CMS Issues Proposed Regulations Interpreting the Physician Payment Sunshine Act

On December 14, 2011, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule interpreting the “sunshine” provisions of the health care reform law that require drug and device companies to report any payments or transfers of value made to physicians or teaching hospitals. The Physician Payment Sunshine Act provisions were included in the Patient Protection and Affordable Care Act of 2009 (H.R. 3590, section 6002), which was signed into law on March 23, 2010. The Sunshine Act provides that any manufacturer of drugs or devices reimbursable by a federal health care program that provides a payment or other transfer of value to a covered recipient (defined as a physician or a teaching hospital) must submit annually to the Department of Health and Human Services (DHHS) certain information regarding the transfer. That required information includes the name and address of the covered recipient, the amount of value paid, the date of the transfer, whether the payment was tied to a specific product, and the nature and form of the payment. The purpose of the law is to create transparency and shed light on the nature and extent of the relationships between manufacturers and physicians, as well as to dissuade inappropriate relationships from forming.

What is an “Applicable Manufacturer” Under the Law?

CMS indicated that it will interpret the phrase “applicable manufacturer” to mean any entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug or device, or an entity that is under common ownership with such an entity. CMS also clarified that as long as a manufacturer sells or distributes at least one covered drug or device in the United States, the company must report all transfers of value to covered recipients under the Act, even if the transfer of value is associated with a different product that is not federally reimbursable.
What is a “Covered Drug, Device, Biological, or Medical Supply” Under the Law?

The Act defines a “covered drug, device, biological, or medical supply” as one for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP). CMS’s proposed regulations clarified that payments are considered “available” under federal health care programs for both items that are separately reimbursable and items included in a composite payment rate such as the Inpatient Prospective Payment System (IPPS), the Outpatient Prospective Payment System (OPPS) or the End Stage Renal Disease (ERSD) prospective payment system.

CMS clarified that “over-the-counter” drugs and biologicals are excluded from the Act and manufacturers of over-the-counter drugs need not report. Similarly, CMS proposed an additional limitation to the definition of covered medical supplies, excluding Class I and Class II devices which are exempt from the FDA’s premarket notification requirements. Thus, only companies that manufacture devices requiring premarket approval by or notification to FDA are required to report under the Act.

What is a “Payment of Other Transfer of Value” Under the Law?

The Act defines “payment of other transfer of value” broadly to capture anything of value given to a physician or teaching hospital. CMS clarified that payments made to a physician group, as well as to an individual physician, must be reported under the Act, and CMS proposed that payments to physician groups should be reported individually under the name of each physician in the group. The regulations do not specifically address how all transfers of value should be allocated among group members, though CMS’s comments regarding food and beverages (discussed below) suggest that payments should be divided among all members of the group and reported separately (e.g., a transfer of value of $100 given to a group with four members will likely have to be reported as four $25 payments). CMS also explained that where a physician requests a transfer of value on behalf of someone or something else, the manufacturer must report the payment under the name of the physician who made the request.

What Does a Manufacturer Need to Report to DHHS?

CMS stated that the following categories of information are required to be reported for each payment or transfer of value provided to a physician or teaching hospital:

- Physician’s Name
- Physician’s Business Address
- Physician’s Specialty and National Provider Identification (NPI) Number
- Date of Payment
  - For payments made over multiple dates, such as a consulting agreement, manufacturers may report the total payment on the first date, or may use separate line items for each payment
- Associated Covered Drug, Device, Biological or Medical Supply
  - If the payment is reasonably associated with one drug or device, the name of that drug must be reported
- Form of Payment
  - Manufacturers must select one of the following: Cash/Cash Equivalent, In-Kind Items or Services, Stocks/Stock Options/Ownership/Dividends/ROIs, Other
• Nature of Payment
  – Manufacturers must select one of the following: Consulting Fees, Compensation for Services other than Consulting, Honoraria, Gift, Entertainment, Food, Travel (including destinations), Education, Research, Charitable Contribution, Royalty or License, Ownership/Investment Interest, Compensation for Faculty or Speaker at Medical Education Event, Grant, Other

CMS clarified that manufacturers must report a single form of payment and nature of payment for each transfer of value made. For example, if a physician received meals and travel in association with a consulting fee, CMS will require that each segregable payment be reported separately in the appropriate category. The applicable manufacturer would have to report three separate line items: one for consulting fees, one for meals and one for travel. The amount of the payment would be based on the amount of the consulting fee, and the payments for the meals and travel. For these lump sum payments or other transfers of value, CMS clarified that the applicable manufacturer must break out the disparate aspects of the payment that fall into multiple categories for both form of payment and nature of payment.

CMS also stated that manufacturers may include with their annual submission a document describing the assumptions used when categorizing the payments, although such a document is not mandatory.

How Should Manufacturers Report Food and Beverage Provided to Physicians?

CMS explained that all food and beverages provided to physicians in excess of $10 must be reported. Where food is provided in a group setting, manufacturers should report the cost per-covered recipient, unless doing so brings the cost per physician below the $10 threshold. For example, CMS stated that where a manufacturer’s sales representative brings $25 worth of bagels and coffee to a solo physician’s office, the per-physician value would be $25 and the transfer of value of $25 must be reported for that physician. However, if a sales representative brings $25 worth of bagels and coffee to a physician group practice with five physician members, the per-covered recipient value would be $5 (regardless of whether all five physicians actually consumed the food) and the payment would not need to be reported. CMS noted that manufacturers would not need to report offerings of food, snacks or coffee at booths at conferences or similar events where it would be difficult to ascertain the identify of individuals who accept the offerings.

How Should Manufacturers Report Research Activities?

CMS recognized that reporting payments for research activities may be complicated, since many activities include large payments spread across numerous activities and parties. Additionally, payments are often provided to a clinic, hospital or other institution being led by a physician-covered recipient as the principal investigator. CMS proposed classifying research payments to clarify whether the transfer of value went indirectly or directly to the covered recipient, and that manufacturers should report these transfers of value accordingly with labels of “indirect research” or “direct research.” Research payments must be reported under the names and NPIs of the physician-covered recipients serving as principal investigators of clinical trials.

The statute does provide for delayed publication of payments from manufacturers to physicians pursuant to product development agreements or clinical investigations in order to maintain confidentiality for proprietary
information relating to the development of new drugs and devices. While these payments will still need to be timely reported, the payments will be not be made publicly available on the HHS website until the first publication date after (1) the FDA approval and licensure of the product; or (2) four calendar years from the date of payment. CMS clarified that manufacturers must identify on their annual reports any payments that should be granted a delay in publication on the public website.

How Should Manufacturers Report Payments for Physician Speakers?

CMS interpreted this category broadly and will require reporting in all instances in which applicable manufacturers pay physicians to serve as speakers, not simply those situations involving “medical education.”

Are Any Transfers of Value Excluded from the Reporting Requirements?

Per the Act, the following types of payments and transfers of value are excluded from the reporting requirements:

- Transfers of value less than $10, so long as the aggregate amount transferred to the covered recipient does not exceed $100 in a calendar year
- Product samples that are not intended to be sold and are intended for patient use
- Educational materials that directly benefit patients or are intended for patient use
- The loan of a covered device for a short-term trial period, not to exceed 90 days
- Items or services provided under a contractual warranty, including the replacement of a covered device
- A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient
- Discounts, including rebates
- In-kind items used for the provision of charity care
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund
- In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan
- In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional
- A transfer of anything of value to a physician if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding
- Transfers of value made indirectly to a covered recipient through a third party in cases when the applicable manufacturer is unaware of the identity of the covered recipient.

What are the Penalties for Non-Compliance?

The Act provides for the imposition of civil monetary penalties (CMPs) for failures to report the required information in accordance with the law. Failure to submit the required information can result in a CMP of at least $1,000, but no more than $10,000, for each payment or transfer of value not reported, not to exceed $150,000 annually. For a “knowing” failure to submit the required information, a manufacturer will be subject to a CMP of at least $10,000 but no more than $100,000, for each payment or transfer of value not reported, not to exceed $1,000,000 annually. CMS clarified that
the term “knowingly” is given the same meaning as in the federal False Claims Act, 31 U.S.C. § 3729(b).

CMS also stated that in determining the amount of the CMP, the following factors will be considered:

- The length of time the applicable manufacturer failed to report, including the length of time the applicable manufacturer knew of the payment or other transfer of value, or ownership or investment interest
- Amount of the payment or other transfer of value or the value of the ownership or investment interest the applicable manufacturer failed to report
- Level of culpability
- Nature and amount of information reported in error
- Degree of diligence exercised in correcting information reported in error

In addition, CMS explained that CMS, DHHS, or OIG may audit, evaluate or inspect any applicable manufacturer for compliance with the Act. To facilitate any potential audit, all covered manufacturers must maintain all books, records, documents and other materials sufficient to enable an audit for at least five years from the date of payment or transfer of value.

What Are the Potential Burdens to Manufacturers to Comply with the Act?

CMS estimates that approximately 1,150 applicable manufacturers will submit reports, including 150 pharmaceutical companies and 1,000 device and medical supply companies. CMS further estimates that, on average, smaller applicable manufacturers will have to dedicate 50 percent of a full time equivalent (FTE) employee (mainly in the range of zero to one), whereas larger applicable manufacturers may have to dedicate 5 to 15 FTE employees to comply with the reporting requirements. CMS estimates the average cost per organization to comply with the Act to be roughly $170,000 in Year 1.

When Must Companies Begin to Comply with the Law?

Due to the delayed publication of the proposed rule, which was supposed to have been issued two months ago, CMS recognized that a final rule will not be published in time for applicable manufacturers to begin collecting the information required on January 1, 2012, as indicated in the Act. CMS clarified that it will not require applicable manufacturers to begin collecting the required information until after the publication of the final rule. As far as submitting the first annual report, applicable manufacturers must report the required payment and other transfer of value information to CMS in an electronic format by March 31, 2013, and on the 90th day of each calendar year thereafter.

How Can Manufacturers Submit a Comment on the Proposed Rule?

CMS is accepting comments on the proposed rule. Comments must refer to file code CMS-5060-P and can be submitted electronically at http://www.regulations.gov, by regular mail to the following address: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-5060-P, P.O. Box 8013, Baltimore, MD 21244-8013, by express or overnight mail to the following address: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-5060-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850, or by
If you have any questions about this Client Alert, please contact one of the authors listed below or the Latham attorney with whom you normally consult:

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**Endnotes**

1 Please note that we have limited this Client Alert to the provisions of the law aimed at manufacturers and have not set forth the regulations pertaining to GPOs, entities which also are required to report transfers of value under the law.