

BUSINESS REVIEW

West Michigan

[What's Next]

Physician Payments Sunshine Law coming soon

Less than one year ago, I wrote an article entitled "Take a Little Sunshine and Call me in the Morning," discussing newly enacted laws from Massachusetts and Vermont that, among other things, required annual reporting of payments by pharmaceutical and medical device companies to physicians.

I also noted that U.S. Sen. Chuck Grassley of Iowa and Herb Kohl of Wisconsin had introduced the Physician Payments Sunshine Bill in the U.S. Senate, which proposed similar federal reporting requirements for payments to physicians by pharmaceutical and medical device companies.

The Physician Payments Sunshine Bill has now become federal law, having been incorporated into the Patient Protection and Affordable Care Act of 2009, more commonly known as the recently enacted health care reform.

The Physician Payments Sunshine Law requires manufacturers of a cov-



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ered drug, device, biological or medical supply to report to the secretary of health and human services all "payments or transfers of value" over \$10 — plus smaller payments totaling more than \$100 over a calendar year — made to physicians and teaching hospitals. The first required report is due March 31, 2013, and will cover payments made during 2012.

This law preempts all similar state disclosure and reporting requirements for payments made after Jan. 1, 2012, except for information a state requires to be reported which is not covered by the Physician Payments Sunshine Law.

The types of payments or transfers of value that must be reported include payments for consulting fees, compensation for services other than con-

sulting, honoraria, gifts, entertainment, food, travel, education, research, charitable contributions, royalties, current or future ownership interests, faculty or speaker fees and other payments as may be identified in the future regulations.

However, certain payments or transfers of value are excluded from the reporting requirements, including but not limited to the provision of product samples, educational materials that directly benefit patients, a loan of a covered device, items provided under warranty, discounts and items for charity care.

The penalties for non-compliance are substantial. Applicable manufacturers that fail to report are subject to a civil monetary penalty of not less than \$1,000 and not more than \$10,000 per payment or transfer of value which was not reported, with a maximum annual amount of \$150,000. However, for knowing violations of the law, these penalty amounts increase to

\$10,000, \$100,000, and \$1 million, respectively.

Starting no later than Sept. 30, 2013, and on June 30 of each calendar year thereafter, the information reported for the prior calendar year shall be made available on a public database that can be searched and downloaded from the Internet.

Manufacturers covered by the law will want to start creating the necessary systems and procedures to capture the required information starting on Jan. 1, 2012.

Manufacturers and physicians need to be mindful that newspapers, federal and state officials charged with enforcing federal and state anti-kickback and anti-fraud laws, malpractice attorneys and patients will be some of those interested in the information reported.

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