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Data Collection Under the Sunshine Act

October 02, 2013

Data collection requirements under the Physician Payment Sunshine Act commenced August 1, 2013. This provision of the Patient Protection and Affordable Care Act and the corresponding regulations require an entity that is engaged in the production, preparation, propagation, compounding or conversion of drugs, medical devices, biologics or medical supplies to track and annually report payments or other transfer of value of over $10 to physicians and teaching hospitals. 42 U.S.C. § 1320a-7h(a). The Sunshine Act additionally requires that these entities, also referred to as "applicable manufacturers," as well as group purchasing organizations (GPO) to report certain ownership and investment interests held by physicians or their family members in such entities. *Id.*

Reporting of Data and Deadlines

The information collected by these manufacturers and GPOs must be electronically submitted annually to the Secretary of the Department of Health and Human Services (HHS), which will make the information publicly available. *Id.* Applicable manufacturers and GPOs that are required to submit a report pursuant to this rule must register with the Centers for Medicare and Medicaid (CMS) within 90 days of the end of the calendar year for which a report is required. 42 C.F.R. § 403.908(c). The first reporting deadline is March 31, 2014. 42 C.F.R. § 403.908(a). Applicable manufacturers, GPOs, physicians, teaching hospitals, and physician owners or investors in such entities will be afforded at least 45 days to review and submit corrections to the information submitted before CMS makes the information available to the public. 42 U.S.C. § 1320a-7h(c)(1)(C)(ix); 42 C.F.R. § 403.908(g). Despite this 45 day period, the information could still be made available to the public. *Id.* **Exceptions to the Reporting Requirements**

The regulations published by CMS delineate specific exceptions to the reporting requirements, which include but are not limited to: (1) certain indirect payments or other transfers of value; (2) product samples not intended for sale; (3) educational materials for the benefit of the patients; (4) short-term loans of a device not to exceed 90 days for the evaluation of the physician or teaching hospital; and (5) discounts and rebates for drugs, devices, biological and medical supplies provided by applicable manufactures to physicians or teaching hospitals. 42 C.F.R. § 403.904(i). **Penalties for Non-Compliance with Reporting Requirements**

Penalties for non-compliance with these reporting deadlines can result in fines between $1,000 and $10,000 for each violation, not to exceed $150,000. 42 U.S.C. § 1320a-7h(b)(1). A knowing failure to

report, however, can result in civil monetary penalties ranging from $10,000 to $100,000 for each unreported payment or other transfer of value or ownership, not to exceed 1,000,000. 42 U.S.C. § 1320a-7h(b)(2). The Sunshine Act utilizes the "knowing" standard contained in the False Claims Act for purposes of the imposition of the latter civil monetary penalties. 42 U.S.C. § 1320a-7h(e)(8); 31 U.S.C. § 3729(b)(1). **Considerations Moving Forward**

To prepare for these new requirements, applicable manufacturers should consider how they will identify and report payments. Given the penalties for non-compliance, it is essential to have policies and procedures in place to identify payments, document the justification for the payments, confirm the accuracy of the information and report the information. In addition, manufacturers should determine how to inform health care providers of its policies and procedures. The health care providers should implement a manner to document this information as well, so as to verify the accuracy of the information being reported by these manufacturers. Furthermore, in developing these policies and procedures applicable manufacturers, GPOs and health care providers alike should keep in mind that this information could be sought during discovery in civil medical malpractice litigation. The information could be sought to assert physician motive for medical decision making, or even to try to hold the manufacturing industry liable for the actions of the physician recipient. Finally, compliance with these reporting requirements does not relieve or exempt applicable manufacturer, GPOs or physician owners or investors from potential liability for payment or other transfers of value pursuant to the Federal Anti-Kickback Statute (AKS) or the False Claims Act (FCA) and the equivalent state laws. It should be equally noted that because this reporting requirement carries little burden of proof – simply proving a lack of reporting – it may be increasingly utilized in conjunction with AKS or FCA lawsuits.

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