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

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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.

A continued enforcement trend

Though both settlements were the first of their kind for PPSA violations, they may serve as an indication of a continued enforcement scheme by the Department of Justice to further the goals of transparency and accountability in healthcare. Moreover, there will likely be an increased number of qui tam actions brought under the provisions of the PPSA resulting in similar settlements. There are currently several cases filed alleging misconduct under the PPSA.

State and global impact

The mission of the PPSA is supported on both a national and global level. While other countries and states have taken varied approaches, the approaches all further the general aim of promoting transparency in the healthcare

industry.

State sunshine acts

Some states have their own physician sunshine acts that were enacted prior to the federal law, including Massachusetts; Minnesota; West Virginia; Maine; Washington, DC; and Vermont.[14] The state laws "vary in terms of the minimum value that triggers reporting of payments, the exceptions that apply, and other material terms."[15] Also of significance, some of the state sunshine laws exempt research-related reporting of clinical trial payments. The PPSA regulates by mandating disclosure of payments. However, some of the state sunshine acts have taken a more aggressive approach and constrain certain types of payments, including Minnesota's general ban on manufacturers providing gifts to physicians. The federal PPSA does contain a preemption provision that addresses some of the gaps between the state laws and the federal statute. It is possible that after recognizing the successes and limitations of the state sunshine laws, the federal PPSA may be revised accordingly again.

The District of Columbia has also attempted to create a licensure requirement for pharmaceutical sales representatives that would impose penalties on representatives for misleading marketing.[16] Fees would be used to fund a state-based academic detailing program while at the same time discouraging inappropriate industry marketing.

Global impact of the PPSA

The American PPSA has gained international attention. While the European Union has not yet enacted a similar statute, some member countries have enacted statutes of their own. For example, after the United States enacted PPSA, France enacted the Bertrand Law of December 29, 2011, referred to as the French Sunshine Act.[17] It was modeled after the PPSA but extended the effect by working in conjunction with several anti-corruption laws and ordinances: specifically, French Law No. 2016-1691, or Sapin II Law, which is a general anti-corruption law intended to increase transparency, and Ordinance No. 2017-49, an anti-gift legislation specifically aimed at healthcare companies. Sapin II differs from the PPSA in several ways (e.g., it imposes fines against companies that fail to prevent and detect corruption even if no misconduct has occurred.)

Other countries that have taken transparency measures after the United States include Portugal, Greece, Romania, Latvia, and Denmark.[18]

While there is a global increase of transparency in healthcare, the United States has continued to enact several other statutes that continue the trend associated with the PPSA, described in the next section.

Future of transparency statutes

Though the PPSA was the first major healthcare transparency statute, its enactment has led to the birth of several more statutes with the same goals. Because of the bipartisan support of the mission, there is a high likelihood of a continued trend of placing a political emphasis on transparency in healthcare.

CMS price transparency regulation

The bipartisan support has led to the enactment and proposal of several new transparency statutes and regulations. While there is support, there is still ambiguity that left many hospital administrators unclear after the passage of the most recent major statute, The Hospital Price Transparency regulation.[19] The long-awaited

regulation does not contain very strong penalties, leading to even further confusion in the industry. The controversy does not end there, as the U.S. Chamber of Commerce has become the most recent agency to file a lawsuit challenging the rule.[20] This section highlights the recent monitoring and penalty schemes that took effect on January 1, 2021, as prescribed by the Code of Federal Regulations.

As with the PPSA, there are interesting questions raised, such as whether this statute will be used to further the transparency goals for which it was intended. Concerns relating to whether patients will actually utilize the information apply to this statute as well. Broadly speaking, the fact remains that the healthcare market is unique, and patients do not always shop around prior to receiving care. Price is not the sole consideration when consumers are shopping for healthcare; concerns of quality, prestige, and convenience also are important considerations for many patients. These points continue to undermine the position that healthcare transparency statutes are intended for the general public. Likewise, the complexities behind the Hospital Price Transparency regulation and the lack of consumer education on the matter lead to the same doubts.

Basis, scope, definitions, and requirements

The first general provision of the Hospital Price Transparency regulation requires "each hospital operating within the United States, for each year, to establish, update, and make public a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups (DRGs) established under section 1886(d)(4) of the Social Security Act."[21] The required data elements are described under 45 C.F.R. § 180.50 and include the gross charge (inpatient), the payer-specific negotiated charge, a deidentified minimum negotiated charge, a deidentified maximum negotiated charge, the discounted cash price, and any code used for the hospital or purposes of accounting for or billing the item of service.

Interestingly, CMS has declined to require hospitals to affirmatively submit a form indicating compliance with the rule. CMS has cited to another commenters' response that "requiring such an attestation would put hospitals at risk of implicating the federal False Claims Act and associated penalties if they were determined to be noncompliant."[22]

The following regulations took effect on January 1, 2021, and outline the methods of monitoring and enforcement of the hospital price transparency requirements: 45 C.F.R. § 180.70, 45 C.F.R. § 180.80, 45 C.F.R. § 180.90 .[23]

45 C.F.R. § 180.70 : Monitoring and Enforcement

45 C.F.R. § 180.70(a)(2) states that CMS may assess hospital compliance through several methods, including, but not limited to: (i) "complaints made by individuals or entities to CMS," (ii) "review of individuals' or entities' analysis of noncompliance," or (iii) "audit of hospitals' websites."

CMS then has the authority pursuant to 45 C.F.R. § 180.70(b) to:

1. "Provide a written warning notice to the hospital of the specific violation(s),"
2. "Request a corrective action plan from the hospital if its noncompliance constitutes a material violation of one or more requirements, according to § 180.80," and
3. "Impose a civil monetary penalty on the hospital and publicize the penalty on a CMS website according to § 180.90."

It is too soon to say what the government enforcement scheme will entail for hospitals affected by this statute

due to its recent implementation as well as the forgiving nature of enforcement, with multiple opportunities for correction prior to any penalties.

45 C.F.R. § 180.80 : Corrective Action Plans

This regulation outlines what forms of noncompliance constitute material violations requiring a corrective action plan. CMS foresees that its review for inaccuracies in reported information would be for "egregious and obvious instances of noncompliance, such as (in the extreme) all items and services made public by a hospital having the same value, or no value at all."[24]

45 C.F.R. § 180.90 : Civil Monetary Penalties

45 C.F.R. § 180.90(a) states that CMS "may impose a civil monetary penalty on a hospital identified as noncompliant according to § 180.70." 45 C.F.R. § 180.90(c)(2) states that "the maximum daily dollar amount for a civil monetary penalty to which a hospital may be subject is $300." This section has been substantially criticized because a penalty of $300 only amounts to $109,500 annually. Many have noted that larger hospitals have the ability to pay this sum rather than comply with the statute. This relatively minor penalty does little to emphasize the importance of transparency in the healthcare industry and may lead to incomplete availability of data, which will discourage consumers from thoroughly comparing various healthcare institutions as the statute intended.

All in all, a review of the forgiving enforcement structure of the Hospital Price Transparency regulation indicates that there will be several years before hospitals reach full compliance, thus enabling patients to compare prices. Even then, there will be questions as to whether the statute serves its intended goals and whether it will change the healthcare shopping experience for consumers.

The Drug Transparency Act

The Prescription Drug Price Transparency Act has also been introduced in the House of Representatives.[25] It requires in part that any pharmacy benefit manager that requires enrollees to use a certain pharmacy that it has an ownership interest in or provides an incentive in the form of a reduced copayment or coinsurance disclose individual drug prices and other pricing data in a spreadsheet that is easily accessible and comparable. Discussions relating to the unintended effects of price transparency, such as causing patient perception of inability to pay, are ongoing.[26]

In addition to the Hospital Price Transparency regulation and the Prescription Drug Price Transparency Act, the Transparency in Coverage final rule has been released.[27] It states that group health plans and health insurance issuers in the individual and group markets must disclose cost-sharing information upon request to any participant, beneficiary, or enrollee. This disclosure must also include "an estimate of the individual's cost-sharing liability for covered items or services furnished by a particular provider." This information must be made available on a website in order to allow participants to shop for items and services by better understanding their out-of-pocket expenses. Plans and insurance issues must also "disclose in-network provider negotiated rates, historical out-of-network allowed amounts, and drug pricing information" via machine-readable files to be posted on a website. Like the PPSA, this rule intends to provide the public with access to health coverage information to efficiently shop for services in order to reduce the costs of care and lessen the amount of spending in the United States.

The release of the final rule has indicated that transparency in healthcare is a trend that is not going away. With

the recent enforcement settlement—and likely more down the line—physician and consumer behavior and industry impacts should be studied in order to best serve the intended goals of the acts.

Conclusion

The Physician Payments Sunshine Act is a major effort to further the goals of transparency in the United States. Because of the bipartisan support on the motivations behind the act, it is likely that the trend will continue to prevail in the industry. Specifically, the existing regulations may evolve to more effectively discourage any fraudulent, illegitimate, and dishonest behavior in an industry that should be focusing on improving the balance between cost, quality, and access to healthcare. As more settlements and prosecutions unfold, the general public and practitioners alike will become more acutely aware of the requirements, implications, and importance of accurate healthcare transparency.

Takeaways

- The healthcare industry has shifted toward a more transparent environment by requiring manufacturers to disclose transfers of value made to physicians and hospitals to the Centers for Medicare & Medicaid Services.
- The public availability of Open Payments data allows healthcare organizations, the government, competitors, and even the press to identify extreme outliers and potential reporting violations.
- Compliance and enforcement of the Physician Payments Sunshine Act is intertwined with the False Claims Act and the Anti-Kickback Statute; the Office of Inspector General has warned against "highly suspect" fraudulent practices relating to the Physician Payments Sunshine Act.
- The recent increase of novel settlements indicates the strong likelihood of a continued enforcement trend.
- Healthcare transparency will continue to prevail, as evidenced by the enactment of several state and foreign sunshine acts and the introduction of additional transparency statutes.

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3 Mary Kate McDevitt and Marc S. Raspanti, "The Physician Payments Sunshine Act and the future of healthcare transparency: Part 1," *Compliance Today*, February 2022.
4 45 C.F.R. § 180 .
5 U.S. Department of Justice, "Medtronic to Pay Over $9.2 Million To Settle Allegations of Improper Payments to South Dakota Neurosurgeon," news release, October 29, 2020, https://www.justice.gov/opa/pr/medtronic-pay-over-92-million-settle-allegations-improper-payments-south-dakota-neurosurgeon.
6 *See* United States ex rel. Bechtold, et al. v. Asfora, et al., No. 4:16-cv-04115-LLP (D.S.D.).
7 U.S. Department of Justice, "Medtronic to Pay Over $9.2 Million."
8 42 U.S.C. § 1320a-7h(b)(1)(B) .
9 42 U.S.C. § 1320a-7h(b)(2)(B) .
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Device Manufacturer to Pay $2 Million to Resolve Alleged Kickbacks to Physicians and Related Medicare Open Payments Program Violations," news release, May 19, 2021, https://www.justice.gov/usao-edpa/pr/french-medical-device-manufacturer-pay-2-million-resolve-alleged-kickbacks-physicians.

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13 U.S. Department of Justice, U.S. Attorney's Office for the Eastern District of Pennsylvania, "French Medical Device Manufacturer to Pay $2 Million."

14 Richard S. Saver, "Shadows amid sunshine: regulating financial conflicts in medical research," *Chest* 145, no. 2 (February 2014), 379–385; Tim Ken Mackey and Bryan A. Liang, "Physician Payment Disclosure Under Health Care Reform: Will the Sun Shine?" *The Journal of the American Board of Family Medicine* 26, no. 3 (May 2013), 327–331.

15 Richard S. Saver, "Shadows amid sunshine."

16 Tim Ken Mackey and Bryan A. Liang, "Physician Payment Disclosure."

17 Marc Stephen Raspanti, Pamela Coyle Brecht, and Michael A. Morse, "Vive La Différence? American and French Healthcare Fraud, Waste, and Abuse Laws," Pietragallo Gordon Alfano Bosick & Raspanti, December 2, 2019, https://www.pietragallo.com/publications/vive-la-difference-american-and-french-healthcare-fraud-waste-and-abuse-laws/

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20 Chamber of Com. of the U.S. v. U.S. Dep't of Health & Human Srvs., No. 6:21-cv-00309 (Aug. 10, 2021).

21 45 C.F.R. §180.10 .

22 Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. Price Transparency Requirements for Hospitals To Make Standard Charges Public, 84 Fed. Reg. 65,524, 65,583 (November 27, 2019) .

23 Enforcement power: The final rule publishes requirements for all hospitals in the United States to make standard charges available to the public pursuant to Section 2718 (e) of the Public Health Service Act. The final rule also establishes an enforcement scheme that is authorized by Section 2718 (b)(3) of the Public Health Service Act.

24 Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS Policy Changes, 84 Fed. Reg. 65,583 .

25 Prescription Drug Price Transparency Act, H.R. 1035, 116th Cong. (2019).

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