Physician Conflicts of Interest and the Sunshine Act

By David E. Schweighoefer, Esq.

THE PHYSICIAN PAYMENTS Sunshine Act, which became operational August 1, 2013, is intended to raise public awareness of the financial relationships between medical device and pharmaceutical companies and doctors and teaching hospitals. The rule requires manufacturers and group purchasing organizations (GPOs) to disclose to the Centers for Medicare & Medicaid Services (CMS) whether any physicians have investment or ownership interests, as well as any payments they may have received as a result of ownership or investment interests. This information will be posted on a public website.

The Act will be administered under a program known as the OPEN PAYMENTS. This program imposes three primary reporting requirements:

Applicable manufacturers must annually report all payments and other transfers of value (TOV) to physicians and teaching hospitals;

Applicable manufacturers and GPOs must report ownership or investment interests held by physicians or their immediate family members;

GPOs must report payments and other transfers of value made to physician owners or investors if they held ownership or investment interests during a reporting year.

Reporting from 2013 extends from August 1 through December 31. Data collected for this reporting period must be submitted to CMS by March 31, 2014, and will be published on the website by September 30, 2014.

Physicians should be aware that the statute requires reporting both the *form* of the payment and the *nature* of the payment. Categories of *form* include: cash or its equivalent, in-kind items or services, stock, stock options, interest, dividends, profits or other returns on investment. Categories of *nature* include, but are not limited to: consulting fees, speaking fees, honoraria, gifts, entertainment, food, travel, education payments, research payments, charitable contributions, space rental or facility fees, and royalties and license fees.

The statute defines ownership or investment interests as well, including vehicles that are direct, indirect and through debt, equity or other means. These interests include, but are not limited to – stock, stock options, partnership shares, limited liability company memberships, loans, bonds or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

Are the reporting entities prepared? General consensus is that many manufacturers are not prepared, and therefore not able to meet their compliance obligations. Manufacturers are advised that this is not a mere bookkeeping exercise, but rather these compliance activities should be integrated into a broader corporate integrity and financial relationship management program. Compliance for makers of drugs, devices, and biologicals is critical because Sunshine Act data could trigger scrutiny from regulators and law enforcement. Civil Monetary Penalties (CMP) can be imposed for failure to report the required information in accordance with the regulations. The penalties under the CMP are at least $1,000 but no more than $10,000 for each payment or other TOV, or ownership or investment interest not reported as required. The maximum total CMP with respect to each annual submission for failure to report is $150,000. For knowing failure, the minimum will be at least $10,000, but no more than $100,000 and the maximum CMP with respect to a knowing failure to report is $1,000,000.

What effect will this Act have on the examination of conflicts of interest involving physicians?

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