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

By Mary Kate McDevitt, Esq., and Marc S. Raspanti, Esq.

Mary Kate McDevitt (mkm@pietragallo.com) is an associate in the Qui Tam/False Claims Act practice group of Pietragallo Gordon Alfano Bosick and Raspanti LLP in Philadelphia. **Marc S. Raspanti** (msr@pietragallo.com) is a name partner of Pietragallo Gordon Alfano Bosick & Raspanti LLP in Philadelphia.

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.*

Mary Kate McDevitt

Marc S. Raspanti

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.