HONIGMAN ALERT

Health Care Department **February 6, 2012**

Physician Payment Sunshine Act Update: Start Date for Reporting Delayed by CMS

The Centers for Medicare & Medicaid Services (CMS) has delayed the start date for data collection of payments made to physicians and teaching hospitals by drug and device manufacturers and group purchasing organizations (GPOs). CMS announced this delay when it issued a proposed rule (Proposed Rule) to implement the Physician Payments Sunshine Act (Sunshine Act), which requires pharmaceutical and medical device manufacturers and GPOs to disclose certain financial relationships with physicians and teaching hospitals as part of an effort to increase transparency and eliminate conflicts of interest in medical research. These disclosures are required to be made public by CMS through a searchable website. For a copy of the Proposed Rule published in the Federal Register on December 19, 2011, click here.

Implementation Delayed

While the Sunshine Act requires manufacturers to begin collecting reportable information beginning January 1, 2012 and to report the first year of disclosures to CMS by March 31, 2012, CMS has stated it will not require the collection of information until after the final rule is published. CMS is considering providing manufacturers 90 days after publication of the final rule to prepare to collect the required information, but has requested comments on how much time reporting entities will need to comply following publication of the final rule. Given CMS' implementation delay, applicable manufacturers and GPOs will likely not have an obligation to collect information about expenditures or ownership and investment interests before the latter part of 2012.

Reporting Requirements

The Sunshine Act requires that two types of information be reported:

- Applicable manufacturers must report payments or other transfers of value to covered recipients
- Applicable manufacturers and GPOs must report ownership and investment interests held by physicians and their immediate family members in the manufacturer or GPO

Under the Proposed Rule, an "applicable manufacturer" is defined as an entity that is either: (1) engaged in the production, preparation, propagation, compounding or conversion of a covered drug, device, biological or medical supply (covered product) for sale or distribution in the United States; or (2) under common ownership with an entity described above and provides assistance or support

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to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered product for sale or distribution in the United States. Under the Proposed Rule, entities that manufacture only over-the-counter drugs and/or certain Class I or Class II medical devices (those that do not require FDA premarket approval or notification) would not be subject to the reporting requirements.

Covered recipients include teaching hospitals and physicians, other than those employed by an applicable manufacturer. Although applicable manufacturers will be required to report information about covered recipients, teaching hospitals and physicians do not have an independent reporting obligation under the Sunshine Act or Proposed Rule.

Penalties for Failure to Report

Under the Proposed Rule, civil monetary penalties would be assessed on applicable manufacturers and GPOs who fail to accurately and completely submit the required information in accordance with CMS' regulations. For knowing violations, the Proposed Rule would impose civil monetary penalties between $10,000 and $100,000 for each payment or transfer of value or ownership or investment interest not reported, with the total penalties for each annual submission, not to exceed $1 million. For all other failures to accurately and completely submit reports, civil monetary penalties between $1,000 and $10,000 would be assessed, subject to a $150,000 limit for each annual submission.

Comments

CMS is soliciting comments regarding several parts of the Proposed Rule, including the most practical and reasonable ways to facilitate the submission of industry reports and public disclosure required by the Sunshine Act. Affected stakeholders should consider submitting comments to assist CMS in creating a final rule that adequately protects industry interests in advancing the practice of medicine, but results in fair public disclosure. CMS will accept comments on the Proposed Rule until February 17, 2012.

For more information about the Sunshine Act or Proposed Rule, please contact any member of the Honigman Health Care Department.