Better Late than Never - The Sunshine Act Final Regulations are Finally Here! - Centers for Medicare & Medicaid Services (CMS)

Wednesday, February 6, 2013

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.

Click each subheading below for a detailed summary of some of the key provisions of the Final Rule:

"Applicable Manufacturers"
"Covered Recipients"
"Payments or Other Transfers of Value"

Reports on Physician Ownership and Investment Interests

Report Submission and Review

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.

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