

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.

Report Submission and Review

Pre-Submission Review is Not Required

Applicable manufacturers may voluntarily provide covered recipients the opportunity to review the data prior to submission to CMS, but doing so is not mandatory.

Deadline for Submission

Reports including 2013 data will be due by March 31, 2014; for future years, reports will be due by the 90th day of the year.

Registration

All applicable manufacturers with payments or other transfers of value to report must register individually, regardless of whether they intend to be part of a consolidated report being submitted by another applicable manufacturer; if they will be submitting data as part of a consolidated report under another applicable manufacturer, they may so indicate during registration. The Final Rule requires applicable manufacturers and applicable GPOs to indicate two points of contact when they register to allow for a primary and backup point of contact for each reporting entity.

Data Submission

The Final Rule indicates that CMS will provide applicable manufacturers and applicable GPOs with reporting templates and more details on reporting. If CMS makes changes to the reporting template or other details for reporting, it will provide them at least 90 days prior to first day of data collection for the next reporting year. The Final Rule indicates that CMS will not grant submission extensions; late data will be considered failure to report and may be subject to penalties.

Attestation Process

The Final Rule requires an authorized representative from each applicable manufacturer and applicable GPO to submit a signed attestation certifying the timeliness, accuracy, and completeness of the data submitted to the best of the signer's knowledge and belief. The Final Rule permits other officers, not just the chief executive officer, chief financial officer or chief compliance officer, to attest, as designated by the company. The Final Rule requires that applicable manufacturers and applicable GPOs must provide an attestation for their data at the time of original submission for it to be considered submitted, and they also be required to provide an attestation any time the data is changed or updated.

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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