ALERTS AND UPDATES

CMS Issues Proposed Sunshine Act Regulations

December 28, 2011

Bright-Light Scrutiny on Payments by Drug and Device Makers to Physicians and Teaching Hospitals and Certain Physician Ownership Interests

The Centers for Medicare and Medicaid Services (CMS) published in the *Federal Register* on December 19, 2011, proposed regulations under the federal Physician Payment Sunshine Act (the "Act"), which Congress passed as part of the 2010 healthcare reform package. The Act requires drug, medical device and other manufacturers to collect data on and annually report to CMS payments to physicians and teaching hospitals. It also requires that these manufacturers, as well as drug and device supplier group purchasing organizations (GPOs), annually report physician ownership and investment interests. Under the Act, data collection activities were to have commenced on January 1, 2012, but CMS was late in issuing regulations. Now, manufacturers and GPOs do not have to begin collecting data until after final regulations are issued, which according to CMS will be sometime in 2012. The first reporting deadline for data collected in 2012 will be March 31, 2013, according to the proposed regulations.

The Act is designed to promote transparency in the relationships between healthcare drug and device manufacturers and physicians and big teaching hospitals, as well as to limit conflicts of interest between these parties. Although manufacturers, physicians and teaching hospitals have been aware since the passage of the Act that these regulations were coming, their effect will be significant. Each covered manufacturer and GPO will have to dedicate staff to collect the data, make the reports and review the data for accuracy before the information is made public. Physicians and teaching hospitals will also have to use staff time to review the data before publication. The consequences of not reporting are considerable, subjecting a non-reporter to civil fines and penalties, from $1,000 for a simple inaccuracy, up to $1 million for a knowing failure to report.

The proposed regulations define several key terms, describe the reporting process and request feedback on several key issues. Covered manufacturers include virtually every entity engaged in the production or preparation of a drug, device, biological or medical supply that is covered directly or indirectly (such as through a composite payment rate) by Medicare or Medicaid. Covered recipients include all physicians except those employed by covered manufacturers, and teaching hospitals that receive graduate medical education funds under Medicare. Covered payments include direct payments as well as any "transfer of value" to a physician or teaching hospital that amounts to $10 or more, or aggregated to $100 in a year. Payments may be in the form of consulting fees, gifts, entertainment, charitable contributions and ownership interests. There are exclusions for, among others, in-kind items used for the provision of charity care, and transfers of value through third parties when the manufacturer is unaware that the transfer is covered under these regulations. There are also special rules applicable to research payments.

The amount of information that a manufacturer is required to report is remarkable, and will be available to the public. For every payment or transfer of value, the manufacturer or GPO has to provide:

- The name of the physician or teaching hospital;

- The business address of the physician or teaching hospital;
- For physicians, the physician's national provider identifier;
- The amount/value of the payment or other transfer of value;
- The dates on which the payment or other transfer of value was provided to the physician or teaching hospital;
- The form of the payment or transfer of value, such as cash, in-kind services or ownership interest;
- The nature of the payment or other transfer of value, such as consulting fees, gifts, entertainment, etc.;
- If a payment or other transfer of value is related to marketing, education or research specific to a covered product, the name under which the covered product is marketed; and
- Other data related to research, payment to a third party, payment to a physician with an ownership or investment interest, and other circumstances.

Drug and device manufacturers and GPOs are also required to report all ownership and investment interests held by a physician or a physician's immediate family member. CMS will be developing an electronic system to receive the reported data, and will provide a 45-day review period during which reporters and the physicians and teaching hospitals named by the reporters can review the data for accuracy.

CMS recognizes the costs and burdens imposed by these regulations and is asking for comments in several areas. For instance, it is proposing to limit drugs and biologicals to those requiring a prescription, thus excluding over-the-counter (OTC) ones. It is also proposing to limit devices and medical supplies to those that require premarket approval by or notification to the federal Food and Drug Administration. CMS is also looking for comments on whether to require all manufacturers and GPOs to register with CMS, and for those who had nothing to report, to provide an attestation to that effect from the CEO, CFO or chief compliance officer.

Comments are due to CMS by February 17, 2012. Even though there will likely be some changes in the final regulations, their basic parameters will not change because they track the Sunshine Act. Drug and device manufacturers, GPOs, physicians, teaching hospitals and others affected by these regulations should closely review them and begin developing a compliance program.

For Further Information

If you have any questions about this *Alert* or would like assistance in understanding the application of Sunshine Act regulations to your entity, or in developing your Sunshine Act compliance program, please contact Lisa Clark, any other member of the Pharmaceutical, Pharmacy and Food industry group or the attorney in the firm with whom you are regularly in contact.