

# Navigating the Global Scope of the US Sunshine Act

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## Who, When and Where

- The Sunshine Act requires, *inter alia*, that “applicable manufacturers” must report payments and other transfers of value to covered recipients
- Applicable manufacturers must begin collecting required data elements on August 1, 2013 and report the data on 2013 payments/transfers to the US Centers for Medicare and Medicare Services (CMS) by March 31, 2014
- CMS will publish the data on 2013 payments/transfers by September 30, 2014
- This data will be aggregated and posted publicly by CMS on a searchable website

## “Applicable Manufacturers”

- “Applicable manufacturer” means an entity that is “operating in the United States” – i.e.,
  - Has a physical location within the United States or in a territory, possession, or commonwealth of the United States

or

- 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

and...

## “Applicable Manufacturers” (cont’d.)

- Falls into one of the following categories:
  - 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 product is solely for use by or within the entity itself or by the entity’s own patients
    - Does not include distributors or wholesalers who do not hold title to the product
  - An entity under “common ownership” with an entity in (1) above, 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 percent or more total ownership of two entities
- This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother/sister corporations

## “Assistance or Support”

- Means 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

## Scope and Limitations

- As a general matter, if an entity qualifies as an applicable manufacturer under *paragraph (1)*, it is required to report *all* payments or transfers of value to covered recipients rather than only payments related to covered products
- Applicable manufacturers under *paragraph (2)* (common ownership) 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 a paragraph (1) applicable manufacturer
- Applicable manufacturers (under either paragraph of the definition) for whom total (gross) revenues from covered products 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 related to one or more covered products

## Scope and Limitations (cont'd.)

- In addition, if an applicable manufacturer (under either paragraph) has a separate operating division that does not manufacture any covered products (e.g., an animal health division), it is only required to report payments or other transfers of value to covered recipients related to the activities of those separate divisions if those payments or other transfers of value are related to a covered product
- 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



## Documenting Assumptions

- Manufacturers *may* submit a document to CMS that explains the “reasonable assumptions made and methodologies used when reporting payments or other transfers of value.”
- Will not be made available to covered recipients or the public.
- “[W]e do not intend to use the assumptions document for prosecution, but acknowledge that the reporting based on the assumptions would be open to prosecution.”
- Other US Department of Health & Human Services (HHS) divisions, the Department of Justice (DOJ), or the Office of the Inspector General (OIG) could request access to the documents as part of an audit or investigation into an applicable manufacturer

## Consolidated vs. Separate Reporting

- 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
- If multiple applicable manufacturers submit a consolidated report, the report must 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

## Note: Indirect Payments

- Manufacturers generally must record and report “indirect payments or other transfers of value,” meaning:
  - Payments/transfers made by a manufacturer through a third party where the 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(s)
    - But indirect payments or other transfers of value are excluded from the reporting requirement if the manufacturer is “unaware of the identity of the covered recipient.”

## Key Questions

- Have you determined all potential applicable manufacturers?
- Which type of “applicable manufacturer” are they?
- Do they need to report all payments and transfers of value to covered recipients, or just those relating to covered products?
  - Are the products ex-US the same as US covered products?
- Have you documented the assumptions underlying those determinations?

## Key Questions (cont'd.)

- Will you file separate reports or a consolidated report?
- Even if an entity is not an applicable manufacturer, is there an indirect payment or transfer of value that must be reported?
- How will you track and report those payments?
  - By entity and covered product?
  - Including payments through third parties (e.g., CROs)?

## Other Questions?

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