



# Making Transparency Matter: Policy Analysis and Technical Recommendations for the Physician Payments Sunshine Act\*

## Introduction:

Signed into law in 2010 as part of the Affordable Care Act, the Physician Payments Sunshine Act (PPSA) requires pharmaceutical, medical device, and other healthcare product manufacturers to disclose nearly all payments to physicians and teaching hospitals<sup>1</sup>; the Centers for Medicare & Medicaid Services (CMS) annually collects, aggregates, and posts the data on a searchable public website, [Open Payments](#).

PPSA is an extraordinary experiment in transparency: Comprehensive data about physicians' and medical institutions' financial ties to industry are now a matter of public record, allowing us to ask – and finally answer – crucial questions about these ties. PPSA also has the potential to improve efforts to manage conflicts of interest (COI) by academic medical centers (AMCs), professional medical societies (PMAs), medical journals, and public health agencies. Given these high stakes, PPSA must be closely followed, its strengths utilized and its weaknesses addressed.

To this end, Columbia University's Center on Medicine as a Profession (CMAP) investigated the law's strengths and weaknesses in making the data accessible to medical stakeholders, patients, journalists, and other users. We analyzed the law's provisions to assess the extent to which PPSA brings full transparency to ties between healthcare manufacturers and those who purchase and prescribe their products. More, we used multiple methods to explore whether PPSA fosters transparency that is useful and meaningful to physicians and the public: 1) We held focus groups exploring physicians' attitudes and experiences around PPSA and Open Payments; 2) we worked with usability experts to conduct a comprehensive assessment of the Open Payments website; and 3) we organized a series of usability tests with physicians and consumers, observing as they interacted with Open Payments. A full report on the findings is available at <http://imapny.org/wp-content/uploads/2016/12/Open-Payments-Technical-Recommendations.pdf>

Our research informed the following recommendations, which seek to maximize PPSA's impact and help promote its success.

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## I. Transparency Challenges: Closing Gaps in PPSA Reporting

Our study analyzed the law’s provisions to assess the extent to which PPSA brings full transparency to ties between healthcare manufacturers and those who purchase and prescribe their products. To be sure, PPSA brings unprecedented transparency to physician-industry ties. However, critical gaps remain:

### Non-Covered Prescribers:

PPSA’s definition of “covered recipients” is limited to teaching hospitals and physicians (chiropractors and doctors of medicine, osteopathy, dentistry, podiatric medicine, and optometry). Industry gifts and payments to other healthcare providers, such as nurse practitioners and physician assistants, remain undisclosed. This transparency gap belies the rising importance of allied health professionals in driving healthcare prescribing and purchasing; it also leaves unmonitored a growing avenue for industry influence among many patients’ primary healthcare providers.<sup>2-3</sup> **To ensure full transparency, PPSA should be expanded to include industry gifts and payments to all healthcare providers with prescribing privileges.**

### Exempted Gifts and Payments

PPSA also exempts from reporting many common industry gifts and payments, including but not limited to: product samples, payments under \$10 (up to \$100 annually), and patient education items. Yet these are all exchanges of value, with the potential to influence prescribing. Drug samples, for example, are integral to the pharmaceutical industry’s marketing efforts. In 2012 alone, drug companies spent \$5.7 billion (over a fifth of their total marketing budget) distributing samples to prescribers.<sup>4</sup> Research shows that samples encourage “non-rational” prescribing, or the use of newer, more expensive, yet no more effective products.<sup>5</sup> Shielding this costly practice from public scrutiny is unnecessary and unjustified. **PPSA should be expanded to include to all exchanges of value between manufacturers and providers, including product samples.**

Additional exemptions have been proposed, as well. Most recently, the 21st Century Cures Act, newly passed by Congress and likely to receive Presidential approval, initially included a provision – widely supported by industry and PMAs – exempting textbooks, article reprints, and continuing medical education (CME) activities from PPSA reporting. These exchanges are an important area of prescriber-industry interface, and exempting them would have considerably weakened transparency under PPSA. Following objections from Senator Charles Grassley (R-IA), Senator Elizabeth Warren (D-MA), and other lawmakers, this provision was removed from the bill.<sup>6-8</sup> **Future efforts to add exemptions to PPSA should likewise be resisted.**

## II. Making the Open Payments Website More User-Friendly

Our study used multiple methods to explore whether PPSA fosters transparency that is useful and meaningful to physicians and the public: 1) We held focus groups exploring physicians' attitudes and experiences around PPSA and Open Payments; 2) we worked with usability experts to conduct a comprehensive assessment of the Open Payments website; and 3) we organized a series of usability tests, observing 17 physicians and 30 consumers as they interacted with Open Payments. In these tests, the participants were guided to carry out representative tasks (e.g. looking up information about a physician) while "thinking aloud," or verbalizing their thoughts. Physician users also were asked to register for Open Payments.

While physicians and consumers in our study were generally positive about the Open Payments website, our research uncovered several user challenges:

### Public Usability Challenges:

Many physicians and consumers in our usability tests had difficulty locating the site's search functions; understanding the site's terminology and purpose; and searching for and making sense of the data. These barriers compromised users' ability to understand and apply the information that Open Payments makes available. Our [full report](#) offers detailed recommendations for how **CMS should address these common problems.**

### Physician Registration

The accuracy and integrity of Open Payments data depends largely on physicians registering with the system to verify or dispute company reports about them. Our focus groups and usability tests found few physicians had participated in registration, citing lack of awareness or interest.

More, in our usability tests, we guided physicians to attempt registration; most struggled to complete the process, with fewer than half (47%) succeeding. Registration failures most commonly involved difficulty creating or retrieving passwords and misunderstandings around registration requirements. For example, physician taxonomy codes, required for registration, were unfamiliar to most physicians and often confused those with multiple specialties.

Given these difficulties, over three-quarters of our physician users reported being unlikely to recommend that colleagues register. To increase physicians' participation and ensure data integrity, **CMS should expand its efforts to educate physicians about the availability and importance of registration, and it must also work to make the registration process as clear and simple as possible.** Again, our [full report](#) offers detailed recommendations for accomplishing these goals.

### Dispute Resolution

Our project identified additional problems with the process by which physicians can dispute company data they believe to be incorrect. CMS expects that, once a physician initiates a dispute through the Open Payments system, the physician and the company will work together offline to resolve the dispute; the company will then post corrected data to Open Payments. However, physicians and teaching hospitals have reported problems identifying or reaching the appropriate industry contacts for dispute resolution. **CMS should require companies to provide adequate contact information for disputes – this relatively simple requirement would facilitate resolution for all parties.**

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## III. Usefulness Issues – Making the Data Meaningful

### Payment Details

Many participants in our focus groups and usability tests also had unanswered questions about what they saw on Open Payments. Physicians and consumers both wanted more detail in the data. They wanted to know, for example, how many hours of work a consulting payment involved, or what exactly companies had provided for payments identified as “food and beverage” or “education.” Physicians worried that, without such information, patients would be predisposed to making negative judgments about industry payments.

These informational demands create tensions when companies have already established systems to meet current reporting requirements and could incur high costs should requirements be significantly altered. To provide more detail within existing reporting guidelines, **CMS should direct companies to make better use of fields like the optional “Notes” section. However, CMS must also prioritize the needs of the public and be willing demand more from companies, even if additional costs are involved.**

### Payment Categories

The law’s “nature of payment” categories were another common source of confusion among physicians and consumers in our study. As defined by the PPSA legislation, some of these categories are overly broad or nonspecific (“Gift”) or use terms unfamiliar to most consumers (“Honoraria”); others obfuscate more than they enlighten (“Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program”). Overlapping categories pose another problem. For example, a “Grant” as defined by CMS could overlap with “Education,” while “Honoraria” could overlap with “Consulting fee” or “Compensation for services other than consulting.”

Refining or better defining these categories is essential. **CMS should clarify and delineate these categories so that reporting is consistent across companies and the data are understandable and meaningful to those viewing it. If necessary, CMS should propose changes to the legislative text.**

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#### **IV. Raising Awareness – Educating Physicians and the Public about Open Payments and COI**

Raising awareness of Open Payments is also vital to PPSA's success. Yet our project found few consumers or physicians were familiar with the website, and this lack of knowledge correlated with negative or neutral opinions: Before participating in our usability tests, only 7% of consumer subjects and 6% of physician subjects reported having positive opinions of Open Payments. After using the website in our study, however, 65% of physician users and 87% of consumer users expressed positive opinions.

Familiarity with the website thus appears to grow public goodwill. It can also help to promote awareness of Open Payments through word of mouth. After participating in our study, 77% of consumer subjects said they were somewhat or very likely to recommend that a friend or family member use the website. **To broaden awareness of and support for Open Payments, CMS should increase outreach to consumer and physician audiences.**

Lastly, increasing awareness of COI in medicine is crucial to making Open Payments data meaningful and useful. Hundreds of research studies document the impact of company ties on prescribers' attitudes, beliefs, and behaviors.<sup>9-11</sup> Yet our project found that many physicians and consumers were unaware of or uncertain about the evidence. To address this knowledge gap and clarify transparency's value, **the Open Payments website should provide information about the research on COI.** Of particular relevance are new studies using PPSA data to gauge the extent and influence of physician-company exchanges.<sup>12-13</sup> **AMCs, teaching hospitals, PMAs, medical journals, and other stakeholders must also intensify their efforts to educate prescribers and the public about these critical issues.**

## References

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