

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.

“Applicable Manufacturers”

Common Ownership Considered to be Ownership by the Same Individuals or Entities of 5 Percent or More in Two Entities

In the Final Rule, CMS defines “applicable manufacturer” as an entity operating in the United States that is (1) engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States; or (2) under common ownership with an entity in the first paragraph of this definition, and which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply. The Final Rule defines “common ownership” as when the same individual, individuals, entity, or entities, directly or indirectly, own 5 percent or more total ownership of two entities (such as parent, brother/sister, and subsidiary relationships).

“Assistance and Support” Required for Entities under Common Ownership

Not every entity under common ownership is subject to the Sunshine Act; only entities under common ownership that provide “assistance and support” for the listed manufacturing activities need to report. In the Final Rule, CMS defines “assistance and support” as being necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product.

Reporting Requirements When a Manufacturer is Considered an Applicable Manufacturer Due to Common Ownership:

When common ownership exists among entities that fall within the definition of “applicable manufacturer” because the entities are all engaged in the production, etc. of a covered product, the Final Rule indicates that such manufacturers may, but are not required to, file a consolidated report for all of the entities.

“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 not 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.

“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.

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).

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.

Womble Carlyle client alerts are intended to provide general information about significant legal developments and should not be construed as legal advice regarding any specific facts and circumstances, nor should they be construed as advertisements for legal services.

IRS CIRCULAR 230 NOTICE: *To ensure compliance with requirements imposed by the IRS, we inform you that any U.S. tax advice contained in this communication (or in any attachment) is not intended or written to be used, and cannot be used, for the purpose of (i) avoiding penalties under the Internal Revenue Code or (ii) promoting, marketing or recommending to another party any transaction or matter addressed in this communication (or in any attachment).*