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The US Physician Payment Sunshine Act: implications for multinational drug and device manufacturers

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The movement toward transparency in relationships between drug, biologic and medical device manufacturers and healthcare professionals has become global. A number of countries have already enacted legislation or codes of conduct requiring manufacturers to disclose transfers of value to healthcare professionals (HCPs) and healthcare organisations:

- Denmark, France, Slovakia, and Turkey have enacted legislation mandating disclosure.
- Other countries rely on industry-developed codes of conduct, including Austria, Czech Republic, Finland, Germany, Ireland, Hungary, The Netherlands, Poland, UK, Russia, Australia, Japan, South Africa and Mexico.

As more countries join the global transparency movement, the task of determining a particular company's obligations, and effectively managing compliance, will become even more complex. To further complicate matters some countries, like the US, recognise that many healthcare product manufacturers are now global in nature. Therefore any law aimed to create true transparency must also capture certain activities of international affiliates with a US nexus. As a result, many companies may not realise the true breadth of their looming US reporting obligations.

On 1 February 2013, the Centers for Medicare and Medicaid Services (CMS) released its highly anticipated final rule, implementing section 6002 of the Patient Protection and Affordable Care Act, known as the Physician Payment Sunshine Act (Sunshine Act) (*Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458 (8 February 2013)) (to be codified at 42 C.F.R. Parts 402, 403*) (Final Rule). The Final Rule is available at *www.gpo.gov/fdsys/pkg/FR-2013-02-08/pdf/2013-02572.pdf*).

The Sunshine Act and corresponding regulations require:

- Certain pharmaceutical, biologic, and medical device manufacturers to annually report to CMS payments or other transfers of value they provide to physicians and teaching hospitals (deemed "covered recipients").
- The same manufacturers as well as group purchasing organisations (GPOs) to report ownership or investment interests in their organisations that are held by physicians or their immediate family.

Specifically:

- These entities must begin tracking and collecting data on 1 August 2013 and submit their first reports to CMS by 31 March 2014.
- CMS must aggregate the submitted data and make it publicly available through a searchable website for the first time by 30 September 2014.

This article explores the implications of these requirements for international healthcare product manufacturers and their affiliated entities, by examining the Sunshine Act requirements, in particular:

- Who must report.
- What transfers of value must be reported.
- When non-US entities must report.
- The reporting requirements for non-US entities.
- The need to carefully consider the Sunshine Act.

WHO MUST REPORT: APPLICABLE MANUFACTURERS

Under the Final Sunshine Rule, entities deemed "applicable manufacturers" are required to submit to CMS annual reports of payments or other transfers of value they provide to physicians or teaching hospitals (covered recipients) (*9458, Final Rule*) (*to be codified at 42 C.F.R. § 403.900*).

The Final Rule defines "applicable manufacturer" as an entity that has a physical location in the US or otherwise conducts activities in the US, whether directly or indirectly through contracted agents (*9460, Final Rule*) (*to be codified at § 403.902*) and that falls into one of two categories:

- 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 (*9461, Final Rule (to be codified at § 403.902)*) (paragraph one applicable manufacturer).
- An entity under common ownership with a paragraph one entity, 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 product. Common ownership refers to circumstances where the same individual, individuals, entity, or entities directly or indirectly own 5% 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 (*9521, Final Rule (to be codified at § 403.902)*) (paragraph two applicable manufacturer).

Analysis

Covered products

Generally, covered products are those for which payment is available under the US Medicare, Medicaid, or the Children's Health Insurance Program, either separately or as part of a bundled payment (irrespective of whether the product is actually reimbursed in a particular situation through one or more of those federal programmes):

- 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 US Food and Drug Administration (FDA) pre-market approval or notification.

Entities that exclusively manufacture over-the-counter drugs and/or certain Class I or Class II medical devices (those that do not require pre-market approval or notification under the 510(k) process, as determined by FDA) are not subject to the reporting requirements and, therefore, their interactions with covered recipients do not have to be publicly disclosed.

Importantly, if an entity qualifies as a paragraph one applicable manufacturer, it must report "all payments or transfers of value to covered recipients rather than only payments related to [covered products]" (*9462, Final Rule (to be codified at § 403.904)*).

Limited reporting for certain applicable manufacturers

However, certain applicable manufacturers may be eligible for more limited reporting requirements:

- Paragraph two applicable manufacturers are only required to report payments or other transfers of value that relate to a covered product for which they provided assistance or support to a paragraph one applicable manufacturer (*9464, Final Rule (to be codified at § 403.904)*).
- Applicable manufacturers with gross revenues from covered products that constitute less than 10% of total gross revenue for the fiscal year preceding the reporting year, are only required to report payments or other transfers of value that relate to covered products (*9462 to 9463, Final Rule (to be codified at § 403.904)*).
- In addition, if an applicable manufacturer has a division that does not manufacture any covered products (for example, an animal health division), the applicable manufacturer is only required to report payments or other transfers of value incurred by that division that relate to covered products (*9463, Final Rule (to be codified at § 403.904)*).
- Applicable manufacturers that do not manufacture a covered product (except when under a written agreement to manufacture the covered product for another entity), do not hold the FDA approval, licensure, or clearance for the covered product, and are not involved in the sale, marketing, or distribution of the product, are only required to report payments or other transfers of value related to covered products (*9462, Final Rule (to be codified at § 403.904)*).

Consolidated reporting

Applicable manufacturers who are under common ownership with one another can, but are not required to, file consolidated disclosure reports. Where manufacturers opt to use consolidated reporting, the applicable manufacturer that files the consolidated report must identify which manufacturer was responsible for each payment, and is also liable for civil money penalties that might be imposed on each applicable manufacturer included in the consolidated report (*9463, Final Rule (to be codified at § 403.908)*).

WHAT TRANSFERS OF VALUE MUST BE REPORTED?

Applicable manufacturers must report direct and indirect "payments and other transfers of value" they provide to covered recipients or to entities or individuals at the request of, or designated on behalf of, covered recipients (*9470, Final Rule (to be codified at § 403.904)*).

Indirect payments

Indirect payments are payments made to a covered recipient through a third party, where 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 (*9471 to 9472, Final Rule*).

However, an indirect payment may be excluded from reporting if it was 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 following reporting year" (*9490, Final Rule*).

CMS defines "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".

What payments are excluded?

The regulations expressly exclude a number of transfers of value, including:

- Educational materials that directly benefit patients or are intended for patient use.
- Product samples (including coupons and vouchers) that are not intended to be sold and are intended for patient use.
- Indirect payments or other transfers of value where the applicable manufacturer does not "know" the identity of the covered recipient (*see above, Indirect payments*).
- In-kind items used in the provision of charity care.
- Discounts and rebates.
- Payments or other transfers of value made solely in the context of personal, non-business related relationships.

There is also an exclusion for transfers of value that are under US$10, where the total value of all payments or transfers of value made to a single covered recipient do not exceed US$100 during the reporting year (*9485, Final Rule*). The US$10 and US$100 thresholds will be annually updated.

REPORTING OWNERSHIP AND INVESTMENT INTERESTS

The Sunshine Act also requires each applicable manufacturer and applicable GPO to report certain information regarding any

"ownership or investment interest" (other than an interest in a publicly traded security or mutual fund) held by a physician (or his immediate family member) in the reporting manufacturer or GPO.

WHEN MUST NON-US ENTITIES REPORT UNDER THE SUNSHINE ACT?

Parent entities

If a parent entity produces a covered product that is not used solely by or within the parent entity itself, it would qualify as a paragraph one applicable manufacturer, to the extent that it "conducts activities within the United States" either directly or indirectly through an authorised agent.

In relation to paragraph two applicable manufacturers (*see above, Who must report: applicable manufacturers*), CMS defines "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 drug, device, biological or medical supply".

CMS clarifies by way of example: "an entity under common ownership which produces an active ingredient for a covered drug and provides it to the applicable manufacturer for inclusion in the final product would be considered necessary to the manufacturing of that product, since the applicable manufacturer could not produce the drug without the active ingredient" (*9463, Final Rule*).

On the other hand, "an entity under common ownership that only aids the applicable manufacturer with human resources administrative functions would not be deemed necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of covered products, since human resources functions are not directly involved with any of these manufacturing processes" (*9463 to 9464, Final Rule*).

Therefore, so long as a subsidiary sells a parent entity's products in the US on a parent entity's behalf, or otherwise provides "assistance or support" as defined in the Final Rule, the parent entity and its subsidiary would both qualify as applicable manufacturers, and therefore be obliged to report.

Other non-US affiliates

Any other affiliate of the parent entity (for example, a non-US affiliate entity) is an applicable manufacturer if it satisfies the following three elements:

- It operates in the US.
- It is under common ownership with an entity that is engaged in the production, preparation, compounding, or conversion of a covered drug, device, biological, or medical supply (manufacturing entity).
- It provides assistance or support to a manufacturing entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product.

An affiliate satisfies the second element if it is under common ownership with a parent entity that produces a covered drug and operates in the US. The first and third elements warrant further examination.

Operating in the US. The first element requires that the entity is operating in the US, which means that the entity either (*9522, Final Rule (to be codified at § 403.902)*):

- Has a physical location in the US or in a territory, possession, or commonwealth of the US.
- Otherwise conducts activities in the US or in a territory, possession, or commonwealth of the US, either directly or through a legally authorised agent.

CMS fails to explain in the Final Rule how it interprets the phrase "otherwise conducts activities within the United States". The only example it provides is an entity that sells products in the US: "We believe that any manufacturer, foreign or not, which operates in the United States (including by selling a product) must comply with the reporting requirements...") (*9461, Final Rule*).

However, CMS did state that it was not intending to capture entities that have no business presence at all in the US, which suggests that entities must have at least some US business presence to satisfy this element: "We appreciate the comments and agree that the proposed definition may have inadvertently captured entities that operate wholly outside of the United States, many of which may have little or no interaction with U.S. health care providers. We did not intend to capture foreign entities that may contribute to the manufacturing process of a covered product, but have no business presence in the United States".

However, beyond the sale of products and having at least some business presence, it is unclear what other types of activities would qualify an entity as "operating in the United States" for the purposes of the Final Rule.

Assistance and support. The third element requires that the non-US affiliate provide "assistance and support" to the parent entity, that is, services that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug. Accordingly, whether the affiliate satisfies the third element depends on the nature of its business function.

If a non-US affiliate operates an independent, but parallel, business to the parent entity's business, through which the affiliate manufactures and/or sells products only in another country and does not indirectly conduct business transactions with US entities through the parent entity, it is not likely to qualify as operating in the US, and therefore would not be an applicable manufacturer. The affiliate would not have to report a payment to a US covered recipient, so long as the payment was not an "indirect payment or other transfer of value". In fact, CMS clearly states that "the final rule does not require entities under common ownership to report when they are not necessary or integral to manufacturing, and are not applicable manufacturers in and of themselves" (*9464, Final Rule*).

However, if the payment to the US covered recipient is an indirect payment, then it would have to be reported (*9488 to 9489, Final Rule*): "Any payment or other transfer of value provided to a covered recipient through a third party, whether or not the third party is under common ownership with an applicable manufacturer or operating in the U.S., must be reported if the applicable manufacturer is aware of the covered recipient's identity".

For example, if a parent entity directs a non-US affiliate to pay a US covered recipient, the parent entity would have to report the indirect payment. Parent entities would only have to report the affiliate's payment if either the parent entity had knowledge that the non-US affiliate was going to provide the payment to the US covered recipient, or learned of this transfer after the fact, but between the report year and second quarter of the subsequent year following the transfer (*9491, Final Rule*) ("Therefore, if an applicable manufacturer becomes aware of the identity of a covered recipient on or before June 30th of the year following the year in which the payment is made by the third party to the covered recipient, then the payment or other transfer of value must be reported").

The definition of applicable manufacturer includes entities under common ownership with an applicable manufacturer. This applies to a variety of corporate arrangements, including, but not limited to, parent companies and subsidiaries and brother and sister corporations.

Reporting obligations on non-US applicable manufacturers

Paragraph one applicable manufacturers and a paragraph two applicable manufacturer (or manufacturers) under common ownership with such a manufacturer can, but are not required to, file consolidated disclosure reports (*9464, Final Rule*).

Where manufacturers opt to use consolidated reporting, the applicable manufacturer that files the consolidated report must identify which manufacturer was responsible for each payment and is also liable for civil monetary penalties that may be imposed on each applicable manufacturer included in the consolidated report (*9526, Final Rule (to be codified at § 403.908(d)(1)(v)*) ("If multiple applicable manufacturers (under paragraph 1 and/or 2 of the definition) submit a consolidated report, CMS requires that the report provide information specified by CMS to identify each applicable manufacturer and entity (or entities) under common ownership that the report covers. Additionally, applicable manufacturers submitting consolidated reports must specify on an individual payment line which entity made which discrete payment or other transfer of value").

Where applicable manufacturers under common ownership decide to file separately, they must keep in mind that each transaction between an applicable manufacturer and a covered recipient must be reported only once (*9464, Final Rule*).

Further, paragraph two applicable manufacturers are only required to report those payments or other transfers of value that relate to covered products ("CMS believes that entities under common ownership that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered product should not have to report all payments or other transfers of value that the entities provide to covered recipients and § 403.904(b)(2) of this final rule states that *they only need to report payments or other transfers of value that are related to covered products*") (emphasis added).

If both the parent entities and other non-parent affiliates are applicable manufacturers then they can, but are not required to, file a consolidated annual report with CMS. If the companies elect to file a consolidated annual report, the parent must report a payment made by the affiliate to a US covered recipient and must identify, among other things, the particular affiliate as the responsible entity of the payment in the final report. The Final Rule does not specify whether CMS intended limited purpose reporting to apply to paragraph two applicable manufacturers when they elect to file consolidated reports. This analysis assumes that limited purpose reporting is not available to paragraph two applicable manufacturers that choose to file consolidated reports.

Alternatively, if the entities elect to file separate reports to CMS, the non-US affiliate must report its payments to the US covered recipient in accordance with the Final Rule when the payment relates to a covered product (*9643, Final Rule; see also 9461, Final Rule*) ("CMS believes that any manufacturer, foreign or not, which operates in the United States (including by selling a product) must comply with the reporting requirements, regardless of where the product is physically manufactured. Therefore, under this final rule, entities based outside of the United States that do have operations in the United States are subject to the reporting requirements").

THE NEED TO CAREFULLY CONSIDER THE SUNSHINE ACT

The Sunshine Act regulations are not a model of clarity, but it is clear that global life sciences organisations that have relationships (consulting, research, medical education and so on) must carefully evaluate whether the transfers of value associated with those relationships must be reported to CMS, and the breadth of that responsibility.

This involves a careful consideration of the relationships and activities of those entities, and could require the development of:

- Associated assumptions documents.
- Revised procedures.
- More integrated accounting systems.

The penalties for non-compliance are substantial:

- If a company knowingly fails to submit the required information in a timely manner, it can be subject to a civil monetary penalty of at least US$10,000, but no more than US$100,000, for each payment or other transfer of value, or ownership or investment interest, not reported as required.
- The maximum penalty for a company's knowing failure to report with respect to each annual submission is US$1 million.

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