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The Sunshine Act And Publicly Available Payment Data

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Introduction

The Physician Payments Sunshine Act ("Sunshine Act") passed as part of the Patient Protection and Affordable Care Act ("Affordable Care Act") in 2010. The Sunshine Act is intended to promote transparency by publishing information on financial relationships (including compensation arrangements and investment or ownership interests) between: (i) manufacturers of pharmaceuticals and medical devices and group purchasing organizations ("GPOs"); and (ii) physicians and teaching hospitals on a publicly accessible database ("Open Payments Database") developed by the Centers for Medicare and Medicaid Services ("CMS").

The first cycle of payment data (covering payments made from August 1, 2013 through December 31, 2013) became publicly accessible in September 2014. The second cycle of payment data covered the calendar year 2014 and became publicly accessible on June 30, 2015. Interested parties can view 2013 and 2014 data on the Open Payments Database website at https://openpaymentsdata.cms.gov/search

Background

Financial relationships between applicable manufacturers and covered recipients are commonplace in the healthcare industry and can include everything from free meals to consulting or speaker fees to direct research funding. These commercial arrangements are often a key component of research and development efforts relating to new product development. However, these arrangements can also create potential conflicts of interest and in some cases can blur the line between promotional activities and the conduct of legitimate medical training, practice and research.

Over the past decade, various professional bodies, academic institutions, and medical journals have implemented a variety of activities aimed at reducing such improper industry influence. There have also been a number of attempts to increase transparency around these relationships, in the hopes that such disclosures would help to reduce the negative consequences of these financial arrangements without unnecessarily blocking constructive relationships between physicians and industry.

Summary of the Law

Key Definitions

The following paragraphs summarize the definitions of certain key terms under the Sunshine Act:

> An "applicable manufacturer" means an entity that: (1) is operating in the United States, (2) is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply (except for any such covered items that are produced, prepared propagated,

compounded or converted solely for use within the entity itself and by the entity's own patients, or (3) any entity under common ownership or control with an entity in item (1) of this paragraph, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered drug, device, biological, or medical supply.

The term, "covered drug, device, biological, or medical supply" is defined as any of those products for which payment is available under Medicare, Medicaid or certain other government programs and which requires a prescription to be dispensed or premarket approval by or notification to the FDA. Over-the-counter drugs and products made by compounding pharmacies are excluded from this definition.

A "covered recipient" is defined to include physicians (other than bona fide employees of an applicable manufacturer) and teaching hospitals. For purposes of the Sunshine Act "physicians" are defined as doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors who are licensed by the State in which they practice. Teaching hospitals as covered recipients are those which receive reimbursement for the provision of medical education to physicians in training (i.e. internship, residency or fellowship programs). CMS will publish a list of teaching hospitals on an annual basis at least ninety (90) days before the beginning of a reporting year.

Payments or Other Transfers of Value

The Sunshine Act requires that applicable manufacturers report a "payment or other transfer of value" made to a covered recipient or "to an entity or individual at the request of or designated on behalf of a covered recipient." CMS requires all applicable manufacturers to make a reasonable, good faith effort to determine the value of a payment or other transfer of value. CMS requires applicable manufacturers to report, in the name of the covered recipient, all payments made at the request a covered recipient, as well as the name of the entity that received the payment.

The specific categories of information required to be reported for each payment or other transfer of value are as follows: physician recipient name; business address, specialty and National Provider Identifier ("NPI"); date of payment; optional context (brief contextual information for each payment or transfer of value); related covered drug, device, biological or medical supply; and form of payment or transfer of value. The categories of payment or transfers of value include the following: (1) cash or cash equivalent; (2) in-kind items or services; (3) stock, stock option, or any other ownership interest; and (4) dividend, profit, or other return on investment.

Exceptions

While these categories of payment cover a very wide range of relationships, certain transactions and transfers are excepted from disclosure under the Sunshine Act. For example, manufacturers are not required to disclose any information on payments under $10 (unless those individual payments total more than $100 annually), on educational materials intended solely for patients, or on product samples. Other exceptions to annual reporting include payments made in support of products to be approved by the FDA that are still under development.

Applicable manufacturers are required to report compensation provided to physician speakers at continuing medical education ("CME") events, unless the manufacturer is unaware of the identity of the recipient during the reporting year. In other words, so long as the manufacturer does not condition its support of a CME program on the participation of particular physicians speakers or faculty, and does not otherwise pay such physicians directly, such payments are excluded from the reporting rules.

Data Reporting Obligations.

Applicable manufacturers must report all payments or other transfers of value provided to covered recipients, irrespective of whether such payments were related to a covered drug, device, biological or medical supply, subject to the exceptions summarized above. Once the applicable manufacturer has submitted the data to CMS, applicable manufacturers and GPOs have forty-five (45) days to review and correct the data attributed to them and an additional fifteen (15) days to resolve the dispute. CMS is not responsible for resolving these disputes, nor will CMS directly mediate such disputes. Disputes that are not resolved within this timeframe are flagged as disputed on the public website. Any further changes to the reported data are made when the database is updated during the next calendar year.

Failure to Comply

The Sunshine Act imposes civil monetary penalties for failure to comply with these reporting requirements. For each payment that a manufacturer fails to report, a penalty of $1,000-$10,000 may be applied. The maximum annual penalty for failure to report is $150,000. The penalties are more severe in cases where the manufacturer or GPO knowingly fails to report. These penalties range from $10,000-$100,000 per payment, up to a maximum penalty of $1 million.

It is important to note that compliance with the provisions of the Sunshine Act does not exclude applicable manufacturers or covered recipients from potential criminal or civil liability related to the financial relationships reported. Any payment or transfer of value that is prohibited under the Anti-Kickback Statute, the Ethics in Physician Self-Referrals Act (a.k.a. Stark Law), the False Claims Act, or any other health care fraud and abuse law may be subject to fines, penalties and sanctions permissible thereunder.

Sunshine Act – Issues and Challenges for the Future

Much of the debate over the Sunshine Act relates to what will happen to applicable manufacturers and covered recipients as a result of this payment information being made available to the public. As a general matter, all applicable manufacturers and covered recipients are concerned that information available in the public domain could unfairly distort the positive nature of the collaborative relationships that physicians maintain with these manufacturers. They argue that without clear communication about the purpose and context of these transfers, it may be difficult to distinguish payments that inappropriately influence prescribing from payments made for services that actually improved and enhance patient care.

The full effects of the Sunshine Act will likely not be felt for several more years, as physicians, teaching hospitals and applicable manufacturers adapt to its requirements and the broader public responds to the information that becomes available. All interested parties agree, however, that simple disclosure, in and of itself, is not sufficient to address financial conflicts of interest. It is believed that the disclosure of such information will lead applicable manufacturers and covered recipients to take additional steps to ensure that these financial relationships comport with existing law, i.e., applicable exceptions and safe harbors under the Stark Law and the Anti-Kickback Statute. Although these exceptions and safe harbors are often criticized as being so narrowly drawn that they are impractical, it is generally accepted that these bodies of law provide established frameworks for determining what kinds of physician-industry relationships are appropriate and acceptable, from a legal standpoint.