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Manufacturers may face issues, concerns under Physician Payments Sunshine Act

Part 3 in this series on the Sunshine Act focuses on manufacturers and considerations for medical device companies.

--By Alan Reider and Abraham Gitterman, Arnold & Porter LLP

The Physician Payments Sunshine Act, now commonly referred to as Open Payments, requires applicable manufacturers of drugs, devices, biologicals or medical supplies covered under Medicare, Medicaid or the Children's Health Insurance Plan to report annually to the Centers for Medicare and Medicaid Services, in an electronic format, certain payments or other transfers of value to covered recipients — physicians and teaching hospitals. Applicable manufacturers were required to begin collecting data on Aug. 1, 2013.

Phase 1 of reporting, which only took place this year to assist CMS with the initial registration process, required applicable manufacturers to electronically register with CMS and provide certain high-level data (for both general payments and research payments), such as the total aggregate spent during the first reporting period, the total number of payments made, and the total number of physicians or teaching hospitals paid. This article discusses a number of potential concerns and issues that manufacturers may face as they prepare to report detailed payment data to CMS in phase 2, which describe the types of interactions they have had with physicians and teaching hospitals.

Who is an applicable manufacturer?

The Sunshine Act applies only to entities that meet the definition of "applicable manufacturer" and have made reportable payments to covered recipients in the applicable calendar year. The regulations define applicable manufacturer as an entity that operates in the United States and is "engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply." CMS refers to these entities as Paragraph 1 manufacturers. A covered product means that payment must be available under Medicare, Medicaid or the Children's Health Insurance Plan and the product requires either a prescription or premarket approval (devices). This includes products that are reimbursed separately or as part of a bundled payment.

The regulations also define an applicable manufacturer as an entity, such as an affiliate or subsidiary that is under common ownership with a Paragraph 1 manufacturer and provides assistance or support to a manufacturer engaged in the production, preparation, propagation, compounding or conversion of a covered drug, device, biological or medical supply. CMS refers to these entities as Paragraph 2 manufacturers. These entities can include, but are not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations. Common ownership means "the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more total ownership of two entities." The regulations define "assistance and support" as "providing a service or services that are necessary or integral to the production, preparation, propagation, compounding, conversion,

marketing, promotion, sale or distribution" of a covered product. For example, CMS would consider a subsidiary that manufactures the active ingredients for a finished product manufactured by a Paragraph 1 entity to be a necessary or integral service to the production of a covered product. As a result, determining the status of an affiliate or a subsidiary under the Sunshine Act is fact specific.

Some manufacturers that are based abroad but that conduct business in the United States (eg, sell their products in the U.S.) have had difficulty determining whether the Sunshine Act is applicable to their foreign entity. The regulations define "operates" as having a "physical location or otherwise conducting activities" or having a business presence in the United States. CMS explained that any entity, foreign or not, that operates in the United States, "including by selling a product," must comply with the Sunshine Act regardless of where the product is physically manufactured. However, the definition does not include an entity that operates wholly outside the U.S., such as those with "little or no interaction with U.S. health care providers."

CMS explained that entities with operations "in the United States are not permitted to circumvent the reporting requirements by making payments to covered recipients indirectly through a foreign entity that has no operations in the United States." CMS explained that "[s]uch payments are considered to be made by the entity that is operating in the United States as an indirect payment or other transfer of value and must be reported as such, so long as the entity operating in the United States is aware of the identity of the covered recipients receiving the payments as required for all indirect payments or other transfers of value."

CMS defines an "indirect payment" as a payment or transfer of value made by a manufacturer to a physician or teaching hospital through a third party or intermediary, in which the manufacturer "requires, instructs, directs or otherwise causes" the third party to provide payment or transfer of value, in whole or in part, to a physician or teaching hospital. The Sunshine Act does not require manufacturers to report indirect payments when the applicable manufacturer is unaware of the identity of the covered recipient during the reporting year or by the end of the second quarter of the following year.

Under the final regulations, a manufacturer is unaware of the identity of a covered recipient if the manufacturer does not know the identity of the covered recipient. The definition of "know" provides that a person has actual knowledge of the information, acts in deliberate ignorance of the information, or acts in reckless disregard of the truth or falsity of the information. Given the broad definition of "operates" and "know," the Sunshine Act likely applies to most manufacturers who sell covered products in the United States. However, CMS does not consider an unrestricted donation to a third party, which could include an affiliate or subsidiary, to use at the organization's discretion to be an indirect payment; rather, only earmarked payments (eg, grants for education, speaking, research or training) would be reportable indirect payments.

Is one covered product enough?

Some manufacturers have had difficulty ascertaining when they or their affiliates or subsidiaries become an applicable manufacturer. CMS explained in the final regulation that once an applicable manufacturer has at least one covered product, a Paragraph 1 manufacturer is subsequently responsible for reporting

all payments to physicians or teaching hospitals, for both covered and non-covered drugs, that the manufacturer or commonly owned entities produce. CMS finalized this position, stating its intent to "require reporting of all payments or transfers of value to covered recipients rather than only payments related to covered" products so that manufacturers would not "avoid reporting by representing certain payments … as being unrelated to covered products."

One issue that has arisen is whether payments that are made by a Paragraph 2 manufacturer to covered recipients for a compound for which reimbursement is not available (eg, a non-covered drug) are reportable. Contrary to the requirements for Paragraph 1 manufacturers discussed above, the final regulations provide that Paragraph 2 manufacturers are "only required to report payments … that are related to a covered drug." In some instances, a Paragraph 1 manufacturer (with at least one covered drug) may have common ownership in a Paragraph 2 manufacturer that has no covered drugs (eg, research only). Under these circumstances, the Paragraph 1 manufacturer, if filing a consolidated report, would be required to report payments made by the Paragraph 2 manufacturer to covered recipients only if they were related to the Paragraph 1 manufacturer's covered products.

Otherwise, as long as the Paragraph 2 manufacturer has no product for which reimbursement is available, registration and reporting would not be required. While CMS may have intended to capture all payments when and only when an entity has at least one covered product (Paragraph 1 manufacturer), the concern CMS may have for entities to avoid reporting or to create loopholes is not present with Paragraph 2 manufacturers that have no covered products because such entities are not reporting any payments to begin with. Nevertheless, once payment is made available to an entity for at least one covered product, the final regulations require the entity to begin tracking and reporting payments within 180 days.

Paragraph 2 manufacturers also should recognize that reporting to CMS may be required if the Paragraph 1 manufacturer that has common ownership made a reportable indirect payment as described above, which requires a fact-specific analysis of the relationship between the entities. Thus, Paragraph 1 and Paragraph 2 manufacturers may be well-served to file consolidated reports, as permitted under the final regulations, to avoid mistakes or omissions.

Part 3 in this series on the Sunshine Act continues in the next issue of OSN.

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For more information:

Alan E. Reider, JD, MPH, can be reached at Arnold & Porter LLP, 555 12th St. NW, Washington, DC 20004-1206; 202-942-6496; email: Alan.Reider@aporter.com.

Abraham Gitterman, JD, is admitted only in Pennsylvania and New Jersey. He is practicing law in the District of Columbia during the pendency of his application for admission to the D.C. Bar and under the supervision of lawyers of the firm who are members in good standing of the D.C. Bar.