



LIFE SCIENCES | DISPUTES, REGULATORY, COMPLIANCE
AND INVESTIGATIONS

NAVIGANT'S TRANSPARENCY CENTER OF EXCELLENCE

Transparency Obligations and Reporting That Improves Decision Making

There is a growing expectation worldwide for transparency into how the life sciences industry conducts business with healthcare providers. In recent years, a major focus for public interest groups, legislators, and now enforcement bodies, has been to “shine a light” on the financial relationships between these companies and doctors. While this trend started in the United States, it has spread globally, with each geographic region putting its own requirements on who is considered a covered recipient and what is reportable. This has left many companies confused as they try to decipher the multitude of evolving rules.

In the U.S., the Open Payments program (also known as the Sunshine Act) requires pharmaceutical and medical device manufacturers to collect and report to the government most payments made to physicians and teaching hospitals. Beginning in 2022, this list will expand to include physician assistants, nurse practitioners, clinical nurse specialists, registered nurse anesthetists, and certified nurse midwives.

Since 2013, manufacturers have been responsible for submitting detailed spending information at the recipient level annually to the Centers for Medicare & Medicaid Services (CMS). This data includes not only direct payments for contracted services, but also “in-kind” transfers of value, such as food and beverages, and is published in a publicly accessible, searchable database.

Additionally, many states and even individual cities have transparency requirements, representative licensing, and/or limitations on how companies may interact with prescribers within that locality that go above and beyond the Sunshine Act. In 2017, for example, Chicago implemented regulations for annual sales representative licensing, including mandated continuing education, and reporting of marketing activities with health care professionals related to Schedule II drugs. Also in 2017, Nevada enacted a law targeting drug price transparency and reporting of company sales representatives' activities. New Jersey also joined the list of states in January 2018 with rules that limit contracting with New Jersey prescribers and cap most meals at just \$15. All three of these new initiatives apply to pharmaceutical companies, but if the past is a predictor of the future, medical device companies can expect these changes to eventually affect them.

The complexity of complying with transparency requirements multiplies when companies start looking at the growing list of related international laws, regulations, and codes. Tracking and reporting spend to doctors practicing in France, Belgium, Denmark, Portugal, South Korea, Indonesia, and Japan (just to name a few countries with such requirements) necessitates a coordinated and organized effort across the company to ensure compliance.

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About Navigant

Navigant Consulting, Inc. (NYSE: NCI) is a specialized, global professional services firm that helps clients take control of their future. Navigant's professionals apply deep industry knowledge, substantive technical expertise, and an enterprising approach to help clients build, manage, and/or protect their business interests. With a focus on markets and clients facing transformational change and significant regulatory or legal pressures, the firm primarily serves clients in the healthcare, energy, and financial services industries. Across a range of advisory, consulting, outsourcing, and technology/analytics services, Navigant's practitioners bring sharp insight that pinpoints opportunities and delivers powerful results. More information about Navigant can be found at navigant.com.

The new and constantly changing rules both in the U.S. and internationally require the support of individuals who not only track and monitor the evolving transparency landscape, but who also have a deep understanding of the industry and operational compliance. As regulatory bodies look closely into companies' financial relationships with healthcare decision-makers, it is important for companies to get this data right and proactively understand how they are spending their money.

Navigant can help. Our experienced life sciences professionals regularly advise pharmaceutical and medical device companies on all aspects of transparency reporting. From working with companies to establish first-time transparency reporting programs, to monitoring and auditing the data that is made public, our team works closely with life sciences companies and their counsel to offer comprehensive solutions that comply with reporting requirements and minimize risks and safeguard reputations. We provide custom technology solutions and expert insights to help companies manage transparency reporting and make more informed spending decisions.

WHO WE ARE

Our professionals have a deep and highly focused subject matter expertise in transparency reporting and compliance requirements specific to the life sciences industry. Our team includes former chief compliance officers, physicians, registered nurses, attorneys, CPAs, project managers, and information technology professionals who specialize in software development and advanced data analytics. Each team member understands the complexities of transparency reporting and compliance and its many nuances, encompassing U.S. regulations, individual state and city regulations, and global rules.

We are thought leaders and industry experts who stay on top of new developments affecting transparency reporting and compliance as they emerge, and keep our clients apprised of key issues.

HOW WE HELP

We help companies of all sizes through the full spectrum of transparency reporting:

- We advise companies to help them develop, enact, and operationalize structured programs for first-time transparency reporting in the U.S. and abroad.
- We help companies craft robust global policies and procedures to guide their transparency reporting programs.
- We audit and monitor transparency data prior to submission to help identify potential trends and assist with remediation efforts to correct problematic transactions before the information is made public.
- We serve as interim management and/or serve as outsource providers of transparency programs.
- We guide and support companies through government inquiries, investigations, or litigation associated with transparency reporting and spend management.

We look comprehensively at our clients' transparency reporting process, data, and controls – helping to ensure the information is accurate and complete, and giving companies insight into how they are allocating their resources. This analysis, as well as our detailed industry benchmarking and vast industry experience, helps companies make better decisions with the information they have at their fingertips.