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The Physician Payments Sunshine Act and the future of healthcare transparency: Part 1

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Part 2 of this article series will be published in the March 2022 issue of Compliance Today *and focus on examples of enforcement actions and examine the future of transparency statutes.*

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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. The act 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.

This two-part article provides a comprehensive analysis of the major healthcare regulatory enforcement statutes and their continuingly expansive use. First, we'll reference the issues in the healthcare industry that led to the enactment of the PPSA that are relevant to an understanding of the current law and its growing enforcement. Next, we'll discuss key statutory language and PPSA's evolution. Then, we'll consider the impact from a fraud and abuse standpoint, which is important to appreciate the significance of the first examples of Department of Justice enforcement of the act that follow, as well as the likely increase of private PPSA enforcement. We'll also highlight other sunshine acts, including state and international ones. Finally, we'll examine the future of transparency statutes, including the Hospital Price Transparency regulation,[3] 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.

The lead-up to the enactment of the Physician Sunshine Act

After years of calls for the healthcare industry to shift toward a more transparent and consumer-friendly environment, the Patient Protection and Affordable Care Act (ACA) passed in 2010, including the PPSA codified at 42 U.S.C. § 1320a-7h, also known as Section 6002 of the ACA. PPSA was originally presented in 2007 but failed to pass. After being incorporated into the ACA, the provisions, described below, took effect on March 31, 2013.[4] After the release of the Institute of Medicine's 2009 report highlighting the risks of financial conflicts between physicians and companies,[5] including "withholding of negative results, erosion of trust, and harm to patients," the industry began to crack down on monitoring and preventing physician's financial interests and ties with

other industries.[6]

Though the discussion surrounding healthcare consumerism has picked up in recent years with the passage of many transparency statues, it can actually be traced back to the 1930s.[7] The term "healthcare consumerism" can generally be understood to mean individuals "proactively using trustworthy, relevant information and appropriate technology to make better-informed decisions about their health care options in the broadest sense, both within and outside the clinical setting."

The Physician Payments Sunshine Act and its basic requirements

In order to effectuate the goals of healthcare transparency, the PPSA ultimately delineated required disclosures that are classified by the nature of the payment. The PPSA sets forth certain information for each type of payment that must be disclosed in order for the payment to remain lawful.

Required disclosures

PPSA requires any applicable manufacturer that provides a payment of a transfer or value to a covered recipient, or to an entity or individual at the request of or designated on behalf of a covered recipient to submit an electronic report including the information listed below.[8] There are three broad categories of payments that must be reported to CMS.[9] The first category applies generally to any transfers of value including meals, travel reimbursement, and consulting fees. The disclosure must include the following information:[10]

> i. The name of the covered recipient.
>
> ii. The business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and National Provider Identifier of the covered recipient.
>
> iii. The amount of the payment or other transfer of value.
>
> iv. The dates on which the payment or other transfer of value was provided to the covered recipient.
>
> v. A description of the form of the payment or other transfer of value, indicated (as appropriate for all that apply) as—
>
> I. cash or a cash equivalent;
>
> II. in-kind items or services;
>
> III. stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or
>
> IV. any other form of payment or other transfer of value (as defined by the Secretary).
>
> vi. A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as—

I. consulting fees;

II. compensation for services other than consulting;

III. honoraria;

IV. gift;

V. entertainment;

VI. food;

VII. travel (including the specified destinations);

VIII. education;

IX. research;

X. charitable contribution;

XI. royalty or license;

XII. current or prospective ownership or investment interest;

XIII. direct compensation for serving as faculty or as a speaker for a medical education program;

XIV. grant; or

XV. any other nature of the payment or other transfer of value (as defined by the Secretary).

vii. ...

viii. Any other categories of information regarding the payment or other transfer of value the Secretary determines appropriate.

The second broad category that must be reported covers payments that relate to research. Specifically, any payment made for participation in "preclinical research, clinical trials, or other product development activities" that are subject to a written agreement or a research protocol must be reported, though they will appear on a separate reporting system in order to compensate for the fact that a research grant may never reach the physician but rather goes to a host organization.[11] The relevant language provides: "If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of that covered drug, device, biological, or medical supply" must be submitted to the U.S. Department of Health & Human Services secretary.[12]

The third category states that if a physician or an immediate family member of the physician has an ownership or investment interest (other than in a publicly traded security and mutual fund), then the physician must disclose the "dollar amount invested" and "the value of terms," as well as any "other transfers of value."[13] This section

includes group purchasing organizations and physician-owned distributors of medical devices.[14]

Certain values of transfer are not required to be disclosed. For example, payments under $10 are not required to be reported unless they reach a total value of $100 annually.[15] Moreover, product samples not intended to be sold, educational materials that benefit patients, the loan of a covered device, discounts, and other enumerated transfers need not be reported.

The disclosed data is published annually in a publicly searchable database that is managed by CMS.[16] A growing number of organizations, such as ProPublica,[17] also use this data in order to make the payments publicly available.

Relevant statutory definitions

Importantly, a "covered recipient" means a physician, teaching hospital, physician's assistant, nurse practitioner, clinical nurse specialist, a certified registered nurse anesthetist, or a certified nurse-midwife.[18] This section was recently amended due to the response to some valid criticisms of the original language of the statute, discussed below.

"Applicable group purchasing organization" is defined in 42 U.S.C. § 1320a-7h(e) as a group purchasing organization "that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply which is operating in the United States." "Applicable manufacturer" is defined therein as "a manufacturer of a covered drug, device, biological, or medical supply which is operating in the United States." A "covered device" is "any device for which payment is available under subchapter XVIII or a State plan." A "'covered drug, device, biological, or medical supply' means any drug, biological product, device, or medical supply for which payment is available under subchapter XVIII or a State plan."

Failure to comply

Penalties are broken down into two main categories: violation of the PPSA and *knowing* violation of the PPSA. This enforcement scheme was of great significance in the first Department of Justice enforcement settlement agreement,[19] discussed below, and will remain prevalent as the statute continues to be enforced. The severity of the penalties can be a substantial deterrent of any illicit reporting behavior.

Notably, "any applicable manufacturer or applicable group purchasing organization that fails to submit [the required information] in a timely manner in accordance with [the above rules and regulations] shall be subject to a civil money penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest not reported as required under" the act.[20] The total amount of civil monetary penalties imposed under this subsection is limited to $150,000.

As stated, in addition to failure to report, knowing failures to report are also penalized as additional violations.

> Any applicable manufacturer or applicable group purchasing organization that knowingly fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such

> subsection.[21]

The total amount of civil monetary penalties imposed under this section with respect to each annual submission of information by an applicable manufacturer or applicable group purchasing organization shall not exceed $1 million.[22]

Therefore, the total potential liability of both knowing and unknowing violations under the PPSA can be up to $1.15 million annually.

Changes to the PPSA

A key feature of furthering the regulatory goals of the PPSA, as with any enforcement statute, is to maintain the ability to evolve and respond to industry concerns and criticisms and obvious loopholes in the law. An original criticism of the statute related to the covered individuals: though physicians were required to report financial relationships to CMS, other positions with prescribing power were not named in the law, including physician's assistants, nurse practitioners, and medical residents.[23] This led to a fear that manufacturers would simply be incentivized to shift financial relationships to those prescribers instead, especially given the expansive role these professionals play in healthcare. As shown above, these categories of providers are now covered by the law as of January 2021 and must also report financial relationships in order to further the goals of transparency and to deter any illicit financial relationships.[24]

Additional methods of suggested improvement structured to enhance the intended goals include creating stricter disclosure requirements and regulatory controls.[25] Proponents of methods such as "banning certain financial ties, restricting investigators with financial interests from direct participation in the research, or moving clinical trials to other institutions with no direct financial interest in the study outcome" state that these regulations would make it harder to conceal any illicit financial relationships. Similar reforms would require that independent entities with oversight by government agencies entirely take over the management of all clinical trials in order to prevent any undue influence. The issue with this approach is that it may not be politically feasible in the current US healthcare industry where collaboration in research, innovation, and protection of proprietary interests is highly valued.

Impact to the entire industry

The regulations that govern the healthcare industry are intricately related. While each regulation has its own distinct purpose, the requirements inevitably affect the objective of others. For example, one stated goal of the PPSA is to promote transparency in the industry. Yet, a significant impact of the disclosure requirements will continue to be to expose fraud, kickbacks, and inappropriate relationships that are increasing the costs of healthcare in the United States.

Fraud, waste, and abuse risk response

An original concern of the PPSA related to the administrative costs associated with reporting requirements. CMS has estimated in 2014 that the overall cost of reporting would be $269 million in the first year and $180 million each year thereafter.[26] These numbers are easily rationalized when linking the PPSA to the costs recovered through fraud and abuse enforcement each year. For example, in the fiscal year 2020, the Department of Justice recovered more than $2.2 billion from False Claims Act cases.[27] As described below, these recoveries are intertwined with the articulated mission of the PPSA.

There are still lingering questions as to whether patients and the general public will use or care about the publicly disclosed information. One study found that very few Americans knew whether their doctor had ever received a payment, or even that the payment information is publicly available.[28] Specifically, only 12% of respondents were aware that payment information was publicly available, and 5% knew whether their own doctor received payments. However, if underlying theories that patients will care are correct, then it will serve as a new incentive for physicians and hospitals to underreport their financial ties in order to avoid the intended backlash.[29] This could unintentionally increase healthcare costs in the United States through fraud and abuse.

The growing prosecutions of drug and device manufacturers under fraud and abuse laws is an example of the major efforts to regulate the physician-industry relationships. Below is an overview of the key laws along with a discussion of how these laws interact with and further the goals of the PPSA.

The federal False Claims Act

The False Claims Act imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."[30] The term "knowingly" does not require specific intent to defraud but rather actual knowledge of the information, or acting in reckless disregard or deliberate ignorance of the truth.[31] A "claim" is a request or demand for money that is presented to the United States. Healthcare providers seek reimbursements for federally funded programs such as Medicaid, Medicare, or TRICARE.

The U.S. Supreme Court has adopted the implied false certification theory that states that liability is established when a claim is presented to the government requesting payment, and the claim makes representations about the goods or services provided but the provider does not disclose noncompliance with material statutory or regulatory requirements.[32]

The False Claims Act is also a means for private individuals known as relators or whistleblowers to bring qui tam actions for violation of the Anti-Kickback Statute, discussed later. Section 6402 of the Affordable Care Act specified that any claims for items and services that were the result of an unlawful remuneration are considered a false claim. Therefore, any inappropriate relationships between doctors and pharmaceutical companies can be civilly pursued under this statute.[33]

The Anti-Kickback Statute

The Anti-Kickback Statute states that whoever "knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly…in cash or in kind to any person to induce…to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony."[34] Therefore, a provider can be criminally prosecuted if they make a payment to induce a person to order or purchase a service or item that is paid for by a federally funded program such as Medicaid or Medicare. It is important to note that the service need not be medically unnecessary or below quality care.

Relation to the PPSA

The Office of Inspector General has expressly warned against "highly suspect" fraudulent practices that are related to the PPSA.[35] Examples of this suspect behavior include paying physicians as consultants for meetings and conferences or paying physicians for time spent listening to sales representatives. Additionally, providing lavish meals, travel, and gifts has a strong potential of violating the Anti-Kickback Statute.

Interestingly, the Department of Justice has recently acknowledged that it has been using data analytics in order to identify "trends and extreme outliers," and it has led to an increase in the number of Department of Justice–initiated False Claims Act cases, rather than relying primarily on whistleblowers and qui tam actions,[36] which accounted for more than 70% of new False Claims Act matters in the fiscal year 2020.[37] With the increased access to CMS data, the Department of Justice is far more easily able to identify potential violations of the Anti-Kickback Statute. It is also possible that competitors and even the press use the data in a similar way in order to alert the government of any potential reporting violations. Alternatively, healthcare organizations could analyze their own data to find outliers before the government does in order to remain compliant with all relevant fraud and abuse provisions.

False Claims Act prosecutions and recent settlements implicate topics that are relevant to the PPSA, which has resulted in corporate integrity agreements and settlements that seem to be in line with the act's requirements. For example, one investigation found that physicians were paid kickbacks in the form of consulting fees and travel at resorts in order to induce their use of artificial hip and knee implants.[38] The settlement required a corporate compliance procedure that mandated physicians with whom the company had a financial arrangement to disclose the arrangement to patients and affiliated hospitals. The company also would post this information to its website. However, the website did not indicate what the funds were used for and did not allow users to perform searches. Furthermore, a 2019 case alleged that Life Spine paid more than $7 million in consulting fees, royalties, and intellectual property acquisitions payments to surgeons and did not report all of these payments to CMS as required by the act.[39] The resulting settlement agreement of nearly $6 million settled the False Claims Act and Anti-Kickback Statute claims but did not specifically penalize the PPSA allegations.[40] The PPSA and its more recent enforcement, described in Part 2 of this article, goes above and beyond the requirements of previous corporate integrity agreements and settlement agreements by imposing penalties for failure to report payments, which more sufficiently furthers the goals of transparency while deterring costly fraudulent behavior.

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 Anti-Kickback Statute; the Office of Inspector General has warned against "highly suspect" fraudulent practices relating to the 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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6 Richard S. Saver, "Shadows amid sunshine: regulating financial conflicts in medical research," *Chest* 145, no. 2 (February 2014), 379–385, https://pubmed.ncbi.nlm.nih.gov/24493509/.
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12 42 U.S.C. § 1320a-7h(a)(1)(A)(vii).
13 42 U.S.C. § 1320a-7h(a)(2).
14 Elizabeth Richardson, "The Physician Payments Sunshine Act."
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16 *See* "Search Open Payments," U.S. Centers for Medicare & Medicaid Services, accessed December 15, 2021, https://openpaymentsdata.cms.gov/search/physicians/by-name-and-location.
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21 42 U.S.C. § 1320a-7h(b)(2)(A).
22 42 U.S.C. § 1320a-7h(b)(2)(B).
23 Elizabeth Richardson, "The Physician Payments Sunshine Act."
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25 Richard S. Saver, "Shadows amid sunshine."
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