U.S. Physician Payment Sunshine Act FAQs for US Companies

The following FAQs relate to the U.S. Physician Payment Sunshine Act, enacted as part of the Affordable Care Act of 2010 (the U.S. Sunshine Act).

The U.S. Sunshine Act requires that certain manufacturers of drugs, devices, biologicals, and medical supplies report annually to the Centers for Medicare & Medicaid Services (CMS) certain payments or transfers of value made to U.S. physicians and teaching hospitals, as well as information on U.S. physician ownership and investment interests. These FAQs are limited to issues related to reporting with respect to payments and transfers of value, and do not address reporting with respect to physician ownership.

These FAQs are intended to provide general guidance with respect to the U.S. Sunshine Act, and do not constitute legal advice. Specific analysis may be required in some instances, as many determinations with respect to the U.S. Sunshine Act are fact-specific, and companies are encouraged to confer with counsel. Included below with each FAQ are definitions for a number of specific terms used throughout the U.S. Sunshine Act.

These FAQs refer to various countries throughout. Such country references are illustrative only and are not based on local law considerations.

Part I – Applicable Manufacturer FAQs

Is a German device manufacturer with U.S. operations subject to the U.S. Sunshine Act?

If a German company is Operating in the U.S. and is engaged in the production, preparation, propagation, compounding, or conversion of a Covered Device, then the German company is an Applicable Manufacturer subject to the U.S. Sunshine Act generally.

Operating in the U.S. means that the German company either (i) has a physical location within the U.S. (or in a territory, possession, or commonwealth of the U.S.) or (ii) otherwise conducts activities within the U.S. (or in a territory, possession, or commonwealth of the U.S.), either directly or through a legally-authorized agent. For example, a German company that has no physical location with the U.S. but sells a product in the U.S. would be Operating in the U.S. (Note: Because many companies are structured differently and the regulations are not clear as to what specifically constitutes “otherwise conduct[ing] activities within the U.S.,” companies are encouraged to consult with legal counsel to determine whether they are subject to these regulations.)
A **Covered Device** means any device (i) that requires premarket clearance by or notification to the Food & Drug Administration (FDA) and (ii) for which payment is available under the U.S. Medicare, Medicaid or CHIP programs. A device that meets both such requirements is a **Covered Device**, regardless of the amount of revenue derived from the product in the U.S. However, as further discussed in the FAQs below, a company that has less than 10% total (gross) annual revenue from **Covered Devices** during the previous fiscal year, may be subject to limited reporting requirements.

Entities that are subject to the U.S. Sunshine Act are referred to as **Applicable Manufacturers**.

**Is a Japanese parent company with a subsidiary that operates in the U.S. and is subject to the U.S. Sunshine Act also subject to the U.S. Sunshine Act?**

If a parent Japanese company has **Common Ownership** with another company that is **Operating in the U.S.** and is subject to the U.S. Sunshine Act, then the Japanese company is also subject to the U.S. Sunshine Act if it provides **Assistance and Support** to the related company. However, such **Common Ownership** company providing **Assistance and Support** will have limited reporting requirements under the U.S. Sunshine Act—such company is only required to report payments or other transfers of value to **Covered Recipients** that are specifically related to **Covered Devices**.

**Common Ownership** refers to circumstances where the same individual(s) or entity(ies) directly or indirectly own 5 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.

The Japanese company provides **Assistance and Support** to a related company if it provides a service or services that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a **Covered Device**.

A **Covered Device** means any device (i) that requires premarket clearance by or notification to the FDA and (ii) for which payment is available under the U.S. Medicare, Medicaid or CHIP programs.

Entities that are subject to the U.S. Sunshine Act are referred to as **Applicable Manufacturers**.

**What if a Brazilian company sells products through distributors in the U.S., and those distributors make payments to U.S. physicians?**

If a Brazilian company sells **Covered Devices** through distributors in the U.S. and the distributors do not **Hold Title** to the **Covered Devices**, then the Brazilian company is subject to the U.S. Sunshine Act generally and responsible for reporting payments made to U.S. physicians by the
distributors. This is because the distributor is essentially acting as an independently contracted sales agent for the company. However, if a distributor holds title to the Covered Devices, then the distributor is independently subject to the U.S. Sunshine Act generally and is itself responsible for reporting the payments made to U.S. physicians.

A distributor holds title to a Covered Device once the distributor takes ownership of a particular inventory of Covered Devices from the Brazilian company and possesses the right to re-sell the inventory that it has purchased. Holding title to a Covered Device in this context is distinct from holding FDA approval, licensure or clearance for a Covered Device. A Covered Device means any device (i) that requires premarket clearance by or notification to the FDA and (ii) for which payment is available under the U.S. Medicare, Medicaid or CHIP programs.

Entities that are subject to the U.S. Sunshine Act are referred to as Applicable Manufacturers.

**Part II – Reporting FAQs**

The following FAQs assume that the company at issue is an Applicable Manufacturer for purposes of the U.S. Sunshine Act.

**When is the U.S. Sunshine Act effective?**

The data collection requirements of the U.S. Sunshine Act began on August 1, 2013. For Calendar Year (CY) 2013, Applicable Manufacturers may register with CMS during the time period February 18, 2014 through March 31, 2014. Reports covering payments and transfers of value from Applicable Manufacturers to Covered Recipients for the time period of August 1, 2013 through December 31, 2013 are due to CMS in May 2014. Covered Recipients are defined as physicians who maintain a current state license to practice medicine in any state in the U.S. and teaching hospitals identified on an annual list published by CMS. CMS is expected to release the CY2013 reported data on its public website by September 30, 2014. For subsequent calendar years, reports covering the preceding calendar year will be due to CMS on the 90th day of each calendar year.

**What if a Swedish company sells products in the U.S. and is subject to the U.S. Sunshine Act, but less than 10% of the company’s total (gross) revenue comes from Covered Devices?**

If a Swedish company sells products in the U.S. and is engaged in the production, preparation, propagation, compounding, or conversion of a Covered Device, then the Swedish company is subject to the U.S. Sunshine Act generally. However, if a Swedish company has less than 10% total (gross) annual revenue from Covered Devices during the previous fiscal year, then it has limited reporting requirements under the U.S. Sunshine Act—the Swedish company is only required to report payments or other transfers of value to Covered Recipients that are specifically related to Covered Devices. In contrast, a Swedish company that qualifies as an
Applicable Manufacturer, and has more than 10% total (gross) annual revenue from Covered Devices during the previous fiscal year, must report payments or other transfers of value to Covered Recipients that related both to Covered Devices and non-covered products.

Covered Recipients are defined as physicians who maintain a current state license to practice medicine in any state in the U.S. and teaching hospitals identified on an annual list published by CMS. A Covered Device means any device (i) that requires premarket clearance by or notification to the FDA and (ii) for which payment is available under the U.S. Medicare, Medicaid or CHIP programs.

If a Japanese company provides a grant (or other reportable transfer of value) to a U.S. physician, must it report such payment or transfer of value?

A Japanese company that qualifies as an Applicable Manufacturer for purposes of the U.S. Sunshine Act must report any grants provided to Covered Recipients either directly or indirectly, unless one of the few reporting exclusions applies. Grants are one of the payment categories that must be reported under the U.S. Sunshine Act. The U.S. Sunshine Act has very few payments and transfers of value that are exempted from reporting, for example, payments or transfers of value less than $10 when the total amount for the specific covered recipient for the year is less than $100, and product samples.

Covered Recipients are defined as physicians who maintain a current state license to practice medicine in any state in the U.S. and teaching hospitals identified on an annual list published by CMS.

In addition, if a U.S.-based company directs that a payment is made through a foreign entity to a U.S. physician, such payment may need to be reported by the U.S.-based company. Whether a company “directs” a payment to be made through a foreign entity to a U.S. physician is a fact-specific analysis, and we encourage companies to review specific fact scenarios with legal counsel to determine whether they are subject to the Sunshine Act’s reporting requirements.

If a Brazilian company brings a Brazilian physician to the U.S. for training, is that reportable?

Payments or transfers of value provided to a Brazilian physician by a Brazilian company that is an Applicable Manufacturer do not have to be reported under the U.S. Sunshine Act unless the Brazilian physician qualifies as a Covered Recipient. For purposes of the U.S. Sunshine Act, the definition of Covered Recipient includes a physician who maintains an active state license to practice medicine in any state in the U.S. Therefore, if the Brazilian physician does not have an active U.S. license, the payment or transfer of value to him/her need not be reported. Note that the definition of Covered Recipient excludes a physician who is a bona fide employee of the Applicable Manufacturer.
Does a German company need to ask if the German physicians it does business with are also licensed in the U.S., and what difference would that make?

If a German physician maintains an active license to practice medicine in any state in the U.S., the physician will qualify as Covered Recipient for purposes of the U.S. Sunshine Act. Any payments or transfers of value provided to such physician therefore must be reported if the German company meets the definition of an Applicable Manufacturer unless a reporting exclusion applies. A German company that is an Applicable Manufacturer must report payments or other transfers of value to Covered Recipients. CMS has not yet provided any guidance regarding whether Applicable Manufacturers must affirmatively determine whether foreign-based physicians hold U.S. state licenses, but such a practice may be advisable depending on the particular circumstances.

If a Japanese company makes a payment to a Japan-based Japanese physician who is also licensed as a U.S. physician, is that reportable?

Payments or transfers of value made by a Japanese company that is an Applicable Manufacturer must be reported if they are made to a Japanese physician who also qualifies as a Covered Recipient for purposes of the U.S. Sunshine Act, unless a reporting exclusion applies. For purposes of the U.S. Sunshine Act, the definition of Covered Recipient includes a physician who maintains an active license to practice medicine in any state in the U.S. The definition of Covered Recipient excludes a physician who is a bona fide employee of the Applicable Manufacturer. Reporting exclusions are very limited but include, for example, payments or transfers of value less than $10 when the total amount for the specific covered recipient for the year totals less than $100, product samples, and educational materials that directly benefit patients. The exclusion for educational materials does not include items that are educational to Covered Recipients (such as medical textbooks and journal reprints), but that are not intended for patient use.

In addition, if a U.S.-based company, which meets the definition of an Applicable Manufacturer, directs that a payment be made through a foreign entity to a U.S. physician, such payment may need to be reported by the U.S.-based company.

If a Swedish company brings a U.S. physician to Sweden to train Swedish physicians, is that reportable?

Payments or transfers of value made by a Swedish company that is an Applicable Manufacturer will be reportable if they are made to a U.S. physician who qualifies as a Covered Recipient, regardless of where the activity occurs (inside or outside the U.S.), unless the U.S. physician is an employee of the Swedish company. For purposes of the U.S. Sunshine Act, the definition of Covered Recipient includes a physician who maintains a current state license to practice medicine in any state in the U.S. The definition of Covered Recipient excludes a physician who is a bona fide employee of the Applicable Manufacturer.
In addition, if a U.S.-based company, which meets the definition of an Applicable Manufacturer, directs that a payment be made through a foreign entity to a U.S. physician, that payment must be reported by the U.S.-based company.

May a company that qualifies as an Applicable Manufacturer request a delay in publication for research-related payments provided to a Covered Recipient?

Certain research payments made to a Covered Recipient by an Applicable Manufacturer under a product research or development agreement may be delayed from publication on CMS’ public web site until the date of FDA approval or four years after the date the payment was made, whichever occurs first. Even if a research payment is eligible for delayed publication, an Applicable Manufacturer is still required to report the research payment to CMS initially and annually during the delay period, but may indicate on its reports that such payment is eligible for delayed publication.

May affiliated Applicable Manufacturers file a consolidated report?

Yes, Applicable Manufacturers that are under Common Ownership with separate entities that are also Applicable Manufacturers may, but are not required to, file a consolidated report for all of the entities. However, if multiple Applicable Manufacturers submit a consolidated report, the report must provide information identifying each entity that the report covers and must specify on an individual payment line which entity made which discrete payment or other transfer of value. The Applicable Manufacturer submitting a consolidated report on behalf of itself and other Applicable Manufacturers is liable for civil monetary penalties imposed on each of the Applicable Manufacturers whose reportable payments or other transfers of value are included in the consolidated report, up to the annual maximum amount for each individual Applicable Manufacturer.