New Federal Health Reform Law Includes "Sunshine" Reporting Requirements for Drug and Device Manufacturers

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On March 23, President Obama signed into law the Patient Protection and Affordable Care Act (Pub. L. No. 111-148). Section 6002 of the Act (the "new federal law") creates significant new obligations for drug and device manufacturers, by requiring annual disclosure filings detailing their financial relationships with physicians and teaching hospitals. These new federal requirements are also known as the "Sunshine" provisions, since they were originally proposed in 2007 as the "Physician Payments Sunshine Act" by Senators Charles Grassley and Herb Kohl.

The new federal law requires drug and device manufacturers to disclose almost all payments and "transfers of value" made to physicians or to teaching hospitals. These disclosures will be made publicly available via a searchable online database. The new federal law also requires manufacturers to disclose specific payments made to individual physicians and teaching hospitals, rather than simply disclosing the aggregate payments.

While the new federal law does contain a limited "preemption" provision that overrides some state laws governing industry-physician disclosures, that provision does not displace state reporting requirements that are more stringent than the new federal law. In addition, the new federal law imposes significant financial penalties for noncompliance.

Given the magnitude of these changes, and the relatively short implementation timeline — manufacturers must be prepared to begin collecting data on January 1, 2012 — understanding the scope and implications of the new federal law is essential to anyone with interests in the health care, pharmaceutical, and medical device industries.

Impact on Manufacturers of Drugs, Devices, Biologics, and Medical Supplies

The new federal law amends Title XI of the Social Security Act (42 U.S.C. § 1301) with a new Section 1128G, entitled "Transparency Reports and Reporting of Physician Ownership or Investment Interests."

The reporting requirements of Section 1128G are not effective immediately. By October 1, 2011, the Secretary of Health and Human Services (HHS) is required to establish procedures for submitting information. Federal preemption of state laws begins on January 1, 2012. The first annual reports, covering the 2012 calendar year, are due on March 31, 2013.

The key elements of the new federal law are summarized below:

- **Applicable Manufacturers.** Any manufacturer of drugs, devices, biologics, or medical supplies that operates in the U.S. is subject to the reporting requirements.
- **Covered Recipients.** Physicians and teaching hospitals are considered "covered recipients," and payments or transfers provided to them by applicable manufacturers must be reported. Physicians employed "in house" by the applicable manufacturer doing the reporting are not considered "covered recipients."
- **Payments or transfers.** The transfer of anything from an applicable manufacturer to a covered recipient with a value greater than $10 must be reported. However, there are also a limited number of express exemptions, including:
  - Product samples that are not intended to be sold;
  - Discounts, including rebates;
  - Payments to employees under a manufacturer's self-insured plan;
  - In-kind items for charity care;
  - Educational materials that directly benefit patients;
  - Short-term loans of certain devices for evaluation by the recipient;
  - Items or services provided under a contractual warranty;
  - Dividends or profit distributions from a publicly traded security and mutual fund;
  - Transfers to covered recipients as patients (when not acting in their professional capacity);
  - Transfers to a covered recipient for non-medical professional services which that individual is licensed to provide; and
  - Payments to a physician solely for services with respect to a civil or criminal action or an administrative proceeding.
- **Reporting Requirements.** For each payment or transfer, the applicable manufacturer must submit the following information to HHS:
  - The name and address of the recipient;
  - The amount and date of the payment or transfer;
  - A description of the form or nature of the payment or transfer; and
  - Whether the payment or transfer is related to marketing, education, or research specific to a product (and the name of the product, if applicable).
- **Physician Ownership.** Manufacturers must also report ownership or investment interests held by physicians.
- **Penalties.** Manufacturers that *unknowingly* fail to report as required are subject to a penalty of $1,000 to $10,000 for each unreported payment, transfer, or ownership interest. Total penalties for unknowing omissions are capped at $150,000 annually. *Knowing* failures to report are subject to significantly steeper penalties: $10,000 to $100,000 per payment, transfer, or ownership interest not reported, with a $1,000,000 annual cap.

- **Delayed Publication of Research and Development Payments.** Payments and transfers associated with research and development of new technologies, new applications of existing technology, or the development of new drugs, devices, biologicals, or medical supplies, must be reported. However, these reports will be kept confidential and not made public until either the new product is approved by the FDA or four years have passed since the payment or transfer was made, whichever comes first.
- **Preemption.** The new federal law preempts only those state-level reporting requirements that either a) duplicate the new federal reporting requirements, or b) require reporting of transfers valued at less than $10. However, any additional reporting requirements that states may choose to impose are not preempted, including state requirements that manufacturers disclose additional information not otherwise covered by the new federal law.

Future Outlook

While the new federal law establishes federal-level requirements for the disclosure of manufacturer payments to physicians and teaching hospitals, states remain free to adjust their policies to the new federal baseline.

For instance, states with existing reporting laws (or states considering implementing such laws) may now consider including provisions requiring disclosure of additional information not covered by the new federal law, or requiring disclosure of payments to additional categories of health professionals not covered by the new federal law (such as pharmacy benefit managers). As a result, the drug and device industries should continue monitoring state law developments, while simultaneously implementing compliance programs that respond to both the new federal law and the growing patchwork of state disclosure laws.

The new federal law is also expected to lead to new HHS regulations that will both interpret substantive provisions of the statute and detail the development of the new data reporting and collection framework. Input from those involved in the biotechnology, health care, and drug and device sectors will be of significant importance during the HHS rulemaking process.

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