Federal Sunshine Law: Proposed Rule and Implementation Delay

On December 14, 2011, the Centers for Medicare & Medicaid Services (CMS) released long-awaited guidance on the implementation of the Federal Sunshine Law (42 U.S.C. 1320a-7h) in the form of a proposed rule. (The rule was subsequently published in the Federal Register on December 19, 2011.)

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 announced in the proposed rule that the agency would not require manufacturers to begin collection of information until after a final rule was promulgated.*

Our detailed analysis of the proposed rule as well as CMS commentary is available here.

Key proposals include:

- Restricting 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 the law applies to any manufacturer of covered products *sold or distributed* in the United States, regardless of where the product is produced;
- Requiring any manufacturer meeting the definition of "applicable manufacturer" to report *all* payments or transfers of value, even those that are not associated with a covered drug, device, biological or medical supply;
- Defining "teaching hospital" as any institution receiving Medicare graduate medical education payments and providing access to a list of teaching hospitals;
- Requiring disclosure of third parties if a transfer of value is provided indirectly to a physician or teaching hospital through the third party;
- Clarifying when manufacturers may rely on the exclusion from reporting indirect transfers of value because the identity of the physician or teaching hospital recipient is not known;
- Allowing manufacturers to include with their submission the assumptions used in preparing the reports submitted to CMS (which assumptions would not be posted on the public website);
- Defining the scope of research and development activities subject to delayed publication; and
- Establishing a process for review, correction and resolution of disputes concerning information submitted in reports to CMS.

Key outstanding issues include:

- Providing additional guidance on when an entity supports the manufacturing, distribution and marketing activities of a manufacturer;
- Clarifying whether and when a manufacturer must report transfers of value made by independent contractor distributors who participate in the marketing of a product;

- Clarifying whether and when the law applies to interactions with individual teaching hospital representatives;
- Providing guidance on how to value transfers (*e.g.*, when the transfer does not involve cash or a good with an established market value); and
- Providing additional guidance on the scope of exclusions from reporting requirements (particularly exclusions for medical device samples and for educational materials).

CMS commentary on the proposed rule indicates that the agency is considering alternatives to a number of its proposals, suggesting that there may be significant changes between the proposed rule and any final rule.

The deadline for submission of comments is February 17, 2012 at 5 p.m. Eastern Standard Time. If you have any questions regarding the proposed rule or would like assistance in preparing comments on the proposed rule, please contact one of the attorneys listed below.

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