

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.

“Payments or Other Transfers of Value”

Payments or Other Transfer of Value Must Have a Discernible Economic Value

In the Final Rule, CMS interprets value as the discernible economic value on the open market in the United States. Applicable manufacturers are allowed flexibility to determine value, and CMS outlines some guidelines to assist manufacturers. First, payments or other transfers of value that have a discernible economic value generally must be reported, even if they do not have a discernible economic value for the covered recipient specifically. Second, a payment or transfer of value must be reported, even if a covered recipient does not formally request the payment or other transfer of value. CMS notes that all aspects of a payment or transfer of value, including tax or shipping, should be included in the reported value. All applicable manufacturers must make a reasonable, good faith effort to determine the value of a payment or other transfer of value, and may include their methodology and assumptions in the applicable manufacturer’s voluntary assumptions document.

Form and Nature of Payment Categories are Distinct From One Another

The Final Rule indicates that the categories within both the form of payment and the nature of payment should be defined as distinct from one another. The form of payment should be considered the modality used to transfer value; the nature of payment is the reason the payment was made. The Final Rule provides that if a payment or other transfer of value for an activity is associated with multiple categories, each segregable payment be reported separately in the appropriate category. With regards to lump sum payments or other transfers of value, applicable manufacturers should break out the distinct parts of the payment that fall into multiple categories for both form of payment and nature of payment. For payments that could fit within multiple possible categories, the Final Rule allows applicable manufacturers flexibility to select the category that best describes the payment, in accordance with the manufacturer’s own documented methodology.

The Final Rule indicates that each form of payment and each nature of payment category is defined according to their dictionary definitions. The Final Rule indicates that for consolidated reports, the applicable manufacturer that submits the consolidated report will be required to attest on behalf of all the entities included in the consolidated report; other applicable manufacturers included on the consolidated report must register with CMS, but CMS is not requiring them to attest.

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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