

HEALTHCARE

THE HYPE OVER TRANSPARENCY: WHAT'S NEW, AND DOES IT WORK?

In this new era of transparency ushered in largely by the Affordable Care Act's Physician Payments Sunshine Act (aka Open Payments), we continue to see increased focus on exactly what "gifts" or monetary payments pharmaceutical and medical device companies are providing to physicians. Indeed, states such as Massachusetts, Vermont, and Minnesota have laws that preceded Open Payments and tracked or prohibited payments and certain transfers of value to physicians and other prescribers, such as nurse practitioners, physician assistants, and pharmacists.¹

Now, two new federal legislative bills seek to expand the reach of the Open Payments law. This, coupled with new or proposed laws by several states and a continuously changing global transparency landscape, often raises two questions: "Is all the effort really worth it and is transparency working?" Companies have invested, and continue to invest, significant sums of money to maintain compliance with global transparency.

FEDERAL AND STATE LEGISLATION

On May 31, 2018, Sens. Chuck Grassley, R-Iowa, Sherrod Brown, D-Ohio, and Richard Blumenthal, D-Conn., introduced a bipartisan bill, S.2891 "Fighting the Opioid Epidemic with Sunshine Act." The bill seeks to expand the tracking and reporting requirements of applicable manufacturers under Open Payments to payments made to other prescribers, such as nurse practitioners, certified nurse anesthetists, certified nurse-midwives, and physician assistants, for promotional talks, consulting, and other interactions.² The senators acknowledge that these additional prescribers write a significant number of prescriptions and expanding the required public disclosures to these individuals could have a positive impact, especially with the increased scrutiny of prescribing in the opioid painkiller space.

A similar bill was introduced in the previous legislative session (October 2017) by Grassley and Blumenthal as part of the 21st Century Cures Act but was defeated. In contrast, recent indications are that S.2891 will be heard as early as the week of September 17 as part of the larger package of bills intended to address the nation's opioid crisis.³

1. This list is not exhaustive, and each state or region should be consulted to determine whom they recognize as "covered recipients" under their jurisdiction.

2. Congress.gov, "S.2891 - Fighting the Opioid Epidemic with Sunshine Act of 2018," May 22, 2018, <https://nav.gt/2OBnB8w>.

3. Sullivan, Thomas, "Senate Expected to Vote on Opioid Legislation Includes Expansion of Open Payments to NPs and PAs," Policy and Medicine, Sept. 10, 2018, <https://www.policyandmedicine.com/2018/09/senate-expected-to-vote-on-opioid-legislation.html>.



On June 7, 2018, Sen. Claire McCaskill, D-Mo., released the “Patient Advocacy Transparency Act of 2018,” which seeks to expand Open Payments reporting to include television programs, websites, payments to patient advocacy organizations, professional societies, clinical trial organizations, and continuing medical education providers.⁴ The bill, which would become effective in 2023, would amend the definition of “covered recipient” to include a broad array of foundations, clinical trial organizations, and education providers that receive financial support and grants from pharmaceutical and medical device manufacturers.

Analysts have been quick to point out, however, that the bill may inherently present constitutional privacy issues in that many of the implicated organizations receive no Medicare or Medicaid funding or reimbursement for patient care and may run afoul of the Supreme Court’s clear case law that does not require reporting of nonprofit revenue.

It is also worth noting that, if the Open Payments law does expand to include, for example, additional prescribers, it might result in less state-by-state reporting due to the Act’s federal preemption clause.⁵ Currently, Open Payments requires reporting for only physicians and teaching hospitals.⁶ For states that include a wider array of covered recipients (e.g., advanced practice nurses, physician assistants, patient organizations) a state report is still required even though that report can omit payments made to physicians already disclosed under Open Payments. If the scope of the Open Payments definition and reporting of covered recipients were to expand under these new bills, however, state reporting of payments to some of those additional recipients may be superseded as well.

On the state front, as previously reported,⁷ a New Jersey law went into effect Jan. 15, 2018, placing a \$10,000 aggregate annual limit on the payments New Jersey prescribers could accept across all pharmaceutical companies for services such as speaking and consulting. It also limited the value of meals offered at promotional and pharma-sponsored educational activities to \$15 per person. Interestingly, the law requires physicians to mostly “self-police” to assure for themselves that they are not accepting payments or meals in excess of the statutory limits.

Now, however, the \$15 per person meal cap for prescribers attending pharma-sponsored educational events is currently under reconsideration at the urging of the state’s attorney general.⁸ A new proposed rule, filed Aug. 6 and open for public comment until Oct. 5, is reportedly in response to allegations that the \$15 per person meal cap is “unrealistic” and was stifling prescriber learning and attendance at educational gatherings.⁹ Changes proposed include eliminating the meal cap for educational events provided through an event organizer — even if supported by a pharma manufacturer — but retaining a meal cap of \$15 (breakfast and lunch) with an increased cap of \$30 for dinner at “promotional activities.”

The term “prescriber” would also be more clearly defined to be those holding an active New Jersey license who practice or have patients in the state, even if their office location is outside of it. Unlike the Sunshine Act, the New Jersey law is already applicable to a broader group of prescribers, including physician assistants and advanced practice nurses.

Additionally, it is worth noting that Minnesota, which has the honor of being the first state to institute prohibitions and limits on gifts to practitioners from pharmaceutical companies in 1993, has recently cited enforcement of those laws in litigation against opioid manufacturer Insys Therapeutics, Inc.¹⁰ Attorney General Lori Swanson asserts that Insys promoted off-label use of its drug fentanyl and violated the Minnesota gift ban by calling payments made to physicians “speaker fees” when they really represented money to “incentivize” them to prescribe. While historically quiet on the gift ban enforcement front, Minnesota may signal an increasing interest in how these types of transparency laws can supplement the state’s arsenal as public interest causes such as the opioid crisis take center stage.

UPDATES ON INTERNATIONAL LEGISLATION

Belgium: While initially developed as a voluntary transparency initiative, Belgium codified its own “Sunshine Act” on Dec. 18, 2016, which was then executed by Royal Decree on June 14, 2017.¹¹ The law requires pharmaceutical and medical device companies to annually report payments and benefits provided directly and indirectly to healthcare professionals (HCPs),

4. Senate.gov, accessed Sept 10, 2018: <https://www.hsgac.senate.gov/imo/media/doc/Patient%20Advocacy%20Transparency%20Act.pdf>.

5. 42 U.S.C. 1320a-7h (d)(3)(A) and (B) whereby payments and transfers of value reported under Open Payments will preempt reporting of that same information if requested by any state or subdivision of a state.

6. See 42 U.S.C.1320a-7h where “physician” is defined to include actively licensed doctors of medicine or osteopathy, podiatrists, doctors of dental surgery, chiropractors, and optometrists.

7. Navigant Consulting, Inc., “Physician Feed Thyself: New Jersey’s Restrictions on Pharmaceutical Payments,” Jan. 15, 2018, <https://www.navigant.com/-/media/www/site/insights/life-sciences/2018/physician-feed-thyself.pdf>.

8. The full text of the proposed amendments to NJAC 13:45J may be found at <https://www.njconsumeraffairs.gov/Proposals/Pages/dca2-08062018-proposal.aspx>.

9. Sullivan, Thomas, “New Jersey: State Attorney General Seeks to Revise ‘Gift’ Ban,” Policy and Medicine, July 30, 2018, <https://www.policymed.com/2018/07/new-jersey-state-attorney-general-seeks-to-revise-gift-ban.html>.

10. Minnesota Office of the Attorney General, Press Release, May 30, 2018, https://www.ag.state.mn.us/Office/PressRelease/20180530_Insys.asp.

11. Information about the act and the history may be found at www.betransparent.be.

healthcare organizations, and patient organizations. HCPs include those who can prescribe, as well as use or administer, medicines and medical devices. This may include, but is not limited to, veterinarians, dentists, physicians, nurses, paramedics, and hospital administrators.

The first publication under the Belgium Sunshine Act became available on June 26, 2018, on their platform, www.betransparent.be, and covers the benefits and payments that occurred in 2017. It is currently searchable by specific company names, or by the name of the particular HCP or organization.

South Korea: The South Korean “Sunshine Act” was passed in early 2017, but tracking and data collection became mandatory on Jan. 31, 2018.¹² While companies are required to create and have available if requested an annual aggregated report within three months after year-end on expenditures with pharmacists, herbalists, medical personnel (including physicians, dentists, midwives, and nurses), and medical institution founders (e.g., directors of medical facilities), there is currently no requirement to post the report in a public forum. Those items that must be tracked include samples, clinical trial funding, academic conference sponsorships, food and beverage at presentations, and discounts on drug or medical devices.

Canada: On Dec. 12, 2017, the Ontario legislature passed the Health Sector Payment Transparency Act. Implementing draft regulations¹³ were published on Feb. 21, 2018, with a comment period to April 6 and would require pharmaceutical and medical device companies to disclose payments, meals, and other transfers of value to healthcare providers of more than \$10. Initial reports were to be made by June 30, 2020, for a period from Jan. 1-Dec. 31, 2019. As of April, this reporting has been delayed as the program infrastructure is being completed. It is believed the regulations will be readdressed in Fall 2018.¹⁴ It is also believed that British Columbia may be considering enacting its own transparency requirements like those for Ontario, but no formal action has yet been taken.¹⁵

Colombia: On July 5, 2018, Resolution n. 2881 became law and requires pharmaceutical and medical device companies to begin disclosure of their payments and in-kind transfers of value to physicians, institutions, and patient organizations. The initial disclosure would be due March 31, 2020, for the period of July 1-Dec. 31, 2019. Reportable payments include meals, clinical research, contracted services fees, travel, lodging, and registrations.¹⁶

Brazil: On Jan. 12, 2018, the Brazilian state of Minas Gerais passed Law No. 22.921, which represents its second transparency initiative. This new law appears to expand prior reporting requirements to now include company sponsorships at scientific events. The original law, Law No. 22.440 enacted on Dec. 21, 2016, mandates all organizations in medicine, orthoses, prostheses, equipment, and implants to annually report (by Jan. 31 of the following year) any type of donation or benefit, whether directly or through third parties, such as gifts, tickets, event registration, lodging, financing of research stages, consulting, and fees for lectures that are given to licensed health professionals. The deadline for reporting of this new sponsorship information will be Jan. 31, 2019. This allows for adaptation to Declara SUS, the state electronic reporting system established under Law No. 22.440, to accommodate the new report.¹⁷

VOLUNTARY TRANSPARENCY INITIATIVE

In another transparency trend, AstraZeneca announced in June that it would begin reporting payment to all physicians worldwide, even in countries where that reporting is not required.¹⁸ Headquartered in Cambridge, UK, the company has affiliates in over 100 countries. While currently reporting pursuant to laws or conduct codes in Europe, U.S., Japan, Australia, Philippines, and Indonesia, the company hopes to extend its reporting to 11 additional countries across Latin America, Asia Pacific, North Africa, and the Middle East by the end of 2019, which will then encompass over 90% of its total payments worldwide.

12. Sullivan, Thomas. “Sunshine Act Takes Effect in South Korea,” Policy and Medicine, Aug. 14, 2017, <https://www.policymed.com/2017/08/sunshine-act-takes-effect-in-south-korea.html>.

13. Ontario Regulatory Registry, <https://www.ontariocanada.com/registry/view.do?postingId=26846&language=en>.

14. Trimble, Ian, and Zborovski, Sara, “Ontario delays Implementation of regulations under the Health Sector Payment Transparency Act,” Pharma in Brief, April 11, 2018, <https://www.pharmainbrief.com/2018/04/ontario-delays-implementation-of-regulations-under-the-health-sector-payment-transparency-act/>.

15. Sullivan, Thomas, “Is British Columbia Set to Follow Ontario in Canadian Pharmaceutical Transparency?,” Policy and Medicine, July 4, 2018, <https://www.policymed.com/2018/07/is-british-columbia-set-to-follow-ontario-in-canadian-pharmaceutical-transparency.html>.

16. Arbini, Michael, “On July 5th, 2018, the Ministry of Health and Social Protection of Columbia passed Resolution n. 2881 (the “Law”),” Polaris Insights, July 16, 2018, <http://polarismanagement.com/legislative-update-colombia/>.

17. Saporito, Giuseppe, and Arbini, Michael, “Transparency Update: Brazil,” Polaris Insights, March 21, 2018, <http://polarismanagement.com/transparency-update-brazil/>.

18. Ralph, Alex, “AstraZeneca to lift lid on payments to doctors,” The Times, June 4, 2018, <https://www.thetimes.co.uk/article/astrazeneca-ready-to-lift-the-lid-on-its-payments-to-doctors-vnd9723t5>; Sullivan, Thomas, “AstraZeneca to Reveal HCP Payments Worldwide,” Policy and Medicine, June 12, 2018, <https://www.policymed.com/2018/06/astrazeneca-to-reveal-doctor-payments-worldwide.html>.

TRENDS IN OPEN PAYMENTS DATA

If one looks at the huge volume of data now available in the public domain from U.S. Open Payments reporting, it is certainly clear that the activities of pharmaceutical and medical device companies and their day-to-day interactions with physicians and teaching hospitals are more “transparent.” But has that transparency had any measurable impact? Are companies complying? And is anyone paying attention to the collected data?

In 2016, we reported that the U.S. Department of Health and Human Services’ (HHS)

Office of Inspector General (OIG) had included an item on its annual work plan for “Review of Financial Interests Reported Under the Open Payments Program.”¹⁹ OIG’s report from that review was published in August 2018, and looked at the data published for the full 2015 year.²⁰ Surprisingly, the OIG found that of the 11.9 million records published, less than 1% were actually missing data elements. Errors in the data were noted, however, including things like mismatching of drug and device names, inclusion of payments from other years, and national drug codes (NDCs) not able to be found.

The report emphasizes the need for data accuracy because “transparency protects patients by revealing the nature and extent of these relationships...” with physicians and teaching hospitals, “...and has the potential to discourage

the development of inappropriate relationships.” The report recommended strengthening of the Centers for Medicare & Medicaid Services (CMS) validation process, requiring more specific device name elements, ensuring all reports contain all data, and ensuring better reporting and validation of NDC numbers. The OIG specifically noted that CMS had yet to conduct any Open Payments audits of companies/GPOs but that it is “compiling a list of noncompliant manufacturers and GPOs for further investigation.”²¹

We now have four full years (2014-2017) of Open Payments data publicly available, and analysis of the data being reported shows a fairly consistent pattern. In 2017, total spend reported was \$8.4 billion, with \$4.66 billion being research and development spend, \$2.82 billion general spend, and \$0.93 billion representing ownership interests.²² A total of 11.54 million records were published representing data submitted by 1,525 manufacturers and group purchasing organizations. This represented a slight decrease from the data posted for 2016, which totaled 12.4 million records across 1,600 companies, with total spend of \$8.81 billion.

Looking at the “nature of payment” categories on the 2017 General Payments report, royalties were again the largest category, followed by compensation for services other than consulting, and then consulting fees.

19. Navigant Consulting, “OIG’s Work Plan Priorities Focus On Review Of Open Payments Data,” 2016, https://www.navigant.com/-/media/www/site/insights/disputes-investigations/2017/dflt_oigworkplanopenpayments_tl_1216.pdf.

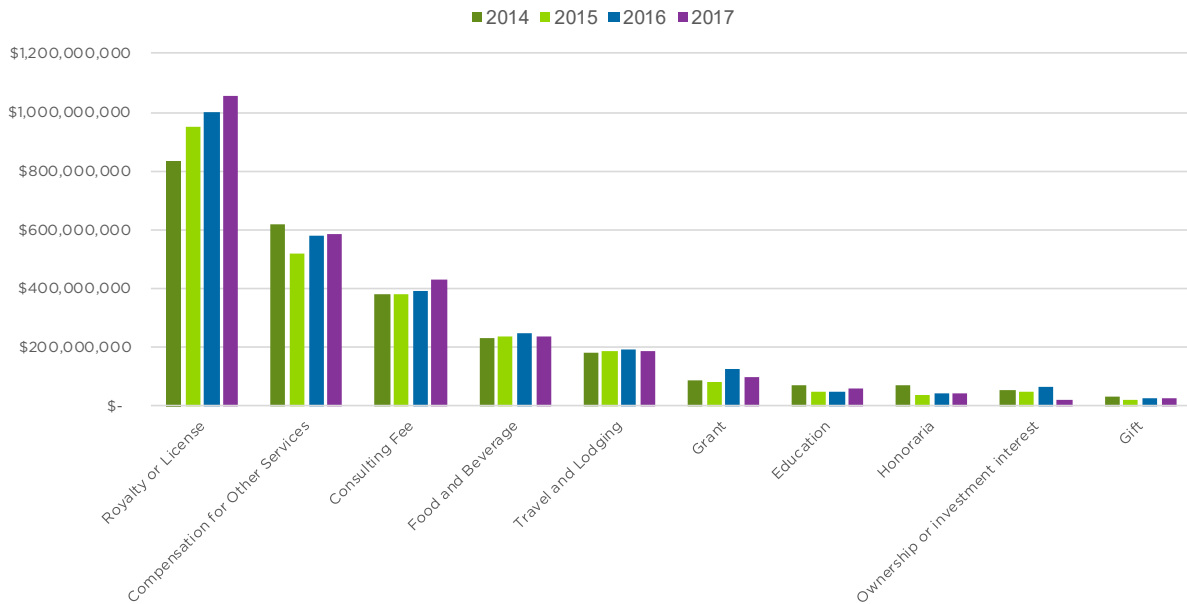
20. Murrin, Suzanne, Deputy Inspector General, “Open Payments Data: Review of Accuracy, Precision, and Consistency in Reporting,” August 2018, <https://oig.hhs.gov/oei/reports/oei-03-15-00220.pdf>.

21. The full report can be found at <http://oig.hhs.gov/oei/reports/oei-03-15-00220.asp>

22. CMS website, “The Facts About Open Payments Data,” <https://openpaymentsdata.cms.gov/summary>.

OPEN PAYMENTS

Top 10 Natures of Payment by Year

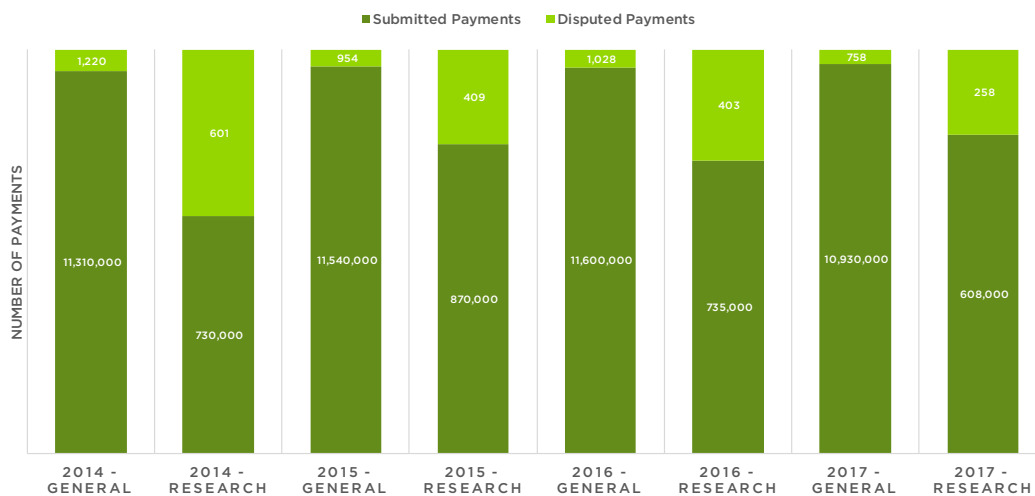


Comparison to the categories in 2016 shows a decrease in 2017 payments related to food and beverage, travel and lodging, grants, honoraria, and ownership interests. Grants took a significant 19.84% decrease, while education spend increased by 11.87%.²³

Finally, it is interesting to note that, in spite of a total of 11.54 million records reported in 2017, the number of physicians and teaching hospitals that have accessed the company-submitted data during the Open Payments review period and officially “disputed” certain entries about them, is exceedingly low. That trend has been constant for all four full years of data reporting.²⁴

OPEN PAYMENTS

Submitted and Disputed Payments



23. Sullivan, Thomas, “Open Payments Data 2017: Significant Drop in Number of Payments,” Policy and Medicine, July 3, 2018, <https://www.policymed.com/2018/07/open-payments-data-2017-shows-significant-drop-in-number-of-payments.html>.

24. CMS website, “The Facts About Open Payments Data,” <https://openpaymentsdata.cms.gov/summary>.

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About Navigant

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CONCLUSION

Whether it is having any impact on how patients feel about their physicians and providers may be unclear, but transparency in manufacturer payments to healthcare providers and institutions appears here to stay. Indeed, the global landscape is seeing a barrage of new transparency initiatives, and each region that includes a public display of data provides a new way the public and investigators alike can gain new insights into the relationships between pharmaceutical and medical device companies, and those professionals who use and prescribe their products. Companies should likewise take the opportunity to use the public data and their internal compliance functions to conduct ongoing benchmarking, monitoring for outliers, and self-assessment to comply with the ever-changing transparency environment.

Navigant Consulting, Inc.'s team of life sciences professionals have deep transparency expertise, having created a transparency center of excellence in order to continuously stay up to date on the changing laws and regulations for U.S. and global transparency. Navigant has prepared and submitted Open Payments reports, written transparency policies and procedures, validated the accuracy and completeness of aggregate spend reporting, performed open payments audits, and compiled and submitted error and correction reports. We have also partnered with transparency software providers prior to implementation to perform requirements gathering, data inventory, and system and process mapping. In addition, Navigant has reviewed payments and control documents (e.g., receipts, invoices, sign-in sheets) for healthcare professionals while serving as an Independent Review Organization. The team includes former chief compliance officers, industry compliance veterans, attorneys/prior in-house counsel, CPAs, physicians, certified privacy professionals, and data analysts.

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