GW GARFUNKEL WILD, P.C. ATTORNEYS AT LAW Legal Alert

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The Physician Payments Sunshine Act: Lots of Rules and Penalties. So Where is the Sunshine?

On February 8, 2013, the Centers for Medicare & Medicaid Services ("CMS") published the Final Rule for the Physician Payments Sunshine Act (the "Sunshine Act") which will impact physicians and teaching hospitals who receive anything of value from manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare, Medicaid, or the Children's Health Insurance Program ("CHIP"). Below are a few of the many questions clients have asked us about the Sunshine Act.

What is the purpose of the Sunshine Act?
The Sunshine Act is intended to address certain potential conflicts of interest caused by payments from manufacturers to physicians and teaching hospitals "that may influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care, and may lead to increased health care costs." The government believes these potential conflicts are important enough to be reported and published on a website.

Will the information on the website be available to the general public?
Yes. The information will be available on a website, currently under development, beginning September 2014. CMS also plans to establish mechanisms to make non-public information available to "researchers".

Who is required to collect and report the information?
Manufacturers and group purchasing organizations ("GPOs") are responsible for collecting and reporting the information. A GPO is an entity that negotiates purchases (in this case purchases of a drug, device, biological or medical supplies covered under Medicare, Medicaid, or CHIP) on behalf of its members at a discount based on the collective buying power of its members.

What are the applicable collection and reporting periods and deadlines?
Manufacturers and GPOs must begin collecting the required information on August 1, 2013 for an initial reporting period ending December 31, 2013 and must initially report such data to CMS by March 31, 2014.

What information needs to be reported?
The Final Rule details the process, content, and format manufacturers and GPOs must follow to fulfill their data collection and disclosure obligations. Manufacturers must disclose the types of payments and transfers of value to physicians and teaching hospitals, whether provided directly or indirectly through a third party. Manufacturers and GPOs must also report certain information regarding the ownership or investment interests held by physicians or their immediate family members in such entities.

What forms of payment must be reported?
The forms of payment categories include (a) cash or a cash equivalent; (b) in-kind items or services; (c) stock, stock option, or any other ownership interest; and (d) dividend, profit or other return on investment.

What are the nature of payment categories?
Payments may be categorized as (a) consulting fees; (b) compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program; (c) honoraria; (d) gifts; (e) entertainment; (f) food and beverage; (g) travel (including the specified destinations); (h) education; (i) research; (j) charitable contribution; (k) royalty or license; (l) current or prospective ownership or investment interest; (m) compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program; (n) compensation for serving as faculty or as a speaker for an accredited or certified continuing education program; (o) grant; and (p) space rental or facility fees (teaching hospital only).

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How is the value of items or services transferred determined?
CMS provides guidance on determining the value of an item or service. Though CMS provides some flexibility regarding the valuation of items and services, manufacturers should establish standard criteria to determine the fair market value of the items and services and must make a reasonable, good faith effort to determine the value of a payment or other transfer of value.

Can a physician or teaching hospital contribute to, or dispute, the information reported?
Yes. Hospitals, physicians and other individuals and entities may dispute and correct the information reported by manufacturers and GPOs prior to such information becoming public, but must do so in the manner and within the time frame specified by CMS. If a dispute cannot be resolved in this time, CMS will nevertheless publish the original and attested data, but will mark it as disputed.

Do all payments and transfers of value by manufacturers to physicians and teaching hospitals need to be reported?
No. The Final Rule provides certain exclusions from the reporting requirements, including an exclusion for a payment or transfer of value up to a maximum of $10; up to a $100 per calendar year for each covered recipient; payments for certain speaking engagements at qualifying continuing medical education events; and educational materials that directly benefit patients or are intended for patient use.

Could payments made to a university affiliated with a teaching hospital be subject to the mandatory collection and reporting requirements of the Sunshine Act?
Yes.

What if a practice or hospital waives a payment and requests that a charitable contribution be made instead?
The payment must be reported. Thus, certain charitable donations made on behalf of physicians or tax-exempt teaching hospitals require disclosure.

Are there any penalties for failure to satisfy the reporting obligations?
CMS and the Office of Inspector General ("OIG") may impose penalties on manufacturers and GPOs of up to $10,000 for each failure to report up to a total of $150,000 per annual submission and up to $100,000 for each knowing failure to report up to $1 million per annual submission. Total annual civil monetary penalties imposed are aggregated separately. Failure to promptly report errors and changes to CMS may be considered incomplete reporting and may give rise to penalties.

How are physicians and teaching hospitals exposed?
In addition to increasing scrutiny of physician and hospital compensation practices, the information that manufacturers and GPOs must disclose may be scrutinized for purposes of determining whether there are any violations of federal and applicable state laws, including, but not limited to, the Anti-Kickback Statutes, False Claims Acts, and Stark Laws. It is therefore imperative that physicians and hospitals review the accuracy of information reported.

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If you are involved in any transaction that is governed by the Sunshine Act, and would like additional guidance, please contact the GW attorney with whom you regularly consult.

About Garfunkel Wild, P.C.

Garfunkel Wild, P.C. was founded in 1980 with a single purpose in mind: to become a pre-eminent health care law firm attending to the unique business and legal needs of its clients. Since then, the firm has grown to over 70 attorneys devoted to addressing the complex legal, regulatory, business and financial needs of its diverse clients.

If you have any questions regarding this Legal Alert, please contact Barry B. Cepelewicz, Esq. at (203) 316-0483.

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