The Physician Payments Sunshine Act: What the CMS Proposed Rule Means for Physicians and Practice Administrators

On December 14, 2011, the Centers for Medicare & Medicaid Services (CMS) released its proposed rule implementing Section 6002 of the Affordable Care Act – also called the "Physician Payments Sunshine Act". This proposed rule, entitled "Transparency Reports and Reporting of Physician Ownership or Investments," requires certain manufacturers of drugs, devices, and biologics to report to CMS information relating to payments and other transfers of value to physicians and teaching hospitals. Within the meaning of "transfers of value" are gifts, consulting fees, research activities, speaking fees, meals, and travel. Further, manufacturers and group purchasing organizations (GPOs) must report to CMS all ownership interests in such organizations that are held by physicians. The proposed rule also calls for the implementation of a public website that will contain the disclosures obtained by CMS in a searchable and downloadable format. Comments on the proposed rule were due on February 17, 2012, and CMS is anticipated to issue a final rule as soon as practicable in 2012. The first disclosure submissions and reports will be due from manufacturers and GPOs by March 21, 2013. Assuming the final rule is implemented in 2012, physicians and practice administrators can expect to receive information requests from manufacturers and GPOs regarding these reports beginning in late 2012. The following paragraphs outline the basic mandates of the proposed rule in order to provide physicians and practice administrators a context for the inevitable communications with manufacturers and GPOs regarding the rule's required disclosures and reports.

WHO IS RESPONSIBLE FOR REPORTING?

All "applicable" manufacturers must comply with the reporting requirements of the proposed rule. In the rule, CMS proposes to define applicable manufacturers as any entity (or any entity under common control of such an entity) that manufactures a drug, device, biological, or medical supplies for sale or distribution in the United States that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program (referred to in the proposed rule as "covered products"). In addition, all "applicable" GPOs must comply with the reporting mandates. CMS proposes defining applicable GPOs as any entity that operates in the Untied States which purchases, arranges for, or negotiates the purchase of a covered product for a group of individuals or entities, and not solely for use by the entity itself.

WHAT IS REPORTED TO CMS?

With respect to payments and other transfers of value, the proposed rule requires reports containing the manufacturer's name; the physician's name, specialty, practice location, and National Provider Identifier (or the name and location of the teaching hospital recipient); the amount, date, form, and nature of the payment or other transfer of value; and the name of the entity that received the payment or other transfer of value (if not the physician directly). For reporting in connection with a physician's ownership interest in a manufacturer or GPO, the proposed rule requires the manufacturer's or GPO's name; the physician's name, specialty, practice location, and National Provider Identifier; whether the ownership or investment interest is held by the physician or an immediate family member; the dollar amount invested; and the value and terms of each ownership or investment interest. A number of items are excluded from the reporting requirements such as payments or other transfers of value under $10, product samples, or interest arising from a retirement plan offered through an employment arrangement. Although direct stock ownership by a physician in a manufacturer or GPO is reportable, a physician holding a

manufacturer's or GPO's publicly traded shares or mutual funds (such as shares traded on the New York Stock Exchange) are not required to be reported. If a physician receives a stock option in a manufacturer or GPO as compensation, the option is not required to be reported unless and until the option is exercised by the physician.

WHAT INFORMATION WILL BE AVAILABLE ON THE PUBLIC WEBSITE?

In the proposed rule, CMS proposes to publish payments or other transfers of value. CMS is considering providing physicians and teaching hospitals 45 days to review and correct information before publishing it on the website.

CONCLUSION

The above information will provide physicians and practice administrators a context for discussions with manufacturers and GPOs that wish to obtain information for the disclosures and reports required by CMS. Several questions that may impact physicians and practice administrators remain unclear under the proposed rule. For example, when a physician and a manufacturer disagree about the valuation of a transfer that must be disclosed to CMS, whose valuation will be reported? How will the disagreement be resolved? We will monitor these and other questions as the comments to the proposed rule are published and CMS moves closer to issuing a final rule.