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CMS Releases Sunshine Act Final Rule, Finally

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After over a year of delays, on February 8, 2013 the Centers for Medicare and Medicaid Services (CMS) published its regulations (Final Rule) implementing the Transparency Reports and Reporting of Physician Ownership or Investment Interests statute, a key facet of the Affordable Care Act known more commonly as the Sunshine Act. The Final Rule was first issued on February 1, 2013 after the release of the Proposed Rule in December 2011 and the myriad industry comments that followed.

The Final Rule maintains the Proposed Rule's significant and far-reaching financial disclosure obligations for drug manufacturers, their affiliates, physicians (including dentists, podiatrists, optometrists and chiropractors) and certain teaching hospitals. The Sunshine Act generally requires manufacturers and their affiliates (applicable manufacturers) of drugs and other products covered under federal health programs (covered products) to report payments or other transfers of value to physicians and teaching hospitals (covered recipients). It further requires manufacturers and group purchasing organizations to disclose certain ownership and investment interests.

Regulators hope the Sunshine Act will increase transparency and deter financial relationships between drug manufacturers and providers that drive up the cost of health care. Affected providers and entities must begin collecting relevant data on August 1, 2013 and must report the data back to CMS no later than March 31, 2014. Some of the Final Rule's most significant changes include:

Applicable Manufacturers

The Sunshine Act defines an "applicable manufacturer" as an entity that operates in the United States and falls within one of two categories:

- An entity that is engaged in the production, preparation, propagation, compounding or conversion of a covered product, 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 (including, but not limited to, repackagers, relabelers and kit assemblers) that do not hold the title to any covered drug, device, biological or medical supply; or
- Any entity under common ownership or control with an entity in the first category, that provides assistance or support to such entity with respect to the

production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered drug, device, biological or medical supply.

In response to concerns regarding the breadth of the definition of "applicable manufacturers," CMS clarified that entities must have a physical location in the United States or otherwise conduct activities within the United States to be subject to the Sunshine Act. Entities are not permitted to circumvent the reporting requirements by funneling payments to covered recipients.

Narrowed Reporting Requirements

CMS also took steps to narrow the reporting requirements for certain entities in response to voluminous comments to its Proposed Rule, released in 2011. These changes will significantly reduce the reporting burden on some entities when data collection begins in August. Among the most significant changes are:

- Entities that are under common ownership that provide assistance with respect to the marketing, promotion, sale or distribution of the covered product need only report payments to covered recipients **that are related to the covered products**. Previously, the rule required these entities to report all transfers of value to covered recipients exceeding $10, or exceeding $100 over a 12-month period.
- Applicable manufacturers who made less than 10% of total gross revenue from covered products during the previous fiscal year need only report payments to covered recipients **that are related to the covered products**.
- CMS also agreed to allow applicable manufacturers a 180-day grace period following a product becoming "covered"—e.g., receiving FDA approval—to begin complying with the data collection and reporting requirements of the Sunshine Act.

Immediate Action Items

The Sunshine Act implements a comprehensive and unprecedented disclosure protocol that will directly impact a wide range of manufacturers and providers. CMS's own estimates project the total cost of Sunshine Act compliance to be approximately $269 million for the first year and $180 million per year thereafter.

To prepare for the data collection period, manufacturers, affiliates and covered providers should:

- Map out financial relationships with applicable manufacturers (whether foreign or domestic) or covered recipients, including M.D.s, D.O.s, dentists, podiatrists, optometrists and chiropractors;
- Identify any covered products for which any payments or other transfers of value are made;
- Ensure that communication exists among drug manufacturers, affiliated entities and health care providers covered under the Sunshine Act to verify they are aware of the applicable data collection and reporting requirements;
- Implement policies requiring administrators and employees to track all spending between covered parties, including royalties, consulting fees, research fees and any payments exceeding $10 or $100 over a calendar year;
- Categorize payments according to the Sunshine Act statute and Final Rule for reporting purposes; and
- Remain on the lookout for additional guidance from CMS regarding data collection and reporting procedure as the enforcement periods approach.