Pharmaceutical and Medical Device Manufacturers Be Advised: Sunshine Act / Open Payments Enforcement is on the Rise

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Pharmaceutical and medical device manufacturers should be advised that the government is using its enforcement authority under the Open Payments Program (otherwise known as the Sunshine Act) in conjunction with the Anti-Kickback Statute (AKS) against manufacturers for alleged kickbacks paid to referring physicians. On May 19, 2021, the Department of Justice (DOJ) announced its second publicly-available settlement involving alleged violations of the Open Payments Program, following on the heels of the DOJ’s first publicly-available Open Payments Program settlement back in October 2020.

The allegations for both settlements are very similar; manufacturers allegedly paid referring physicians in the form of meals, travel expenses, and entertainment to
induce them to use the manufacturers’ medical devices. Working in partnership with the Centers for Medicare & Medicaid Services (CMS), the DOJ asserted not only that the entertainment expenses were kickbacks in violation of the AKS, but also that the manufacturers failed to report to CMS the entertainment expenses as payments to the physicians in violation of the Open Payments Program.

**Background on Open Payments**

The Open Payments Program requires manufacturers of drugs, biologicals, devices, or medical supplies covered by Medicare, Medicaid, or CHIP to track and report annually to CMS certain payments or transfers of value made to physicians, teaching hospitals, and other advanced practice clinicians. CMS publishes this data in a [searchable online database](https://openpaymentsdata.cms.gov) accessible by the general public. The Open Payments Program authorizes the imposition of Civil Monetary Penalties (CMPs) up to $176,000 for non-knowing violations and up to $1,176,000 for knowing violations (both adjusted for inflation) per year.

The factors considered in determining the amount of the CMPs include, but are not limited to:

- The length of time the manufacturer failed to report, including the length of time the manufacturer knew of the payment;
- The amount of the payment that the manufacturer failed to report;
- The level of culpability;
- The nature and amount of information reported in error; and
- The degree of diligence exercised in correcting information reported in error.

**Open Payments Enforcement**

Though Open Payments reporting has been in effect for more than seven years (the first reporting period was August 2013 to December 2013), there has been very minimal enforcement activity. But in March 2019, the [Senate Finance Committee requested](https://www.finance.senate.gov/pressrelease/senate-finance-committee-asks-hhs-to-enforce-open-payments) that the Department of Health and Human Services (HHS) begin [investigating and enforcing Open Payments non-compliance](https://www.finance.senate.gov/pressrelease/senate-finance-committee-asks-hhs-to-enforce-open-payments), and HHS appears to be answering that request.

In October 2020, the DOJ announced its first settlement involving alleged Open Payments violations. Though the allegations were yet another example of the DOJ’s numerous enforcement actions against manufacturers for alleged kickbacks paid to physicians in the form of meals and entertainment, the settlement was the first time that the DOJ linked AKS violations to Open Payments violations. Not only did the manufacturer allegedly pay kickbacks to referring physicians in the form of meals and entertainment, it also did not accurately report the payments for physicians’ meals and entertainment to CMS as required by the Open Payments program. In the [DOJ’s press release](https://www.justice.gov/opa/pr/doj-announces-first-settlement-involving-alleged-open-payments-violations), then-acting HHS Deputy General Counsel and CMS Chief Legal Officer, Brenna E. Jenny, hinted that more Open Payments enforcement actions may be expected in the near future, stating that “CMS looks forward to continued
partnership with the Department of Justice to resolve allegations of manufacturers skirting their Open Payments obligations."

The May 17th settlement involved similar conduct. The medical device manufacturer allegedly paid for meals, alcoholic beverages, entertainment, and travel expenses for physicians at a research event held in September 2013. The suit was brought via a *qui tam* complaint, which alleged violations of the AKS and the False Claims Act. The government intervened and added alleged Open Payments Program violations. Of note, the payments at issue were made in September 2013, which was during the Open Payments Program's initial reporting period. Though there was some speculation that CMS would not exercise its enforcement authority for reports made during the initial start-up of the Open Payments Program, that appears not to be the case when allegations of fraud are also at play.

**Open Payments Enforcement Actions in the Future**

Given the Senate Finance Committee’s call for HHS and CMS to enforce the Open Payments Program and these two factually-similar settlements, medical device and drug manufacturers should be on notice that the government likely intends to continue enforcing Open Payments violations in conjunction with AKS violations going forward. Manufacturers should take steps to ensure they are timely and accurately submitting reports and not underreporting applicable payments. We will continue to monitor and report enforcement activity under the Open Payments Program.

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