed to help applicable manufacturers and applicable GPOs prepare and submit data to CMS.[102]

¶21,660 Conclusion

The federal Physician Payments Sunshine Act has broad implications for life sciences manufacturers and health care professionals and organizations.

[95] 42 C.F.R. §403.912. The penalty amounts set forth in the final rule are increased annually in accordance with annual inflation adjustments using the percent increase in the Consumer Price Index for all Urban Consumers. Final rule, 78 FR 9458, February 8, 2013.

[96] 42 C.F.R. §403.908(h)(1).

[97] Final rule, 78 FR 9458, 9507, February 8, 2013.

[98] Audits and Penalties, CMS Open Payments, https://www.cms.gov/OpenPayments/Program-Participants/Applicable-Manufacturers-and-GPOs/Audits-and-Penalties.html.

[99] 42 C.F.R. §403.912(e).

[100] Id.

[101] 42 C.F.R. §403.914.

[102] Resources, CMS OPEN PAYMENTS, available at https://www.cms.gov/OpenPayments/About/Resources.html.

Interested stakeholders should study the rule's provisions to understand its impact on their day-to-day activities. Among other effects, these transparency requirements have resulted in increased scrutiny of relationships between manufacturers and health care professionals by government enforcement authorities, media outlets, and patients.

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