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A Broader Perspective

Alert

Life Sciences and Health Care Client Service Group

To: Our Clients and Friends December 19, 2011

Sunshine Law Proposed Regulations Published; Reporting Requirements Delayed

Today (December 19, 2011) the Centers for Medicare and Medicaid ("CMS") published proposed rules for implementation of the federal payment sunshine law (the "Sunshine Law"), [1/] which was included within the federal health care reform law passed in March 2010. The Sunshine Law imposes reporting obligations on manufacturers of drugs, medical devices, biologicals and medical supplies who make payments to physicians or teaching hospitals. The Sunshine Law also imposes reporting obligations on manufacturers and group purchasing organizations ("GPOs") that have physician owners. The proposed rules represent CMS' effort to define the scope and process for such reporting obligations. Public comment is being solicited on the proposed rules. Final rules incorporating or otherwise addressing such comment are expect to be published next year.

Timing

The Sunshine Law anticipated an implementation date of January 1, 2012. However, because of its delay in promulgating regulations, CMS has stated that it will delay implementation. CMS is considering requiring manufacturers to begin tracking payments 90 days following the publication of final rules, with a partial year report due on March 31, 2013. However, CMS solicited comments regarding the amount of time manufacturers will need following publication of the final rules and whether it will be feasible to submit the required information by March 31, 2013.

Interested parties can submit comments on the proposed rules until February 17, 2012. After CMS reviews the comments, it will consider the comments and publish final rules. It is possible that the final rules will be significantly different from the proposed rules.

1/ § 6002 of the Patient Protection and Affordable Care Act of 2010.

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Applicability

The Sunshine Law requires that payments or other transfers of value provided to any "covered recipient" by an "applicable manufacturer" be reported to CMS by the applicable manufacturer on an annual basis. "Covered recipient" is defined as physicians and teaching hospitals. Any payments made to a third party on behalf of a physician or teaching hospital must also be reported.

Applicable manufacturer is broadly defined to include any entity that is engaged in the "production, preparation, propagation, compounding or conversion" of a covered drug, device, biological or medical supply for sale or distribution in the United States and any affiliates of such an entity. Clearly, the goal of this broad definition is to protect against payments being made by affiliates to avoid the reporting obligations.

"Covered drug, device, biological or medical supply" is defined as drugs, devices, biologicals, or medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program ("CHIP"), either as part of a fee schedule payment or as part of a composite payment rate. With respect to a drug or biological, the definition includes only those drugs and biologicals that require a prescription to be dispensed. With respect to a device or medical supply, the definition only includes those devices and medical supplies that require premarket approval by or premarket notification to the Food and Drug Administration.

It is important to note that a company that manufacturers any covered drugs, devices, biologicals or medical supplies will be responsible for reporting all payments to physicians and teaching hospitals even if those payments relate to non-covered products.

Payment Reporting Obligations

Manufacturers of covered products are required to report certain types of payments that are made to physicians and teaching hospitals as further described below. Manufacturers are not required to report sales data even if sales are made directly to physicians or teaching hospitals. Further, manufacturers are not required to report marketing or other payments that are made to or for the benefit of persons other than physicians and teaching hospitals.

The proposed rules require that all manufacturers of covered products who provide payments or any other transfer of value to, or on behalf of, a physician or teaching hospital report to the CMS the following information:

- 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;
- A description of the form of the payment or transfer of value as:

    - Cash or cash equivalent;
    - In-kind items or services; or
    - Stock, stock option, or any other ownership interest, dividend, profit, or other return on investment;
- A description of the nature of the payment or other transfer of value as:
    - Consulting fees;
    - Compensation for services other than consulting;
    - Honoraria;
    - Gift;
    - Entertainment;
    - Food and beverage;
    - Travel and lodging;
    - Education;
    - Research;
    - Charitable contribution;
    - Royalty or license;
    - Current or prospective ownership or investment interest;
    - Direct compensation for serving as faculty or as a speaker for a medical education program;
    - Grant; or
    - Other;
- 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;
- If the payment or other transfer of value is made to an entity at the request of a physician or teaching hospital, the name of the other individual or entity that receives the payment or other transfer of value; and
- Whether the payment or other transfer of value was provided to a physician who holds an ownership or investment interest in the applicable manufacturer.

The following are not considered to be payments or other transfers of value and therefore do not need to be reported:

- An indirect transfer of value through a third party if the manufacturer is unaware of the identity of the ultimate recipient.
- A transfer of anything the value of which is less than $10, unless the aggregate amount transferred to the covered recipient during the calendar year exceeds $100.

- 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, to permit evaluation of the covered device by the covered recipient.
- Items or services provided under a contractual warranty.
- 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 such licensed non-medical professional.
- In the case of a covered recipient who is a physician, expert witness fees in connection with a civil or criminal action or an administrative proceeding.

Physician Ownership Reporting Obligations

Manufacturers and group purchasing organizations ("GPOs") must also submit information regarding ownership or investment interests in such entities held by physicians or immediate family members of physicians. Despite this general obligation, ownership interests in publicly traded companies and mutual funds need not be reported. The proposed rules list the information that must be reported, including, the physician's name, address, specialty, national provider identifier, the dollar amount invested and the value and terms of each ownership or investment interest.

Publication of Data

After manufacturers and GPOs report the required information to CMS, CMS will compile it. CMS will then give manufacturers, GPOs, physicians and teaching hospitals 45 days to review the data before making it publicly available. CMS solicited comments on how to structure the website for ultimate usability, but it is expected that the data when published, will be searchable by manufacturer, GPO and recipient. The proposed rules set up a mechanism for disputing any of the data, but CMS indicated that it was interested in receiving comments regarding how to resolve disputes.

If any payments are made to a physician or teaching hospital in connection with a product research or development agreement or in connection with a clinical investigation, publication of such payments may be delayed, but payments must still be reported.

Penalties

Any applicable manufacturer that fails to accurately and completely submit the required information in a timely manner is subject to a penalty of between $1,000 and $10,000 for each payment that is not reported, with a cap of $150,000. Any manufacturer that knowingly fails to accurately and completely submit required information in a timely manner is subject to a penalty of between $10,000 and $100,000 for each payment that is not reported, with a cap of $1,000,000.

State Law Preemption

These rules preempt state laws that require manufacturers to disclose or report, in any format, the type of information regarding the payment or other transfer of value required to be reported by the Sunshine Law. However, the preemption does not apply to information required to be reported to a governmental agency for public health surveillance, investigation or other public health purposes or health oversight purposes.

Moving Forward

We would be pleased to discuss the impact of the proposed rules on your organization. Please feel free to contact any member of the Bryan Cave Life Sciences and Health Care Client Service Group.