

Drug and Medical Device Manufacturers Need to Comply with the ACA's Sunshine Act – Part One

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The Affordable Care Act includes a provision called the “Sunshine” Rule. More formally, the rule is called “*The National Physician Payment Transparency Program: Open Payments*.” [The Centers for Medicare & Medicaid Services \(CMS\)](#) announced the terms of the rule in 2014. The rule is designed to help patients and others understand when the medications and medical devices their doctors recommend come with a catch – that the doctor has a financial interest with the drug company that makes the drugs or the device manufacturer that make the medical devices.

According to the CMS deputy administrator for Program Integrity, “*Disclosure of these relationships allows patients to have more informed discussions with their doctors.*” The rule applies to drugs, devices, biologicals, and medical supplies – that are covered by Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP). The manufacturers are required to report any payments or transfers of items of value that the manufacturers make to doctors and teaching hospitals – to CMS. CMS will post that information on its public website. The rule also mandates that the manufacturers and group purchasing organizations (GPOs) disclose to CMS any doctor ownership or investment interests.

The aim of the rule is to provide increased transparency. The rule is designed to “*help reduce the potential for conflicts of interest that physicians or teaching hospitals could face as a result of their relationships with manufacturers.*” The rule became effective on August 1, 2013. CMS began disclosing the data on [its website](#) on September 30, 2014. The rule can be viewed at Federal Register: Federal Register Documents Currently on Public Inspection

[According to Health Affairs](#), the Sunshine rule, also called, “*The Physician Payments Sunshine Act*,” is based on [section 6002 of the Affordable Care Act \(ACA\)](#) of 2010.

Why was the Sunshine Rule enacted?

Drug and medical device manufacturers rely on doctors to refer their products to their patients. It’s one thing for a doctor to refer a drug or device based on an independent review by the doctor of all the appropriate drugs and devices (and the brands of each drug and device) – and another to make a recommendation based on a conflict of interest. Doctors should recommend medical products based on the best health outcomes for their patients and not on their own financial interests.

The concern about a conflict of interest between the patient and doctor is so concerning that there are several federal laws that regulate referrals by doctors of all medical products in which the doctor has a financial interest in the product or has been given a financial incentive to recommend the medical product.

- **Stark Law.** Stark Law prohibits healthcare providers from making referrals to certain designated medical practices such as laboratories in which the physician or a close family member has a financial interest. Stark law applies to services and

products that are ordered for Medicare patients. A financial interest includes compensation, investment, and ownership. There are some exceptions that generally do not endanger a patient's health.

- **The Anti-Kickback Statute (AKS).** This law is a criminal statute that forbids medical companies from paying or providing financial incentives to physicians to refer the company's products to the patients of the physicians. Some safe harbors do apply to the AKS.

The drafters of the ACA were concerned about incentives such as free meals and speaker, or consulting fees paid to the doctors. According to Health Affairs, the financial relationships:

"Can have many positive outcomes and—particularly in the context of consulting and research funding—are often a key component in the development of new drugs and devices." However, they can also create conflicts of interest and in some cases can blur the line between promotional activities and the conduct of medical research, training, and practice.

The financial interdependence between physicians and the manufacturers of medications, medical devices, biologicals, and medical supplies is far from minimal. According to a 2009 nationwide survey, nearly 84 percent of doctors had some type of financial relationship with the manufacturers. — of which, more than ½ were meals provided in the workplace. About 20 percent of doctors were reimbursed for attending a meeting or CME (continuing medical event). Less than 15 percent of doctors received payment for professional services.

The numbers for the survey were lower than a similar survey taken five years earlier. One of the factors for the decrease, according to Health Affairs,

"may be the growing awareness among researchers and policy makers of the ways that physician-industry relationships can bias physician decision making, encourage inappropriate prescribing that drives up health care costs, and undermine the independence and rigor of clinical research."

Professional bodies, academic institutions, and medical journals have all begun to implement conflict-of-interest protocols.

Five states and the District of Columbia, prior to the ACA, had already passed laws mandating that the makers of drugs, devices, medical supplies, and biologicals report certain details of their financial relationships with clinicians. The US National Institutes of Health requires that all grantees disclose *"Significant financial relationships with manufacturers."* The Food and Drug Administration (FDA) requires that *"drug sponsors report on any financial ties with clinical investigators that reach certain monetary thresholds (which are higher than those set by the Sunshine Act)."*

Some drug manufacturers and medical device companies, prior to the Sunshine Rule, were required to disclose these relationships as part of legal settlements with the US DOJ (Department of Justice).

In 2008 and 2009, respectively, the Medicare Payment Advisory Commission and the Institute of Medicine published influential reports on physician conflicts of interest — documenting the need for more transparency of physician-industry relationships. *"Both documents also called for the establishment of a standardized, nationwide, mandatory public reporting program, which could supplement or replace the patchwork reporting system currently in place."*

Senators Chuck Grassley and Herb Kohl first introduced the Physician Payments Sunshine Act in 2007. That initial version of the bill did not pass. The provisions were later amended and incorporated into the ACA as section 6002.

STARK LAW EXCEPTIONS THAT MIGHT APPLY TO YOU

In today's video, we discuss some exceptions to Stark Law, which deals with improper referrals by physicians and healthcare

practitioners.

NEW PROPOSED RULES FROM THE CMS AND THE OIG-HHS ON STARK LAW AND FROM THE ANTI-KICKBACK STATUTE

The CMS and HHA are proposing new rules, such as the Patients over Paperwork Initiative, where the focus of Stark and AKS will be on value-based arrangements

What are the provisions of the Physician Payments Sunshine Act?

The Sunshine Rule applies to manufacturers of drugs, devices, biologics, and medical supplies. The Rule applies to three different categories of payments when the bills for the payments are covered by Medicare, Medicaid, or CHIP.

1. **General payments or transfers of value.** These include travel reimbursement, meals, and consulting fees.
2. **Ownership and investment interests, in manufacturing companies, by the physicians (or immediate family members).** Ownership and investment interests in group-purchasing organizations (GPOs). GPOs are *“entities that negotiate pharmaceutical contracts on behalf of health care providers.”* All physician-owned distributors of medical devices are also expected to report.
3. **Research payments.** This category includes payments for participation in preclinical research, clinical trials, or other product development activities. *“To qualify as research under the final rule, it must be subject to a written agreement or a research protocol.”* The amount of the payments will be handled separately *“to reflect the fact that a research grant made to an investigator typically flows through a host organization and may not directly accrue to the physician leading the research.”*

Some exemptions from the disclosure requirement do apply. Drug and medical device manufacturers do not need to disclose payments under \$10 – unless the individual payments add up to more than \$100 for the year. Manufacturers are also exempt from disclosing payments for educational materials that are intended solely for the patients – or for product samples. However, manufacturers must still submit data to the FDA about the *“identity and amount of samples requested and distributed to physicians.”*

Other exemptions may apply to products that are still in development and have yet to be approved by the FDA. Payments to a CME organization *“to subsidize educational events will also be exempt from reporting, provided the event is accredited by a provider association (any one of five associations identified by CMS) and the manufacturer in question has had no direct role in the choice or compensation of the speaker(s).”*

Our skilled healthcare lawyers can explain whether any of these exemptions still apply in 2022. Generally, once the data is posted – the manufacturers, GPOs, physicians, and teaching hospitals have 45 days to review the data attributed to them and 15 days after that to dispute and correct the data.

The Physician Payments Sunshine Act imposes the following penalties (our lawyers can explain any changes) for failing to comply with the ACA reporting requirements:

The penalty for each payment a manufacturer or GPO doesn't report is between \$1,000 and \$10,000. The maximum yearly penalty amount for non-compliance is \$150,000. The penalties increase if the manufacturer or GOP *“knowingly”* failed to report a payment, for knowing violations, the penalties for each violation range from \$10,000 to \$100,000. The maximum penalty is \$1 million.

The CMS rules also provide that complying with the Physician Payments Sunshine Act (PPSA) does not protect the manufacturer, GPO, doctor, or teaching hospital from Stark Law, the AKS, the False Claims Act, or other healthcare referral

laws. The reverse is often the case – meaning that the disclosure of the payments increases the likelihood of an inquiry into these civil and criminal laws.

The Physician Payments Sunshine Act is part of the Affordable Care Act requires manufacturers, GPOs, physicians, and teaching hospitals to disclose certain payments and transfers of value to the physicians they work with or that receive the payments/transfers. These companies and practices should review the PPSA and other federal and state laws that regulate physician referrals and recommendations with experienced health care lawyers. There are specific requirements. Some exceptions may apply. There are severe penalties for failing to comply with the PPSA.

AFFORDABLE CARE ACT CREATES SCOPE OF PRACTICE LEGISLATIVE SCRAMBLE FOR HEALTHCARE PRACTITIONERS

Healthcare reform is creating incentives for even more legislative scrambles by different practitioner lobbying groups for favorable legislation that will protect, preserve, and expand their own [...]

Medical companies, doctors, and teaching hospitals should contact Cohen Healthcare Law Group, PC to ensure compliance with the CMS Sunshine Act. Our experienced healthcare attorneys advise medical business practices about their healthcare compliance requirements and the dangers of non-compliance.

Contact our healthcare law and FDA attorneys for legal advice relevant to your healthcare venture.