Here Comes the Sun: Final Rules Implementing the Federal Sunshine Law

On February 1, 2013, the Centers for Medicare & Medicaid Services (CMS) released the long-awaited final rule implementing the Federal Sunshine Law (42 U.S.C. 1320a-7h). (The rule was subsequently published in the Federal Register on February 8, 2013.)

The Federal Sunshine Law requires manufacturers of drugs, biologics, devices and medical supplies covered under Medicare, Medicaid and the Children's Health Insurance Program to report payments and other transfers of value made to physicians and teaching hospitals to CMS for subsequent public disclosure. Collection of information was to begin January 1, 2011, but CMS had delayed collection pending promulgation of the final rule. *The final rule requires collection of information beginning August 1, 2013 with information collected for 2013 to be reported to CMS on March 31, 2014.*

CMS, in the final rule, responds to feedback from stakeholders as well as the HHS Office of Inspector General and implements regulations that depart from the proposed rule in significant ways. These departures reflect a better understanding of interactions between manufacturers and covered recipients and the agency's intent to ensure that the transparency created by the law discourages inappropriate relationships without harming beneficial relationships. CMS further seeks to allow reporting flexibility while providing the detail, clarity and standardized processes necessary to ensure accurate information.

Our detailed summary analysis of the final rule and CMS commentary is available here.

Key provisions in the final rule and clarifying commentary include:

- Limiting application of the law to manufacturers that have a physical presence or conduct activities in the United States (which includes selling a product in the United States);
- Finalizing the proposal to restrict application of the law to manufacturers of *prescribed* drugs and biologics (effectively excluding manufacturers of over-the-counter drugs) and to manufacturers of medical devices *for which premarket approval by or premarket notification to the U.S. Food and Drug Administration is required* (effectively excluding manufacturers of many Class I devices and some Class II devices);
- Clarifying that an entity under common ownership or control with a manufacturer (with common ownership requiring a minimum 5% ownership interest) is also a manufacturer only if the entity provides assistance or support that is "necessary or integral" to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered product.
- Allowing certain manufacturers (*i.e.*, certain contract manufacturers; entities that are manufacturers because the entities support commonly owned or controlled manufacturers; separate operating divisions of manufacturers that do not manufacture any covered products; and manufacturers with less than 10% of gross revenues from covered products (which entities are required to register with CMS and provide attestation regarding this threshold)) to report only transfers of value "related to" a covered product;
- Clarifying that residents are not physicians for reporting purposes;

- Finalizing the proposal to define "teaching hospital" as any institution receiving Medicare graduate medical education payments and providing access to a list of teaching hospitals;
- Expressly requiring disclosure of all direct and indirect transfers of value and interpreting indirect transfers of value broadly to include all transfers to a covered recipient through a third party if the applicable manufacturer "requires, instructs, directs or otherwise causes" payment to be made to the covered recipient, other than those transfers in which the identity of the covered recipient is unknown during the reporting year and the following six months;
- Finalizing the proposal to require reporting of third parties through which an indirect payment to a covered recipient is made but providing that, if the third party is an individual rather than an entity, the individual's name is not required and the report should instead state "individual";
- Expanding and revising the categories of transfers reported (*e.g.*, dividing the category for "direct compensation for serving as a speaker for a medical education program" into two categories—one for accredited programs and one for unaccredited programs—and adding a category for "space rental or facility fees");
- Retaining the "gift" category as the catch-all category in identifying the nature of transfers reported by not finalizing the agency's proposal to add an "other" category;
- Establishing special rules for reporting "research" payments (eliminating the direct and indirect categorization of research payments included in the proposed rule);
- Establishing special rules for reporting payments to "continuing education programs;"
- Finalizing the proposal to exclude from tracking buffet meals and refreshments provided to all participants of a large-scale conference or similar large-scale event and including detailed and revised guidance on how to allocate transfers of value related to food and beverages;
- Providing significant guidance on transfers of value *excluded* from reporting, including:
    - *De Minimis*: Excludes transfers valued at less than $10 and made at large-scale conferences and events (*e.g.*, pens and note pads);
    - *Educational Materials*: Excludes both materials and services but not materials or services that benefit only the physician, such as textbooks or article re-prints; and
    - *Short Term Loans of Devices*: Excludes the provision of an appropriate amount of disposable supplies to use in connection with a loaned device;
- Finalizing the proposal to allow manufacturers to include with their report submissions to CMS, on a voluntary basis, the assumptions used in preparing the reports (which assumptions would not be posted on the public website);
- Finalizing the proposal to require senior management of a manufacturer to certify to the accuracy of the submission;
- Finalizing the proposal to allow delayed publication for only: (1) research/development of new covered products or new applications of existing covered products; and (2) clinical investigations regarding new covered products (but not new applications of the covered products); and

- Finalizing the proposed process for review, correction and resolution of disputes concerning information submitted in reports to CMS, with the change that disputes may be initiated through a CMS website and that only the information reported by the manufacturer will be posted if disputes are not resolved.

Manufacturers must act promptly to ensure that the appropriate policies, processes and systems are in place to track and report the required information. Manufacturers that had delayed action pending promulgation of the final rule will now need to move quickly to be ready. Manufacturers that have already taken action will need to re-evaluate policies, processes and systems in light of the final rule (and departures from the proposed rule). Covered recipients must be prepared to respond to manufacturer requests for information as well as the subsequent public disclosure.

If you have any questions regarding the final rule or would like assistance in implementing appropriate policies, processes and systems in response to the final rule, please contact Ropes & Gray.