

Where Do We Go from Here? Practical Considerations for Implementing “Sunshine”

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Key Issues for Consideration

- Entities subject to Sunshine reporting requirements
- Covered Recipients
- Payments or Other Transfers of Value
- Public availability of reported information
- Organizational Readiness

Entities Subject to Sunshine Requirements

- How to determine whether a parent or affiliate is an “applicable manufacturer” subject to reporting
 - Example: A foreign manufacturer with a subsidiary that sells its products in the U.S.
- How to treat entities that engage in activities wholly unrelated to covered Rx products
 - Example: Companies with both Rx entities and consumer health entities
- Limitations in available resources to apply these requirements universally

Covered Recipients

- Difficulty in identifying individuals and entities as Covered Recipients
 - Examples:
 - Physicians with multiple NPI numbers
 - Physicians that maintain an active license, but who no longer practice
 - Hospitals that receive CME funding, but do not hold themselves out as “teaching facilities”

Payments or Other Transfers of Value

- Determining which items or materials constitute a “transfer of value” and, if so, how do you determine the “value” to report
 - **Examples:**
 - Promotional leave behinds and economic models or data that are developed internally by a reporting entity
 - Overhead costs incurred in connection with advisory board meetings
- Developing the capability to track certain items or materials
- Developing a process for “opt-outs”

Payments or Other Transfers of Value (cont'd)

- Challenges in capturing Payments and Other Transfers of Value made by third-party vendors on behalf of reporting entity
- For co-promote arrangements, determining how spend to a Covered Recipient will be reported and by which entity

Public Availability of Reported Information

- Practical difficulty that the public will encounter in meaningfully understanding disclosed information if it is not presented appropriately
- Potential for misperception of publicly disclosed data if sufficient background information on each reporting entity is not provided
 - Example: Possibility that reporting entities' publicly disclosed information will be compared without regard to each reporting entity's size or primary industry

Organizational Readiness

- Developing a methodology to document how categories of spend are defined, tracked and reported, and assumptions made in these determinations
- For reporting entities under the same parent or with multiple divisions, harmonizing reporting methodologies to help ensure better consistency in reporting
- Preparing the field *and* home office to track *all* appropriate spend
- Establishing a process for ensuring accountability across the entire organization
 - **Examples:**
 - Quarterly reviews by each accountable functional area
 - Certification process