

Client Alert

February 2013

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.

"Covered Recipients"

Physicians

The Final Rule retains the proposed definition of "physician" as meaning doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors, who are legally authorized to practice by the state in which they practice. All physicians that have a current license to practice will be considered covered recipients, unless they are employees of the applicable manufacturer submitting the report to CMS.

CMS clarifies in the Final Rule that applicable manufactures are <u>not</u> required to payments or other transfers of value made to residents (including residents in medicine, osteopathy, dentistry, podiatry, optometry and chiropractic.

Teaching Hospitals

The Final Rule adopts the proposed definition of "teaching hospital" as any institution that received payments for indirect medical education (IME), direct graduate medical education, or psychiatric hospital IME during the most recent year for which such information is available.

CMS clarifies in the Final Rule that payments to non-healthcare departments of universities affiliated with teaching hospitals are not included in the reporting requirements. However, CMS notes that any payments or other transfers of value made through these departments to a covered recipient as indirect payments or other transfers of value must be reported as required for indirect payments.

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 <u>Sarah Crotts</u>, the author of this alert. You may also contact the Womble Carlyle attorney with whom you usually work, or any of our <u>Healthcare Industry Team</u> attorneys.

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