SHUMAKER®
Shumaker, Loop & Kendrick, LLP

News Alert

Business Information for
Clients and Friends of
Shumaker, Loop & Kendrick, LLP

July 29, 2013

Regarding Physician Payments Sunshine Act

On August 1, 2013 a new reporting obligation under the federal Physician Payments Sunshine Act ("Sunshine Act") takes effect. The Sunshine Act was originally signed into law on March 23, 2010, as part of the Patient Protection and Affordable Care Act ("ACA"). The purpose of the Sunshine Act is to promote transparency in relationships between the pharmaceutical and drug manufacturing industry and physicians or teaching hospitals. Under the Sunshine Act, certain information is required to be reported and made public. Pharmaceutical, medical device, biological, and medical supply manufacturers are required to report to Health and Human Services any "payment or other transfer of value" to physicians and teaching hospitals. Also, applicable manufacturers and group purchasing organizations are required to report information about certain ownership and investment interests held by physicians and their immediate family members in such entities. Each report must include the following information: (1) the amount of the payment, (2) the date on which the payment was made, (3) the form of payment, and (4) the nature of payment (gifts, consulting fees, entertainment).

Much of the information contained in the manufacturers' reports will be available on a public, searchable website. Physicians will have the right to review these reports and challenge those reports that are false, inaccurate or misleading. Physicians will have a process to challenge or mark as disputed these reports. For purposes of the Sunshine Act, a "physician" means a doctor of medicine, a doctor of osteopathy, a doctor of dentistry, a doctor of dental surgery, a doctor of podiatry, a doctor of optometry and a doctor of chiropractic medicine. Medical residents are excluded from the definition of physicians.

The reporting obligation is triggered for transfers of $10 or more per item or $100 in the annual aggregate. Covered items include drugs, devices, biological or medical supplies that are paid for under Medicare, Medicaid or CHIP and/or require a prescription to be dispensed or premarket approval by or notification of the FDA.

Exclusions from the reporting requirement include: (1) de minimis payments of less than $10 (unless the aggregate amount transferred to on behalf of the covered recipient by the applicable manufacturer is greater than $100 per year); (2) product samples; (3) educational materials directly benefitting patients; (4) the loan of a medical device for a short-term trial period not to exceed 90 days; (5) items or services provided under a contractual warranty where the terms of the warranty are set forth in the purchase or lease

agreement for the covered device; (6) 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; (7) discounts (including rebates); (8) in-kind items used for the provision of charity care; (9) a dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund; (10) 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; (11) does not apply to physicians in their capacity as patients; and (12) in the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient 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.

If you have questions concerning the Sunshine Act, please call Erin Aebel at (813) 227-2357 or Elena Kohn at (813) 227-2244. This newsletter is designed to provide general information on matters of interest to Florida individuals and entities and is not intended to constitute legal advice.

Erin Smith Aebel
eaebel@slk-law.com
813.227.2357

Elena A. Kohn
ekohn@slk-law.com
813.227.2244