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Centers for Medicare and Medicaid Services Releases Final Sunshine Act Rule

On February 8, 2013, the Centers for Medicare & Medicaid Services (CMS) released a final rule regarding transparency reports, and the reporting and publication of physician ownership or investment interests in certain manufacturers, also known as the Sunshine Act (collectively, the Final Rule).

In accordance with the Final Rule, the collection of certain data regarding payments made to individual physicians and teaching hospitals from, and ownership interests in, certain manufacturers (Manufacturers) of drugs, devices, and biological and medical supplies (collectively known as Covered Products) begins on August 1, 2013, and must be reported to CMS on March 31, 2014. Such data will be published on a publically accessible website beginning in 2014. The intent of the Final Rule is to promote transparency and increase public awareness of financial relationships between certain health care providers and Manufacturers of Covered Products. Some highlights of the Final Rule are summarized below.

IMPORTANT DEFINITIONS

The Final Rule clarifies some of the important definitions that apply to the required reporting by Manufacturers:

- **Covered Recipient:** Covered Recipients include (1) certain health care practitioners, including any physician, doctor of osteopathy, dentist, podiatrist, optometrist, and chiropractor, unless such health care practitioner is an employee of a Manufacturer or (2) a teaching hospital, defined as those hospitals that receive graduate medical education payments. CMS declined to include (i) medical residents or (ii) other practitioners with prescribing authority in the definition of Covered Recipient.
- **Applicable Group Purchasing Organization (GPO):** A GPO is an entity that purchases, arranges for, or deals in the negotiation of the purchase of a Covered Product for a group of individuals or entities. This definition also includes those entities that are physician-owned distributors of Covered Products.
- **Payments or Other Transfers of Value (Payments):** Payments are construed as anything that can be interpreted to have an economic value on the open market in the United States. When calculating the value of Payments, a Manufacturer must include tax and shipping costs.

PAYMENT REPORTS

The Final Rule requires Manufacturers to report annually to CMS all Payments with a value greater than $10 made to Covered Recipients (a Payment Report). A Payment Report must include: each applicable Covered Recipient's name, business address, specialty, NPI number, and state license number(s) (if applicable); the amount of Payment made; the date of Payment; the related Covered Product(s); and the form and nature of the Payment. Payments must be reported in one of the following forms: cash or cash equivalent; in-kind item or service; stock, stock option, or any other ownership interest; or dividend, profit, or any other return on investment. Manufacturers are required to categorize the "nature" of Payments as one of numerous categories, including, but not limited to: consulting fees; compensation for services; gifts; and space rental and facilities fees.

A number of Payments from Manufacturers to Covered Recipients are not subject to the Final Rule's reporting requirements. The exclusions include, but are not limited to:

- Any indirect Payments made through a third party, provided that the Manufacturer does not have actual knowledge of the identity of the recipient and is not acting in deliberate ignorance or reckless disregard of such identity;
- Payments to Covered Recipients not exceeding $10, unless the aggregated amount transferred to the Covered Recipient exceeds $100 annually;
- Product samples; and
- Educational materials that directly benefit patients or that are intended for patient use.

While the Sunshine Act does not impose reporting requirements on Covered Recipients, Manufacturers or GPOs may seek to shift some of the data collection burdens to the Covered Recipients. For example, a Manufacturer may request or require that a Covered Recipient track and report to such Manufacturer any Payments received by such entity or Payments received by physician employees in the case of a teaching hospital. Such requirements will impact Covered Recipients by creating an additional administrative burden.

REPORTS ON PHYSICIAN OWNERSHIP AND INVESTMENT INTERESTS (INVESTMENT REPORTS)

The Final Rule requires Manufacturers and GPOs to report annually to CMS certain information regarding direct and indirect ownership and investment interests held by physicians and their immediate family members in such Manufacturers and GPOs. This information must be reported regardless of whether the physician is an employee of the Manufacturer or the GPO. Ownership and investment interests do not include retirement plans, stock options, and convertible securities until such interests are converted into equity.

An Investment Report must include, but is not limited to, the following information: the name, address, specialty, NPI, and state license number(s) of the physician owner or investor; the dollar amount invested; and the value and terms of the ownership or investment interest. In the event that an individual is both a Covered Recipient and a physician owner/investor, a Manufacturer is required to report a Payment once on the Payment Report, but a Manufacturer should mark that such Payment was provided to a physician owner or investor.

PUBLICATION OF PAYMENT REPORTS AND INVESTMENT REPORTS

All data submitted to CMS through the Payment Reports and/or Investment Reports will be published by CMS on a publically available website following a period during which Covered Recipients and physician owners/investors will be able to review and submit corrections to

data reported to CMS. Failure by a Manufacturer or GPO to submit required Payment Reports or Investment Reports will result in the imposition of civil monetary penalties. Manufacturers and GPOs must retain their records for at least five years after the Payment or ownership or investment interest has been published on the public website.

PREEMPTION

The Final Rule preempts any state or local laws that require reporting of the same type of data as required by the Payment Reports, effective as of February 8, 2013, but state or local governments may require reports for information not required to be reported by the Final Rule. Additionally, federal, state, or local government agencies seeking to collect information reportable under the Final Rule for public health and/or health oversight purposes are able to collect such information. CMS' commentary to the Final Rule states that some preemption determinations will be made on a case-by-case basis.

Current Massachusetts laws require mandatory disclosure to the Massachusetts Department of Public Health (DPH) of certain sales and marketing activities engaged in by pharmaceutical and medical device companies, including payments greater than $50 made to health care practitioners and organizations, and prohibit specific types of payments and interactions between physicians and pharmaceutical manufacturers. At the time of this publication, DPH has not issued formal guidance regarding the preemption of the Massachusetts reporting requirements as the result of the Final Rule. Based on guidance issued by the DPH in December of 2011 with respect to the proposed rule, we anticipate that, due to the duplicative reporting requirements, the application of the Massachusetts reporting requirements to individual physicians and teaching hospitals will likely be preempted by the Final Rule. Other elements of the Massachusetts reporting requirements and the gift ban prohibition will likely remain in effect.

If you have any questions regarding any portion of the Sunshine Act, please contact a member of the Robinson & Cole's Health Law Group.

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