

The Federal Payment Sunshine Law

On January 1, 2012, Will You Know Where Your Payments Are Going?

On January 1, 2012, manufacturers of drugs, biologics, devices and medical supplies covered under Medicare, Medicaid and the Children's Health Insurance Program must begin tracking payments and other transfers of value made to physicians and teaching hospitals in order to comply with federal requirements known as the federal payment sunshine law ("Sunshine Law").¹

Compliance Challenge

Manufacturers currently face a challenge in ensuring timely compliance with the Sunshine Law. Although many manufacturers have been preparing for the implementation of the law, the law contains a number of ambiguities that must be resolved in order for manufacturers to establish the policies, procedures and tracking systems necessary for compliance. Ambiguities include:

- Which manufacturer has the reporting obligation when manufacturers share responsibility with respect to the manufacture or promotion of a single drug, biologic, or device? *For example, which company or companies report transfers of value in a co-promote arrangement?*
- How are teaching hospitals defined and identified? *For example, how will a manufacturer know if a hospital has a teaching component? What about payments to a university that has a teaching hospital? Are payments to teaching hospital employees reportable?*
- When are transfers of value made to third parties other than physicians and teaching hospitals reportable? *For example, does a manufacturer need to track payments made to a third party such as a research institution or contract research organization that has its own arrangement with a physician investigator or track financial support provided to an educational institution for a scholarship when the educational institution selects the physician recipient?*
- How broad is the scope of the transfers of value exempt from reporting? *For example, when are medical devices provided at no cost exempt from reporting as product samples or educational items?*
- What is a manufacturer of a "medical supply" subject to the law? *Does "medical supply" encompass more than FDA-regulated medical devices?*

The Sunshine Law also creates operational challenges for companies seeking to implement policies, procedures and tracking systems to ensure compliance. Operational challenges include:

- How does a manufacturer ensure that all transfers of value are identified and tracked?
- How does a manufacturer ensure that transfers of value are captured with all the information necessary to ensure complete reporting?
- How does a manufacturer reconcile different obligations under state and federal laws, including different requirements for the characterization and reporting of payments?

The Centers for Medicare & Medicaid Services ("CMS") is required to establish procedures for reporting under the law by October 1, 2011, and the agency has indicated its intent to issue implementing regulations. Even if the regulations are issued by October 1, 2011, however, manufacturers will only have three months to adjust policies, procedures and tracking systems to the clarified requirements.

¹ The Sunshine Law was enacted as Section 6002 of the *Patient Protection and Affordable Care Act of 2010*.

Compliance Assistance

Over the years, Ropes & Gray has closely monitored the progress of the various federal proposals calling for disclosures of payments from industry to physicians and other health care providers that ultimately culminated in the enactment of the Sunshine Law. Our attorneys are currently working with a number of manufacturers to prepare for the impending implementation of the Sunshine Law.

Assistance with the federal law has already included:

- Assisting with the preparation of comments to CMS in connection with the development of agency guidance;
- Analyzing whether the law applies to companies based on the companies' products or relationships with pharmaceutical or medical device manufacturers;
- Advising on applicability of reporting duties to companies involved in co-development arrangements;
- Guiding internal assessments undertaken to identify the universe of transfers of value to be tracked or to evaluate existing company tracking capabilities and gaps;
- Providing guidance on addressing ambiguities in the law pending CMS guidance, including benchmarking on industry interpretations;
- Developing policies and procedures to track, capture, characterize and report transfers of value; and
- Coordinating state, federal and international aggregate spend tracking and disclosure obligations.

Compliance Expertise

Ropes & Gray is uniquely positioned to assist manufacturers in complying with the Sunshine Law. Our attorneys possess an in-depth understanding of the pharmaceutical and medical devices industries. In particular, we recognize the differences in the way the two industries operate and we understand the practices within each industry that give rise to transfers of value.

Not only are we assisting manufacturers with the Sunshine Law now, but we have long been assisting manufacturers to comply with analogous state marketing laws that mandate tracking and disclosure of payments made to certain health care professionals and other providers. In so doing, we have worked successfully with legal or compliance personnel, internal cross-functional teams, and outside consultants.

Assistance with these state laws has included:

- Assessing the applicability of the state laws to specific types of companies;
- Preparing state-specific policies for tracking and categorizing payments;
- Enhancing business processes to facilitate tracking of payments or minimize reporting obligations;
- Developing and conducting training on state law requirements;
- Obtaining critical guidance from state regulators;
- Providing ongoing advice on interpretations of, and compliance with, state laws;

- Responding to state inquiries and audits; and
- Disclosing and addressing non-compliance.

Our experience with these laws has prepared us to anticipate issues with the implementation of the Sunshine Act and act proactively to develop practical solutions proven in the state law context.

Compliance Contacts

If you have questions about the Sunshine Law or its implementation, please contact one of the attorneys listed below.

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