

Employee Benefit Plan Review

Heating Up: Federal Sunshine Act Enforcement on the Rise

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After several years without any enforcement, the U.S. Department of Justice (“DOJ”) recently penalized medical device and life sciences companies for violating the U.S. Provider Payments Sunshine Act (“Sunshine Act”).¹ The Sunshine Act was introduced originally to bring greater transparency to payments made by pharmaceutical and medical device companies to physicians and teaching hospitals. The Sunshine Act is implemented by the U.S. Centers for Medicare and Medicaid Services (“CMS”).

This new level of enforcement follows both the 2019 CMS expansion of payment categories ((1) “debt forgiveness”; (2) “long-term medical supply or device loans”; and (3) “acquisitions”) and the implementation of the 2018 Substance-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (“SUPPORT Act”).

The SUPPORT Act, which took effect in January 2021, expands the Sunshine Act’s definition of “covered recipients” beyond physicians and academic medical centers. With this expansion, covered recipients now include:

- (1) Physician assistants;
- (2) Nurse practitioners;
- (3) Clinical nurse specialists;

- (4) Certified registered nurse anesthetists; and
- (5) Certified nurse midwives.²

With the expansion of the Sunshine Act’s ambit, the government has increased use of companies’ disclosures under the law as an enforcement tool – both enforcing the requirements of the Sunshine Act itself but also using the disclosures to prove or demonstrate kickbacks. Over the past year, the government has reached settlements with several medical device manufacturers and distributors over Sunshine Act claims brought in connection with Anti-Kickback Statute allegations. Two of the three most recently announced settlements involve the same physician’s failure to report payments and benefits received in connection with his use of certain medical devices. The third settlement involves expenses paid by a medical device manufacturer in connection with a physician’s conference. Importantly, the Medical Designs/Sicage settlement — which involved the use of a physician-owned distributorship (“PODs”) — predates a recent set of proposed regulatory changes; namely, CMS proposed to enhance its requirements for companies to disclose as PODs, among other areas.

A more in-depth summary of these cases is below. Note that these claims, resolved by settlement, are allegations only with no determination of liability.

MEDTRONIC USA INC.

According to the DOJ,³ medical device manufacturer Medtronic USA Inc. (“Medtronic”) paid for social events at Carnaval Brazilian Grill (“Carnaval”) for the benefit of South Dakota neurosurgeon, Wilson Asfora, M.D. Knowing that Dr. Asfora’s restaurant, Carnaval, was struggling, a Medtronic sales representative agreed to host events at Carnaval, allegedly in an effort to convince Dr. Asfora to use Medtronic’s SynchroMed II intrathecal infusion pumps.

From 2010 to 2019, Medtronic hosted over 130 events at Carnaval, paying over \$87,000 to the restaurant, 74 of these events were held after the Sunshine Act was in effect. Medtronic sales personnel allegedly falsely stated that these events served educational purposes, when there was little to no discussion surrounding Medtronic products during the dinners.

Further, Dr. Asfora allegedly personally selected the guests for these events, inviting his friends, partners, favored colleagues, and other social acquaintances as well as their significant others. Medtronic only reported the total amount of food and drinks that individuals consumed during these dinners, but did not report the total amount paid to Dr. Asfora through Carnaval. The government claims that this underreporting violated the Sunshine Act and that the events themselves amounted to kickbacks under the Anti-Kickback Statute.

Medtronic paid \$1.1 million to settle the Sunshine Act claim, as well as an additional \$8.1 million to resolve the related Anti-Kickback Statute and False Claims Act allegations.⁴

MEDICAL DESIGNS LLC AND SICAGE LLC

The second Dr. Asfora-related settlement involves government claims that between 2010 and 2019, Dr. Asfora solicited and received improper remunerations for using

spinal devices made by Medical Designs LLC (“Medical Designs”) and Sicage LLC (“Sicage”). The companies allegedly violated the Sunshine Act by their failure to disclose Dr. Asfora’s ownership interests in Medical Designs and Sicage.

In exchange for using Medical Designs and Sicage spinal devices, Dr. Asfora allegedly received profit distributions from the companies. Medical Designs also allegedly acted as a distributor for Dr. Asfora, reselling other manufacturer’s spinal devices to Dr. Asfora and splitting the profits with him when he used those devices in surgery. The government further alleged that Dr. Asfora would sometimes use these devices to perform medically unnecessary procedures and then submit false claims to government entities.⁵ Note that this implicates the anti-kickback statute concerns associated with PODs that the U.S. Department of Health and Human Services’ Office of Inspector General addressed in their March 2013 Physician-Owned Entities Special Fraud Alert.⁶ The government’s case against Dr. Asfora incorporates not just these offenses but also the above discussed 2020 Medtronic Suit.

To settle the matter, Dr. Asfora, along with Medical Designs and Sicage, agreed to pay \$100,000 to resolve the Sunshine Act claims and an additional \$4.4 million to resolve the False Claims Act and Anti-Kickback Statute allegations. Under the terms of the settlement agreement, Dr. Asfora, Medical Designs and Sicage will each be excluded from participating in federal healthcare programs for a period of six years.

MEDICREA USA INC.

The third Sunshine Act settlement, brought by the Eastern District of Pennsylvania,⁷ involves claims regarding physician entertainment expenses paid by Medicrea USA Inc. (“Medicrea”), a French medical device manufacturer, which markets

and sells their products in the United States.

The government alleges that Medicrea provided U.S.-based physicians with meals, alcoholic beverages, entertainment, and travel-related expenses for attending the Scoliosis Research Society’s September 2013 congress in France. Medicrea covered the value of travel for the physicians as well as their family members. Medicrea allegedly offered these benefits in an attempt to get the physicians to purchase Medicrea spinal devices. Following this event, and from a period between April 2014 and March 2018, Medicrea failed to report the full value of the benefit payments made to the physician attendees.

To resolve the Sunshine Act claims, Medicrea agreed to pay \$1 million and an additional \$1 million to resolve the related Anti-Kickback Statute and False Claims Act allegations.⁸

STRESS TESTING SUNSHINE ACT COMPLIANCE PROCEDURES

These recent settlement agreements suggest a trend of increased Sunshine Act enforcement by the DOJ. They serve as a good reminder for healthcare companies to stress test their Sunshine Act compliance procedures and ensure reporting policies comply with Sunshine Act requirements.

Below are some helpful tips for healthcare companies navigating this process below:

- *Update Your Sunshine Act Compliance Policies:* Review your compliance plan to ensure it properly accounts for the new Sunshine Act payment categories as well as the expanded scope of Sunshine Act covered recipients. A good compliance plan must offer guidelines for accurate and timely Sunshine Act reporting. It is important that these policies are documented to create a paper

trail in the event of a government investigation.

- **Set Training and Monitoring Procedures:** Ensure sales representatives are trained on the Sunshine Act, Anti-Kickback Statute, and False Claims Act. Companies can be held liable for Sunshine Act violations even if, at the time, they did not know about the misconduct. In the Medtronic suit, for example, Medtronic was held liable despite learning of the improper payments after the fact and penalizing the responsible employee. Proper training and internal control procedures can prevent representative misconduct and force them to verify any improper spending on covered recipients.
- **Audit Your Open Payments Data:** Each of these enforcement actions all involve companies being penalized for failing to report payments that were made when the Sunshine Act first came into effect. Make sure there are no gaps in your reporting records and that applicable payments to covered recipients, both past

and present, are being reported in a timely and accurate manner. If any improper payments are uncovered make sure to record the accurate value of such payments in the Open Payment System. 🌟

NOTES

1. 42 U.S.C. § 1320a-7h, <https://www.law.cornell.edu/uscode/text/42/1320a-7h>.
2. Implementation of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018: Dispensing and Administering Controlled Substances for Medication-Assisted Treatment Pub. L. 115-271, Stat. 3894, Subt. L, § 6111 (Oct. 24, 2018); <https://www.federalregister.gov/documents/2020/11/02/2020-23813/implementation-of-the-substance-use-disorder-prevention-that-promotes-opioid-recovery-and-treatment>; see also 42 C.F.R. § 403.904, <https://www.federalregister.gov/documents/2020/11/02/2020-23813/implementation-of-the-substance-use-disorder-prevention-that-promotes-opioid-recovery-and-treatment>.
3. <https://www.justice.gov/opa/press-release/file/1332261/download>.
4. Medtronic to Pay Over \$9.2 Million To Settle Allegations of Improper Payments to South Dakota Neurosurgeon (Oct. 29, 2020), U.S. Dep't of Justice, <https://www.justice.gov/opa/pr/medtronic-pay-over-92-million-settle-allegations-improper-payments-south-dakota-neurosurgeon>.
5. Neurosurgeon and Two Affiliated Companies Agree to Pay \$4.4 Million to Settle Healthcare

- Fraud Allegations (May 3, 2021), U.S. Dep't of Justice, <https://www.justice.gov/usao-sd/pr/neurosurgeon-and-two-affiliated-companies-agree-pay-44-million-settle-healthcare-fraud>.
6. https://oig.hhs.gov/documents/special-fraud-alerts/867/POD_Special_Fraud_Alert.pdf.
7. <https://www.policymed.com/wp-content/uploads/2021/06/210519-Medicare-Settlement-Fully-Executed.pdf>.
8. French Medical Device Manufacturer to Pay \$2 Million to Resolve Alleged Kickbacks to Physicians and Related Medicare Open Payments Program Violations (May 19, 2021), U.S. Dep't of Justice, U.S. Att'y's Off. E.D. Pa., <https://www.justice.gov/usao-edpa/pr/french-medical-device-manufacturer-pay-2-million-resolve-alleged-kickbacks-physicians>.

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