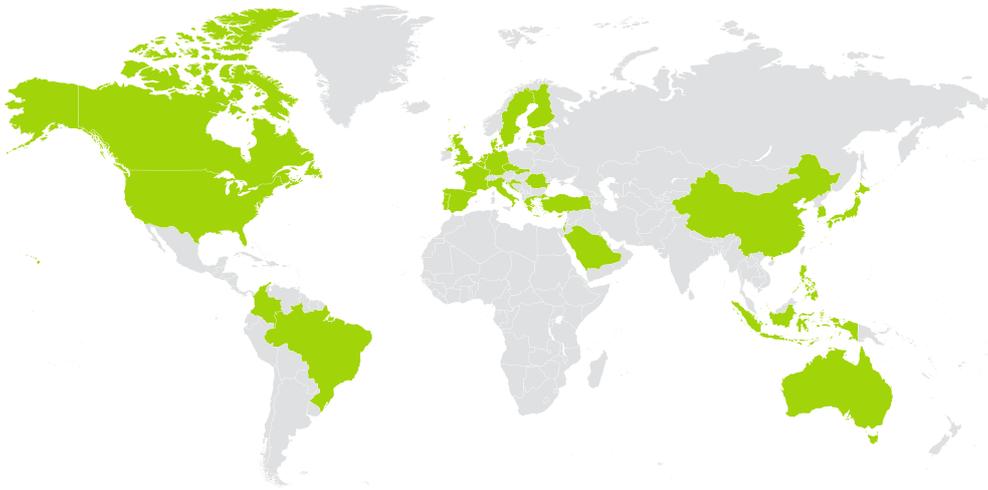


Guidehouse's Transparency Center of Excellence

Transparency Obligations and Reporting That Improves Decision Making



- **30** standards around the globe
- **32** applicable countries
- **5** continents
- **11** industry codes
- **19** national laws

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.

In Europe, some countries such as France have national laws that require life science companies to collect and report transfer

of values to healthcare professions. Other jurisdictions have codes of conduct by industry associations on regional and national level such as EFPIA for Europe and ABPI for the UK, that regulate member’s reporting obligations.

Other markets have developed their own standards over the past years, for example in 2018 Colombia passed a law that requires pharmaceutical and medical device manufacturers to report transfer of values to healthcare professions from the first quarter of 2020. South Korea on the other hand has been reporting the same since 2019.

The complexity of complying with transparency requirements multiplies when companies start looking at the growing list of related international laws, regulations, and codes, in addition to other regulations such as the European Union’s General Data Protection Regulation (GDPR) where consent is sought before reporting. 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.

The new and constantly changing rules both in the U.S. and internationally require the support of dedicated 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.

Guidehouse 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, qualified accountants, 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 country regulations, industry codes and standards around the globe.

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 internationally.
- 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.

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About Guidehouse

Guidehouse is a leading global provider of consulting services to the public and commercial markets with broad capabilities in management, technology, and risk consulting. We help clients address their toughest challenges with a focus on markets and clients facing transformational change, technology-driven innovation and significant regulatory pressure. Across a range of advisory, consulting, outsourcing, and technology/analytics services, we help clients create scalable, innovative solutions that prepare them for future growth and success. Headquartered in Washington DC, the company has more than 7,000 professionals in more than 50 locations. Guidehouse is a Veritas Capital portfolio company, led by seasoned professionals with proven and diverse expertise in traditional and emerging technologies, markets, and agenda-setting issues driving national and global economies. For more information, please visit: www.guidehouse.com.

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