

Client Alert

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CMS Releases Proposed Physician Payments Sunshine Rule

The Centers for Medicare & Medicaid Services (“CMS” or “Agency”) released on December 14, 2011, its long-awaited proposed rule to implement the Physician Payments Sunshine Act (“Act”). The Act is a section of the Patient Protection and Affordable Care Act that requires pharmaceutical and medical device manufacturers to report, among other things, payments and other transfers of value made to physicians or teaching hospitals. CMS is accepting comments on the proposed rule until February 17, 2012, and the Agency has indicated that it will respond to them in a final rule to be published sometime in 2012.

As observed in CMS’s proposed rule, the Act’s transparency reporting requirements consist of two parts. The first part requires that drug and device manufacturers report any “payment or other transfer of value” provided to physicians or teaching hospitals. The second part requires that such manufacturers also report certain information concerning ownership and investment interests of physicians and their immediate family members, along with information regarding any “payment or other transfer of value” provided to such physician owners or investors. Although CMS acknowledges that “there is some overlap between these submissions,” the Agency seeks comments on its proposal “that these two types of information be reported separately to ensure that the relevant reporting obligations . . . are clearly distinguished.” The Act requires CMS to publish manufacturers’ submitted payment and ownership information on a public website.

The proposed rule specifically exempts numerous types of payments or other transfers of value from the reporting requirements. Among these are educational materials that directly benefit patients; loans of a device for a short-term trial period; discounts or rebates; in-kind contributions used for charity care; and payments made indirectly to a physician through a third party, where the manufacturer is unaware of the identity of the physician. In addition, for CY 2012, 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. The proposed rule also exempts product samples from the reporting requirements, though a separate section of the Patient Protection and Affordable Care Act requires companies to report sample information to federal regulators.

CMS proposes that manufacturers’ reports must contain all of the following information for each payment or other transfer of value:

- The name of the recipient;
- The business address of the recipient;
- In the case of a recipient who is a physician, the specialty and National Provider Identifier (“NPI”);
- 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 non-consulting services, honoraria, gifts, entertainment, food, travel, education, research, charitable contributions, royalty or license fees, speaker program 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 subject to 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.

In addition, CMS proposes special requirements for reporting research payments.

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

- The name of the physician, and whether the ownership or investment interest is held by an immediate family member of the physician;
- The business address of the physician;
- The physician owner's specialty and NPI;
- 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.

CMS proposes that data collection not begin on January 1, 2012 (as required by the Act); rather, manufacturers would not be required to begin data collection until the Agency issues its final rule. Depending upon the timing of the final rule, CMS proposes that manufacturers would be required to submit information for a partial year on March 31, 2013. Once CMS receives the information from manufacturers, the Agency proposes that it would aggregate the submissions at the individual physician and teaching hospital level, provide them with a 45-day period to confidentially review and, if necessary, correct the data, and make the data publicly available by September 30, 2013.

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