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Ready or Not - Sunshine Act Data Collection Starts Today

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Today pharmaceutical and medical device manufacturers and group purchasing organizations ("GPOs") start to collect data on their financial arrangements with physicians and teaching hospitals to comply with the Physician Payments Sunshine Act (''Sunshine Act''). In February the Centers for Medicare & Medicaid Services (''CMS'') published the final rule implementing the Sunshine Act, which was passed as part of the Affordable Care Act. The Sunshine Act requires manufacturers of drugs, devices, biologics, or medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program to report payments and other transfers of value to physicians and teaching hospitals. The Sunshine Act also requires manufacturers and GPOs to disclose ownership or investment interests held by physicians or their immediate family members. The Final Rule specified August 1st as the start date by which manufacturers and GPOs must begin collecting the required data, and they must report data for the remainder of 2013 to CMS by March 31, 2014.

The Final Rule set off a frenzy of compliance activity among manufacturers and GPOs to be ready for today's start date, including securing final software changes from vendors, testing these new systems, assuring payments meet legal requirements, integrating internal computer systems, developing internal reporting systems and protocols, and training marketing and sales representatives. Despite these herculean efforts, manufacturers and GPOs will almost certainly encounter glitches and flaws during the first year or two of data collection. Some errors may be spotted quickly if companies invest in early warning compliance reviews while others may not be discovered until much later when companies start to complete their reports and when the required dispute period starts, when physicians may review and question the data.

Manufacturers, GPOs, and other affected parties interested in hearing the latest guidance from CMS should consider participating in an upcoming national provider call on August 8th at 1:30 p.m. Eastern.

Authors

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Karen advises industry clients on regulatory, transactional, operational, and enforcement matters. She has deep experience handling FCA investigations and qui tam litigation for laboratories and diagnostics companies.