

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.

Reports on Physician Ownership and Investment Interests

The Sunshine Act requires applicable manufacturers, as well as applicable GPOs, to report to the Secretary, in electronic form, certain information concerning ownership and investment interests held by physicians or their immediate family members in such applicable manufacturers and applicable GPOs, and payments or other transfers of value to such physician owners or investors.

“Applicable GPOs” Defined

The Final Rule defines "applicable GPOs" as an entity that: (1) operates in the United States, or in a territory, possession or commonwealth of the United States; and (2) purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, and not solely for use by the entity itself. The Final Rule adopts the interpretation included in the Proposed Rule, and interprets this definition to not include entities that buy covered drugs, devices, biologicals, or medical supplies solely for their own use, such as some large practices or hospitals (including those owned by physicians).

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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