

## **Better Late than Never - The Sunshine Act Final Regulations are Finally Here!**

Late afternoon on Friday February 1, 2013, the Centers for Medicare and Medicaid Services ("CMS") published the final rule regarding Transparency Reports and Reporting of Physician Ownership or Investment Interests ("Final Rule"). The Final Rule will be published in the Federal Register on February 8, 2013, effective 60 days later (April 9, 2013). The Final Rule has been long-delayed, since CMS published the proposed rule on December 19, 2011 (76 FR 78742) ("Proposed Rule"). This alert is intended to highlight a few of the Final Rule's key provisions.

Applicable manufacturers must begin collection of required data on August 1, 2013, and make their first report of data to CMS by March 31, 2014. CMS will then release the data on a public website by September 30, 2014.

Applicable Manufacturers Must Report All Payments or Transfers of Value to Covered Recipients. In the Final Rule, CMS finalizes its proposal to require reporting of all payments or transfers of value to covered recipients, rather than only payments related to covered drugs, devices, biologicals, and medical supplies.

### **"Applicable Manufacturers"**

#### Common Ownership Considered to be Ownership by the Same Individuals or Entities of 5 Percent or More in Two Entities

In the Final Rule, CMS defines "applicable manufacturer" as an entity operating in the United States that is (1) engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States; or (2) under common ownership with an entity in the first paragraph of this definition, and 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 drug, device, biological, or medical supply. The Final Rule defines "common ownership" as when the same individual, individuals, entity, or entities, directly or indirectly, own 5 percent or more total ownership of two entities (such as parent, brother/sister, and subsidiary relationships).

#### "Assistance and Support" Required for Entities under Common Ownership

Not every entity under common ownership is subject to the Sunshine Act; only entities under common ownership that provide "assistance and support" for the listed manufacturing activities need to report. In the Final Rule, CMS defines "assistance and support" as being necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product.

#### Reporting Requirements When a Manufacturer is Considered an Applicable Manufacturer Due to Common Ownership:

When common ownership exists among entities that fall within the definition of "applicable manufacturer" because the entities are all engaged in the production, etc. of a covered product, the Final Rule indicates that such manufacturers may, but are not required to, file a consolidated report for all of the entities.

## Other Provisions

The Final Rule includes significant discussion regarding each of the form and nature of payment categories, as well as each exclusion type. In addition, the Final Rule includes detailed information regarding research, delayed publication under certain circumstances, report content, report review and correction, the public website, and penalties for failure to report.

If you have questions regarding this Final Rule, please contact [Sarah Crotts](#), the author of this alert. You may also contact the Womble Carlyle attorney with whom you usually work, or any of our [Healthcare Industry Team](#) attorneys.

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