

HEALTH CARE
&
HUMAN
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Physician Payment Sunshine Law Sets National Standard for Reporting Payments by Drug and Device Companies

As part of the health care overhaul signed into law on March 23, 2010, pharmaceutical and medical device manufacturers will be required to report annually to the U.S. Department of Health and Human Services (“HHS”) certain information regarding their payments to health care professionals. Known as the Physician Payment Sunshine Provision, the intent of the law is to provide full disclosure to allow consumers to view and search online the financial relationships between their physicians and the health care industry that markets its products to them. The following is a summary of the new law.

What is required? Covered manufacturers must report to HHS on an annual basis any payments made to covered recipients, whether in cash or in kind, including: consulting fees; other compensation; honoraria; gifts; food, travel and entertainment; research grants and charitable donations; royalties and license fees; and stock, options and other equity interests. Covered manufacturers must disclose the name and address of the covered recipient, and the date, amount and purpose of the payment. When a payment is related to the development or marketing of a specific product, the name of the product must also be disclosed. HHS will post the information online, and will submit annual summary reports to Congress and to the states.

Who are covered manufacturers? Covered manufacturers are companies that operate in the United States or its territories and that manufacture drugs, devices, biologicals or medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program.

Who are covered recipients? Covered recipients are physicians and teaching hospitals, other than physicians who are employees of the covered manufacturer.

When does the law take effect? The first report is due on March 31, 2013 and annually thereafter, for payments made during the previous calendar year. In other words, all covered manufacturers must begin tracking their payments to covered recipients starting January 1, 2012. The first report will be made available to the public by

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September 30, 2013. Reports for each calendar year thereafter will be made available by June 30. The reports will be searchable and sorted by each covered manufacturer and covered recipient.

Any confidentiality exceptions? For payments made to a covered recipient in connection with a product research or development agreement related to a new technology, the disclosure will be deferred until the earlier of (i) the date of the approval or clearance of the drug or device or (ii) four years after the date on which the payment was made.

Are any types of payments exempt? The law exempts any payment less than \$10, unless the aggregate amount paid to the recipient during the calendar year exceeds \$100, at which point all payments made to the recipient during the year must be disclosed. These thresholds will be adjusted each year after 2012 in accordance with the consumer price index.

The law also exempts product samples intended for patient use and evaluation devices loaned to a recipient for less than 90 days. It exempts educational materials that directly benefit patients or are intended for patient use; items or services provided under a contractual warranty; a transfer of anything of value to a recipient when the recipient is a patient and not acting in the professional capacity of a covered recipient; discounts (including rebates); in-kind items used for the provision of charity care; and a dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.

What are the penalties for noncompliance? Penalties include civil fines of \$1,000 per unreported payment, up to a maximum of \$10,000, with a total annual cap of \$150,000 per covered manufacturer. For knowing violations, the civil fine is \$10,000 per unreported payment, up to a maximum of \$100,000, with a total annual cap of \$1 million per covered manufacturer.

Will this law preempt state disclosure laws? For any payment or other transfer of value received by a covered recipient on or after January 1, 2012, this law will preempt any state laws or regulations that require disclosure of the same types of information covered by this law. However, this law will not preempt any state laws or regulations that apply to a broader range of manufacturers or recipients, that require the reporting of different types of information than what is required to be reported under this law, or that require the reporting of information that is exempt from reporting under this law (except this law will preempt state laws to the extent that they exempt *de minimis* payments greater than the threshold established under this law). States may also continue to collect data for public health purposes or legal proceedings. ■

If you have any questions or would like assistance creating or reviewing your policies and procedures to ensure that they are ready to begin tracking payments by January 1, 2012, please contact Holly Hoehner.

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