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The Physician Payments Sunshine Act and the future of healthcare transparency: Part 2

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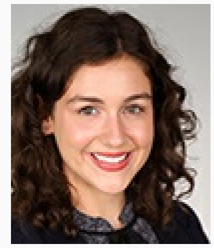

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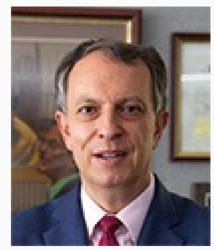

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The Physician Payments Sunshine Act (PPSA) took effect in 2013.[1] It requires medical product manufacturers to disclose to the Centers for Medicare & Medicaid Services (CMS) payments or transfers of value made to physicians or teaching hospitals. PPSA also requires manufacturers and group purchasing organizations to disclose any physician's ownership or financial interest in those companies. The disclosed data is published annually in a publicly searchable database.[2] The rationale behind the public availability of the data is to empower patients through transparency to mitigate the putative effect of financial incentives on clinical behavior and the public and prevent physician-industry conflicts of interest.

Part 1 of this article[3] offers a comprehensive analysis of the major healthcare regulatory enforcement statutes and their continuingly expansive use. First, it considers the issues in the healthcare industry that led to the enactment of the PPSA are relevant to an understanding of the current law and its growing enforcement. Next, it discusses PPSA key statutory language and its evolution and considers the impact from a fraud and abuse standpoint.

Part 2 of this article reviews the significance of the first examples of Department of Justice enforcement of the act, as well as the likely increase of private PPSA enforcement. Other sunshine acts, including state and international acts, are also highlighted. Finally, an examination of the future of transparency statutes, including the Hospital Price Transparency regulation,[4] the newest major transparency statute proposed; the Prescription Drug Price Transparency Act; and the Transparency in Coverage statute, which support the notion that transparency is a trend in the healthcare industry that will withstand the test of time.

Enforcement so far

Though the PPSA has been in place for several years, there is only a handful of public examples of enforcement that have been announced so far. The below examples serve as a solid starting point of a likely trend in healthcare transparency and accountability enforcement.

Medtronic

The United States Department of Justice settled its first enforcement action in October 2020 against Medtronic USA Inc.[5] The settlement was the result of an investigation by the Civil Division of the Department of Justice, the U.S. Attorney's Office for the District of South Dakota, and the Office of Inspector General.

Medtronic is a large medical device–making company based out of Minnesota. The settlement resolved claims of liability under of the False Claims Act, the Anti-Kickback Statute, and reporting violations under CMS Open Payments Program as required by the PPSA.

Specifically, Medtronic was alleged to have been involved in a scheme with neurosurgeon Wilson Asfora, MD. Over the course of several years, the government claimed that Medtronic paid for more than one hundred social events with expensive food and drinks held at a restaurant that Medtronic knew Asfora owned. Asfora would invite social acquaintances, business partners, colleagues, and potential and existing referral sources. According to the government, the motivation for these payments was to induce Asfora "to use Medtronic's SynchroMed II intrathecal infusion pumps, which are implantable devices used to deliver medication to patients."

In addition to the kickback scheme, the government alleged that Medtronic "violated the Open Payments Program by failing to accurately report payments it made" to Asfora to CMS. The investigation determined that despite Medtronic knowingly making payments to Asfora's restaurant at his request, the company underreported those transfers of value to CMS. According to the government, rather than reporting the total amount paid to Asfora and his restaurant as required by the Sunshine Act, Medtronic only reported the attributed value of the food and drinks that each individual physician at the event consumed, leading to a severely diminished total reported.

Brenna E. Jenny, former U.S. Department of Health & Human Services deputy general counsel and CMS chief legal officer, has commented on the future of CMS Open Payments enforcement by stating, "CMS' Open Payments Program is intended to promote transparency and accountability in the healthcare system. Manufacturers that misreport their financial relationships with healthcare providers erode the integrity of the Open Payments Program and will be held accountable." She continued, "CMS looks forward to continued partnership with the Department of Justice to resolve allegations of manufacturers skirting their Open Payments obligations." Government enforcement of the reporting requirements aim to protect patients by encouraging doctors to make medical decisions based on quality of care rather than illegal financial incentives.

Medtronic agreed to pay over $9.2 million: $8.1 million to resolve violations of the False Claims Act and $1.11 million to resolve the violations of the Open Payments Program. As part of the agreement, Medtronic cooperated with the ongoing investigations and litigation against other parties, including the case against Dr. Asfora.[6] Medtronic also took remedial action pursuant to the agreement.[7] After learning of the wrongdoing, Medtronic terminated the employment of two employees, while disciplining twelve other employees involved in the scheme. The news release notes that the claims resolved by the settlement were only allegations, and the settlement declines to determine or admit liability by Medtronic.

As discussed in Part 1 of this article, the PPSA limits the total civil monetary penalties for failure to fully report to CMS to $150,000.[8] The government may also penalize each knowing violation, up to a maximum of $1,000,000 per year.[9] Therefore, penalties are limited to a total of $1.15 million annually. In this case, the agreement penalty amount of $1.1 million nears the maximum annual penalty. This serves as an aggressive precedent to deter any manufacturers or pharmaceutical companies from negligent or willful failure to adhere to the reporting requirements of the PPSA.

Dr. Asfora's PPSA accountability

In May 2021, months after the release of the Medtronic settlement, the Department of Justice released the settlement and penalties for Dr. Wilson Asfora's role in the alleged Medtronic scheme.[10] Asfora and the two medical device distributorships he owns, Medical Designs LLC and Sicage LLC, agreed to pay $4.4 million total in order to resolve False Claims Act and Anti-Kickback Statute allegations. Both companies were also required to pay an additional $100,000 as a penalty for the Open Payments Program violations for failing to report Asfora's ownership interests and payments made by the companies to the disgraced neurosurgeon.

Dr. Asfora, Medical Designs, and Sicage are also all excluded from participation in federal healthcare programs for six years as a result of the settlement. Acting Assistant Attorney General Brian M. Boynton of the Department of Justice's Civil Division forewarned that the government "will continue to hold physicians and medical device companies accountable for unlawful financial arrangements that undermine the integrity of federal healthcare programs."

Medicrea USA Inc.

On May 19, 2021, the Department of Justice announced another Open Payments Program settlement arising from private qui tam litigation in the Eastern District of Pennsylvania.[11] The settlement was "among the first settlements to resolve allegations under both the False Claims Act and the Open Payments Program" as encouraged by the Senate Finance Committee's March 2019 request to investigate and pursue noncompliance with the PPSA.

The settlement is the result of qui tam allegations that Medicrea, a small French medical device manufacturer, and its United States affiliate Medicrea USA Inc., violated the Anti-Kickback Statute by hosting United States physicians at a 2013 Scoliosis Research Society's conference in Lyon, France. At this conference, Medicrea allegedly provided value to the physicians "in the form of meals, alcoholic beverages, entertainment, and travel expenses." Medicrea also allegedly engaged in other improper business practices in order to induce these physicians to purchase their spinal devices that treat a variety of diseases of the spine and encompassed the sole source of revenue for the company.[12] Importantly, the settlement also resolved the associated Open Payments Program violation allegations that Medicrea failed to fully report these physician entertainment expenses to CMS.[13]

The settlement only resolved alleged claims and did not determine any liability of Medicrea or any of its employees. As a result of the agreement, and without conceding liability, Medicrea paid $1 million to the United States and participating states for resolution of the False Claims Act and the Anti-Kickback Statute allegations as well as an additional $1 million to the United States for alleged violation of the Open Payments Program. According to the government, the settlement is meant to encourage manufacturers to accurately and timely report all applicable payments of value to CMS through the Open Payments Program.