

March 30, 2010

Physician Payment “Sunshine Provisions” Signed into Law as Part of Health Care Reform Legislation

On March 23, President Obama signed into law the Patient Protection and Affordable Health Care Act (H.R. 3590) (the “Act”), which includes new “Sunshine Provisions,” requiring pharmaceutical, medical device, biological, and medical supply manufacturers to begin reporting to the federal government the payments they make to physicians and teaching hospitals. The new provisions also require manufacturers and group purchasing organizations (GPOs) to report physician ownership interests in those entities. Additionally, the law requires the Secretary of Health and Human Services (“the Secretary”) to make this payment and ownership interest information available on a publicly accessible, searchable, and downloadable website. As a result, manufacturers’ payments to consultants, researchers, and others; physician ownership interests held in a manufacturer or GPO; and important information related to such payments and disclosures, will now be a matter of public record.

Ropes & Gray will be monitoring implementation of the Sunshine Provisions as many of the details remain to be worked out by the Secretary through regulation in the coming months. In addition, Ropes & Gray is tracking the myriad other developments of the new health reform law. You can find a wide range of related material, including enacting language, implementing documents, and analysis through the [Health Reform Resource Center](#).

Below is a summary of the key elements of the Sunshine Provisions, as provided in the Act.

Reporting Entities

- The law requires pharmaceutical, medical device, biological, and medical supply manufacturers to report payments to physicians and teaching hospitals¹ (so-called “covered recipients”). Manufacturers plus GPOs also must report any ownership interests by a physician.

Reporting Requirements

- Beginning March 31, 2013, the above entities must report the following information on an annual basis to the Secretary:
 - Payments to Covered Recipients (Manufacturers Only)
 - Any payment or “transfer of value” (to be defined in regulations) to a covered recipient. The report must identify the recipient, the amount and date of payment, and the form and nature of such payment. If payment or transfer of value relates to marketing, education, or research of a drug, device, biological, or medical supply, the product must also be identified. The Secretary may announce additional reporting requirements by regulation.
 - A number of items are excluded from the reporting obligation, including:
 - Payments under \$10, unless the aggregate amount paid to a covered recipient exceeds \$100 per year;
 - Product samples and educational materials for the benefit of patients;
 - Loan of a covered device for a trial period under 90 days;
 - In-kind items provided for use in charity care;
 - Items or services provided under a warranty; and
 - Discounts (including rebates).

¹ Note that the term “teaching hospitals” was not defined in the statute, leaving open for now the question as to whether it will include only the hospital itself, or if it will encompass other key components of an academic medical center, such as a school of medicine.

- The scope of reportable payments is broad and includes consulting fees, compensation for non-consulting services, honoraria, gifts, entertainment, food, travel, education, research, charitable contributions, royalties or licenses, current or prospective ownership or investment interests, direct compensation for serving as faculty or as a speaker for a medical education program, and grants.
- Physician Ownership and Investment Interests (Both Manufacturers and GPOs)
 - Manufacturers and GPOs will be required to report ownership or investment interests of any physician or immediate family member, other than interests in mutual funds or publicly-traded securities. Such report must identify the dollar amount of the investment, its value and terms, and any payment to the physician holding such ownership or interest.

Penalties for Noncompliance

- **Generally:** \$1,000-\$10,000 civil money penalties for failure to report each payment, transfer of value, or ownership or investment; total penalties for each entity may not exceed \$150,000 for each annual submission.
- **Knowing Failure:** \$10,000-\$100,000 civil money penalties for knowing failure to report each payment, transfer of value, or ownership or investment interest; total penalties for each entity may not exceed \$1 million for each annual submission.

Preemption of State Laws

- A number of jurisdictions, including the District of Columbia, Maine, Massachusetts, Minnesota, Vermont, and West Virginia already have disclosure laws. Effective January 1, 2012, the federal Sunshine Provisions will preempt state disclosure laws, except for state requirements to report additional information not required to be reported under the Act, including:
 - Additional types of payments over \$10 in value (or an aggregate \$100 annually) otherwise excluded from reporting requirements under the Act;
 - Payments by entities or persons other than manufacturers;
 - Payments to entities other than physicians and teaching hospitals; and
 - Payments required to be reported to federal, state, and local agencies for public health surveillance purposes.

Implementation Dates

- October 1, 2011: The Secretary will establish procedures for manufacturers and GPOs to report payments, and will provide details on how such information will be made available to the public.
- January 1, 2012: Manufacturers and GPOs will begin recording payments and ownership interests. In addition, provisions in the Act will preempt state law, subject to exceptions.
- March 31, 2013: Manufacturers and GPOs must begin reporting to the Secretary annually.
- September 1, 2013 (and each June 30 thereafter): The Secretary must publish all reported payments and ownership interests to the public via the Internet.

The Sunshine Provisions can be found at [Section 6002](#) of the Act.

If you have any questions about the new requirements or related issues, please contact your usual Ropes & Gray attorney.

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