February 2013

CMS Releases Final Sunshine Act Rule

Finally. On February 1, 2013, the Centers for Medicare & Medicaid Services ("CMS" or "Agency") released its long-awaited rule implementing the Physician Payments Sunshine Act ("Act"). The "sunshine" rule, which was issued as a proposed rule in December 2011, provides clarification and guidance regarding the Act's requirement that pharmaceutical and medical device manufacturers report annually payments and other transfers of value made to physicians or teaching hospitals. The rule also will require public disclosure of physician ownership or investment in manufacturers and group purchasing organizations ("GPOs"), including physician-owned distributorships ("PODs").

The rule will be published in the Federal Register on February 8, but a copy is available here. In addition, a CMS Fact Sheet discussing the rule is available here.

The rule provides that manufacturers must begin to collect data on August 1, 2013. Manufacturers then will be required to submit information for a partial year on March 31, 2014. When CMS receives the information from manufacturers, the Agency will aggregate the submissions at the individual physician and teaching hospital level, provide physicians and teaching hospitals with a 45-day period to confidentially review and, if necessary, correct the data, and make the data publicly available by September 30, 2014.

Reporting Requirements

Payment Disclosures

The rule implements two reporting requirements imposed by the Act. First, drug and device manufacturers must report all payments or transfers of value (including gifts, consulting fees, research activities, speaking fees, meals, and travel) provided to physicians or teaching hospitals. The rule applies to drug and device manufacturers who manufacture a drug, device, biologic, or medical supply that is reimbursed by a federal health care program and entities under common ownership with such manufacturers. Second, manufacturers and GPOs must report certain information concerning ownership and investment interests of physicians and their immediate family members in such entities. The rule also establishes the process by which CMS will publish manufacturers' submitted payment and ownership information on a public website.

Under the rule, manufacturers' reports must contain all the following information for each payment or other transfer of value:

- The name of the recipient, as listed in the National Plan & Provider Enumeration System ("NPPES") if the recipient is a physician;
- The primary business address of the recipient;
- In the case of a recipient who is a physician, the physician's specialty, National Provider Identifier ("NPI") number, and state professional license number;

- The amount of the payment;
- The date of the payment;
- The form of the payment (e.g., cash or cash equivalent, in-kind items or services, stock, etc.);
- The nature of the payment (e.g., consulting fees, compensation for nonconsulting services, honoraria, gifts, entertainment, food, travel, education, research, charitable contributions, royalty or license fees, investment ownership, speaker fees, grants, etc.);
- If the payment is related to a drug or device, the name of the drug or device;
- If the payment is made in accordance with a product research or development agreement, or in connection with a clinical investigation, a statement that the payment is eligible for delayed publication;
- If the payment is made to an entity or individual at the request of the physician, the name of the other individual or entity that receives the payment; and
- Whether the payment was provided to a physician who holds an ownership or investment interest in the manufacturer.

The rule requires that reports on physician ownership or investment interests must include the following information:

- The name of the physician (as listed in the NPPES), and whether the ownership or investment interest is held by an immediate family member of the physician;
- The primary business address of the physician;
- The physician owner's specialty, NPI number and state professional license number;
- The dollar amount invested by each physician or immediate family member of the physician;
- The value and terms of each ownership or investment interest; and
- For any payment or other transfer of value provided to a physician holding an ownership or investment interest, the information enumerated above.

Manufacturers may submit an "assumptions document" that explains the "reasonable assumptions made and methodologies used" when reporting payments.

Exemptions

The rule specifically exempts numerous types of payments or other transfers of value from the reporting requirements. Among these are indirect payments where the manufacturer does not know the identity of the physician; samples not intended to be sold that are intended for patient use; educational materials that directly benefit patients; loans of a device for a short-term trial period; items or services provided under a contractual warranty; discounts, including rebates; and in-kind contributions used for charity care. In addition, for CY2013, payments less than $10 are exempt, unless the aggregate amount paid to a physician during the calendar year exceeds $100, in which case all payments must be reported. (In subsequent years, this threshold will rise with inflation.) The proposed rule also exempts product samples from the reporting requirements, though a separate provision of law requires companies to report sample information to federal regulators (see here).

Research Payments

Although not exempt from reporting and public disclosure, payments made by manufacturers to physicians "under a product research or development agreement" may be published on CMS's website on a delayed basis. Such agreements must include "a written agreement, a research protocol, or both." Research-related payments will be delayed from publication if the payment was made in connection with:

- Research on or development of a new drug, device, biologic or medical supply, or a new application of an existing drug, device, biologic or medical supply; or

- Clinical investigations related to a new drug, device, biologic, or medical supply.

Publication will be delayed until the first annual publication date after the earlier of (1) Food and Drug Administration ("FDA") approval, licensure or clearance of the drug, device or biologic; or (2) four years after the payment was made.

Dispute Resolution and Penalties for Noncompliance

Under the rule, physicians will be provided at least 45 days to review and dispute information about payments they received that is submitted by manufacturers. When reported information is ready for review, a physician will be able to log in to a secure website to view all information reported about that physician. Any disputes are to be resolved directly between the physician and the manufacturer.

There are significant penalties for failing to comply with the rule. Failing to comply with reporting requirements may result in civil monetary penalties ("CMPs") of as much as $150,000, which may increase to $1,000,000 if the failure to report is knowing. The Office of the Inspector General ("OIG") at the U.S. Department of Health and Human Services is authorized to audit, evaluate, and inspect manufacturers for compliance with the rule.

Preemption of State Laws

The rule preempts "any statute or regulation" of a state that requires a manufacturer "to disclose or report, in any format, the type of information regarding the payment or other transfer of value required to be reported" by the rule. This preemption provision, however, does not relieve manufacturers of having to report information required by states "for public health surveillance, investigation, or other public health purposes or health oversight purposes," such as "preventing or controlling disease, injury, [or] disability" or conducting "audits, investigations, inspections, licensure or disciplinary actions, or other activities necessary for oversight of the health care system."

How We Can Help

Hunton & Williams' Food and Drug Practice has extensive experience developing and advising on comprehensive drug and device marketing compliance programs, including those required by state and federal sunshine laws. Our lawyers have helped guide pharmaceutical and medical device companies through difficult investigations, settlements and post-settlement compliance activities. We have advised pharmaceutical and medical device clients on a wide array of enforcement and regulatory proceedings, including matters implicating the Federal Food, Drug, and Cosmetic Act , the federal Anti-Kickback Statute and similar state statutes, the Prescription Drug Marketing Act, the False Claims Act, the Stark physician referral statute, and current good manufacturing practice ("cGMP") and quality system regulation ("QSR") requirements. We also have advised drug and device clients in Foreign Corrupt Practices Act ("FCPA") matters. If you need assistance in developing, revising or implementing your

organization's compliance practices, or have questions regarding any facet of state and federal fraud, abuse and disclosure laws, please contact us.

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