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Be Wary Of Medical Companies Bearing Gifts

Health care reform brings restrictions on what physicians can accept

By JOAN W. FELDMAN and WILLIAM J. ROBERTS

For many years, both Congress and numerous states have debated adopting laws which would either prohibit or restrict physicians from receiving gifts and other transfers of value from pharmaceutical, medical device and medical supply companies. Advocates for such laws have argued that when a physician receives gifts or other items of value, his or her judgment becomes clouded and could potentially result in the physician having a conflict of interest.

While many of the legislative efforts, including a 2009 proposal, in Connecticut, languished due to various concerns and opposition from physicians and pharmaceutical, medical device and medical supply companies, the federal health care reform enacted in March of 2010 (the "Affordable Care Act") includes comprehensive disclosure and reporting rules applicable to many participants in the health care and bioscience sectors.

Under the Affordable Care Act, if a drug, device, biological or medical supply is one that is covered under Medicare, Medicaid or the Children's Health Insurance Program, Congress requires that the manufacturer track and disclose payments and other "transfers of value" to "teaching hospitals" and physicians. The first disclosures are due to the U.S. Department of Health and Human Services (HHS) on March 31, 2013 for the preceding calendar year. Therefore, manufacturers will need to begin tracking the necessary information on Jan. 1, 2012 and should take time now to either curtail their practices or develop and implement an appropriate tracking system.

Joan w. Feldman

William J. Roberts

The definition of "anything of value" is broad and includes consulting fees or other compensation, honoraria, gifts, entertainment, travel, food, education, research, charitable contributions, royalties and licenses, ownership interests and grants. Notwithstanding, certain transfers are excluded, such as: transfers of anything of value less than $10 (or $100 in the aggregate per calendar year – to be increased after 2012); product samples intended for patient use and not to be sold; educational materials for patient use; short-term equipment loans (up to 90 days); items or services provided under contractual warranty, discounts and in-kind items used for charity care. Many physicians will be pleased with this exemption because it allows them to continue to give patients free samples.

To properly disclose these transfers to the Department of Health and Human Services, the manufacturer must track the name and address of the recipient, the recipient's National Provider Identifier number and specialty (if applicable), the amount of the transfer, the form and nature of the transfer, the date of the transfer and whether the transfer was related to marketing, education or research specific to a drug, device, biological or medical supply.

Reporting Physician Ownership

Beginning March 31, 2013, manufacturers and certain group purchasing organizations (GPOs) must report ownership or investment interests held by a physician or a physician's immediate family member in that GPO or manufacturer (other than ownership or investment through a publicly traded security or mutual fund).

Joan Feldman is a partner in the Hartford office of Shipman & Goodwin. She advises health care providers on matters such as mergers and acquisitions, state and federal regulatory issues, corporate compliance and Medicare and Medicaid reimbursement. She can be reached at jfeldman@goodwin. William Roberts also practices in the area of Health Law. He is an associate in the firm's Hartford office, where he can be reached at wroberts@goodwin.com.

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The GPO or manufacturer must disclose to the federal government the dollar amount, value and terms of the ownership or investment interest and any payments made to the physician holder of the ownership or investment interest. Again, the reason for this disclosure is to assure full transparency, especially in the areas of research and physician education.

Public Availability

The information disclosed by manufacturers and GPOs will be collected by the Department of Health and Human Services and then made publically available via a web site. While not yet established, the web site will be public and allow for easy aggregation and downloading.

The web site will also contain background information on industry-physician relationships, descriptions of enforcement actions against entities that fail to make the required disclosures and other information that may be required by HHS.

Reporting Drug Samples

As of Jan. 1, 2011, manufacturers and distributors of prescription drugs must track and report certain information regarding the distribution of drug samples to licensed practitioners and pharmacies of hospitals or other health care entities.

Since the first report must be filed with HHS by April 1, 2012 for the 2011 calendar year, compliance efforts should begin now. The report must include, among other things: the identity and quantity of drug samples requested by a licensed practitioner; the identity and quantity of drug samples distributed pursuant to such request; the name, address, professional designation and signature of the practitioner (or his or her designee) making the request; and any other information deemed appropriate by HHS.

Physicians should know that even though they are not charged with the responsibility of reporting, if they accept the samples, their name will become part of the public record.

Failure to Report

Failing to report gifts or payments to physicians or physician ownership interests may result in penalties between $1,000 and $10,000 per incident (up to $150,000 per year). A "knowing" failure to report may result in even higher penalties.

Looking Ahead

The Affordable Care Act's reporting and disclosure requirements will entail a significant administrative burden for manufacturers, group purchasing organizations and distributors. Entities should act now to ensure compliance, especially since the Office of the Inspector General has identified the tracking and reporting of payments to physicians and drug samples as "key areas of focus" for future enforcement activity.

The key to an effective tracking and reporting program is training. Sales representatives, marketing personnel, and other relevant staff and contractors should be trained to appropriately track and report data within the entity's information collection system. An entity should also consider implementing periodic internal compliance reviews to ensure that tracking and reporting are conforming to the Affordable Care Act and any future implementing regulations. ■