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# NAVIGATING THE CHALLENGES OF MULTI-JURISDICTIONAL REPORTING

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# INTRODUCTION

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Transparency is absolutely essential to the life sciences industry—as much in selling drugs and therapies as in developing and manufacturing them. Tracking spend and relationships with customers is not simply a matter of avoiding fines or ticking regulatory boxes—it’s about building a trustworthy brand and ensuring fair play in the marketplace.

So, what exactly is **spend transparency**? In a nutshell, it is the process of cataloging and reporting on the relationships and interactions of value between pharmaceutical companies and healthcare professionals.

Spend transparency underscores your company’s commitment to ethical practices and public trust — and following these regulations is table stakes for most pharmaceutical companies to operate. But achieving it is no small feat. The regulatory terrain of spend transparency is notoriously complex, with differing requirements across jurisdictions posing a significant challenge.

The stakes are high. The risk of non-compliance extends beyond legal penalties to potential reputational damage that could profoundly damage your brand's value or even cost millions.

This guide will give an overview of these complexities and a peek at the intricate variations of regulations—especially across the U.S.. Through careful planning, strategic implementation, technology, and partnership with experts, companies can use these best practices to achieve transparency across all the jurisdictions they serve.

# NAVIGATING A MAZE OF COMPLEX REGULATIONS

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As you navigate the rocky waters of spend transparency, you'll find some general hurdles that can complicate compliance efforts. Here are some roadblocks to watch out for:

## **Regulatory Variability**

The landscape of regulatory requirements is anything but uniform. Companies must contend with differing definitions of what constitutes a reportable expense, varied reporting thresholds, and a multitude of submission formats. This variability can lead to confusion and increase non-compliance risk, especially for companies operating across multiple jurisdictions

## **Data Collection and Management**

Collecting and managing data from diverse sources in various formats is a significant challenge. With information streaming in from clinical trials, marketing and sales efforts, and numerous other interactions with healthcare professionals and organizations, the task of compiling and standardizing this data can be daunting. The variance in data formats and sources necessitates robust systems capable of efficiently handling this complexity.

## **Timing and Deadlines**

Another major challenge is managing the myriad of reporting deadlines that differ from one jurisdiction to another. Keeping track of these deadlines, each with its own set of requirements, and ensuring timely submissions, is a complex logistical task that demands meticulous planning and organization.

# UNDERSTANDING THE GLOBAL REGULATORY LANDSCAPE

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Let's start with the regulatory variability. The pharmaceutical industry faces an astonishingly diverse regulatory environment when it comes to spend transparency. This complexity is made even more complicated by the variance in legislation across different jurisdictions, not just internationally but within the United States itself.

Note, the information we've provided below is merely to give you a sense of the scope of differences and complexities in jurisdictional requirements. It is in no sense meant to be complete or exhaustive. Staying up to date on regulations is best accomplished through the use of software or the assistance of experts.

This is something RLDatix can help with, through the use of our General Spend Transparency (GST) platform — part of our Compliance Suite of products and services, which help you monitor and audit engagements and transfers of value via comprehensive aggregation technology, dashboards, and analytics.

# KEY REGULATORY JURISDICTIONS

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## **United States Federal Requirements:**

At the federal level, the Physician Payments Sunshine Act mandates comprehensive reporting of payments and other transfers of value to healthcare professionals and teaching hospitals. This act serves as the foundational transparency requirement for pharmaceutical companies operating in the U.S. and is table stakes for payers like the Centers for Medicare & Medicaid Services (CMS).

Here's a brief overview of the Physician Payments Sunshine Act:

### **Scope:**

Applicable to manufacturers of drugs, devices, biologicals, and medical supplies covered by Medicare, Medicaid, or the Children's Health Insurance Program (CHIP). The Act requires reporting of payments or other transfers of value to all physicians and teaching hospitals.

### **Types of Payments to Report:**

- Consulting fees, speaking fees, and other compensation.
- Gifts, entertainment, food, and travel.
- Research funding and grants.
- Investment interests held by physicians in the reporting entity.

Certain types of transfers of value are exempt from reporting, such as educational materials that directly benefit patients. There is also a de minimis threshold for reporting small payments, updated annually, below which payments may not need to be reported unless they cumulatively exceed a certain amount over the calendar year.

# KEY REGULATORY JURISDICTIONS

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## **Reporting Requirements:**

- Detailed information about the nature and amount of each payment or other transfer of value.
- Identification of the recipients, including their names and business addresses.
- Submission of reports to the CMS on an annual basis.

## **Public Disclosure:**

CMS publishes all reported data on the Open Payments website, making it accessible to the public. The goal is to inform patients about the financial relationships their healthcare providers have with pharmaceutical companies. Physicians and teaching hospitals can review and dispute reported data before it is made public and manufacturers are required to work with the disputing party to resolve disagreements and ensure accuracy.

## **Penalties for Non-Compliance:**

- Failure to report required information can result in significant financial penalties.
- Penalties are tiered based on the nature of the violation, ranging from unintentional to knowing failures to report or comply.



# UNITED STATES

## STATE-LEVEL REQUIREMENTS

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The landscape at the state level is where things start to get messy, with a complex picture of regulations aimed at enhancing spend transparency within the pharmaceutical industry. As of now, a growing number of states have started to implement laws that require pharmaceutical companies to report on their spending activities related to travel, research, gifts, samples, speaking engagements, meals, entertainment, education, and other purposes.

Each state has its own unique set of requirements, often involving detailed reporting through state-run online portals, with some making this information publicly available. In addition to federal requirements, many states have its own unique set of requirements, with reporting done via state-run online portals. In many cases, this reporting is also made publicly available.

States also have different filing deadlines, ranging from March 1st in Nevada to July 1st in Massachusetts. In some cases even counties (Dade County in Florida) or cities (Chicago) get into the action.

*Here are some examples of different regulations:*

- California has been at the forefront of spend transparency, requiring companies to report payments to healthcare professionals, as well as marketing and advertising expenditures for each drug. California's Sherman Food, Drug, and Cosmetic Law also requires disclosure of lobbying activities and contributions to patient advocacy groups. Along with Connecticut, California requires that pharmaceutical companies adopt a compliance program in alignment with the PhRMA Code on Interactions with Health Care Professionals.
- Connecticut in 2023 passed new legislation bolstering its existing prescription drug reporting and updates to existing manufacturer transparency reporting, now requiring companies to report on the aggregate number of contacts that sales representative have with prescribing practitioners and pharmacists, samples and gifts, and others, following the PhRMA Code.
- Maine, similar to its approach in drug price transparency, requires pharmaceutical companies to report detailed financial information that includes profits and expenditures across the supply chain, aiming to provide a comprehensive picture of where money is spent in relation to the drugs being sold.

# UNITED STATES

## STATE-LEVEL REQUIREMENTS

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- Massachusetts mandates pharmaceutical companies to report research and development costs, including clinical trial expenses, for drugs that have a significant impact on state healthcare expenditures.
- Minnesota and Vermont require detailed reporting of all payments to healthcare providers, including speaking fees, consultancy payments, gifts, and other forms of compensation, to ensure transparency around potential conflicts of interest.
- Nevada has similar requirements to California and Connecticut, but also requires a certified audit annually.
- New Jersey requires reporting around HCP engagement, regulating the receipt and acceptance by prescribers of anything of value from pharmaceutical manufacturers to ensure that such relationships do not interfere with prescribers' independent professional judgment.
- Oregon not only requires drug price transparency but also demands that pharmaceutical companies report on marketing and advertising expenses, including the allocation of these expenses towards healthcare professionals versus direct-to-consumer advertising.
- Washington DC requires special worksheets reporting on gift expenses, advertising expenses, and aggregate costs.

Legislation is also pending in several states, indicating a growing interest in expanding spend transparency requirements to ensure that the financial practices of pharmaceutical companies are made transparent to the public, healthcare providers, and policymakers.

Furthermore, amendments to existing laws and the establishment of oversight boards in states like California reflect the evolving nature of spend transparency legislation, emphasizing the need for pharmaceutical companies to remain vigilant and adaptable.

It's important to note that spend transparency also extends beyond pharmaceutical companies to include insurers, pharmacy benefit managers (PBMs), and other actors in the healthcare supply chain, requiring a comprehensive approach to transparency that encompasses the entire ecosystem of healthcare financing and drug distribution.



# INTERNATIONAL LANDSCAPE

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Many international entities also have reporting requirements—similar to the Sunshine Act — that you will need to be familiar with if you are selling overseas. Below are some highlights to consider, but it is important to consult with any jurisdictions in which you do business to ascertain what their requirements are.

## Code Based Requirements:

- **European Union:** The EFPIA Disclosure Code guides transparency efforts, with variations in its implementation across member states reflecting the diverse regulatory environment within the EU.
- **Medicines for Europe:** Representing the generic, biosimilar, and value-added medicines industries in Europe, Medicines for Europe advocates for transparency in generic drug pricing and the costs associated with bringing biosimilars to market. While not directly imposing reporting requirements, the association supports initiatives that enhance the understanding of medicine pricing and access issues.
- **MedTech Europe:** As the European trade association representing the medical technology industries, MedTech Europe has a strict Code of Ethical Business Practice that its members must follow. This code includes detailed provisions for transparency in all interactions with healthcare professionals and organizations, including the disclosure of consultancy fees, sponsorship, and educational grants. MedTech Europe's code is a testament to the industry's commitment to ethical practices and transparency, particularly in the rapidly evolving medical technology field.
- **Mecomed:** Serving as the trade association for the medical devices and diagnostic industry in the Middle East and North Africa, Mecomed's guidelines encourage members to report any transfers of value to healthcare professionals and healthcare organizations, aiming to foster a culture of integrity and ethical business practices in the region.

# INTERNATIONAL LANDSCAPE

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## Code Based Requirements:

- **Canada:** The Pharmaceutical Advertising Advisory Board (PAAB) sets the transparency guidelines in Canada, with provincial differences adding layers to the compliance requirements, similar to that of U.S. states. Additionally, the province of Ontario passed its extensive Health Sector Payment Transparency Act in 2017.
- **Japan:** The Japan Pharmaceutical Manufacturers Association (JPMA) has established transparency guidelines, emphasizing the global reach of transparency initiatives.
- **United Kingdom:** The UK has its transparency regulations governed by the ABPI (Association of the British Pharmaceutical Industry) Code of Practice. The Code requires pharmaceutical companies to report payments made to healthcare professionals, including consultancy fees, sponsorship, and expenses related to attendance at meetings. Additionally, the UK has specific regulations for disclosure of clinical trial data and research investments, emphasizing the importance of transparency in research and development expenditures.
- **France:** In France, the "Loi Bertrand," or the French Sunshine Act, requires pharmaceutical companies to make public all agreements with healthcare professionals and the benefits provided to them. This includes consultancy fees, research funding, and sponsorship for attending scientific events. France's approach is one of the most stringent in Europe, with the transparency database publicly accessible, allowing for scrutiny of the financial relationships between the pharmaceutical sector and healthcare providers.

# DIFFERENCES, SIMILARITIES, AND ENFORCEMENT

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While there are many through-lines in these spend transparency reports — like the types of expenses to report and the necessity for data accuracy — significant nuances do exist. These include different thresholds for reporting, specific expense categories, and the level of public disclosure. Navigating these disparities is important.

Across jurisdictions, regulatory bodies such as the CMS in the USA or the EFPIA in Europe play critical roles in enforcing spend transparency. Penalties for non-compliance can be severe, and underscore the importance of diligent compliance efforts and the potential reputational and financial risks associated with failures in transparency.

By understanding these diverse requirements and adopting a strategic approach to compliance, companies can navigate these challenges effectively, leveraging transparency to build trust and ensure fairness in the marketplace.

# BEST PRACTICES FOR ENSURING COMPLIANCE

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In addition to the differing regulations, jurisdictions often have different requirements for timing and data management. Given these challenges, adopting best practices is crucial for ensuring compliance with all existing and emerging legislation.

Best practices include:

## **Centralized Data Management**

Create a centralized system for data collection and management. This system can streamline the process of gathering, standardizing, and reporting data, reducing the risk of errors and omissions. A centralized approach not only simplifies internal processes but also aids in maintaining a consistent record for auditing and compliance verification purposes.

## **Regular Training and Education**

Keeping compliance teams updated on regulatory changes and best practices is essential. Regular training ensures that everyone involved in the compliance process is aware of the latest requirements and understands the company's obligations under the law. Continuous education serves as a proactive measure against compliance risks.

## **Engaging with Experts**

Working with regulatory experts with expertise in each jurisdiction can provide invaluable insights into specific regulatory nuances. These experts can offer guidance on how to navigate local regulations effectively and ensure compliance strategies are robust and tailored to the unique demands of each jurisdiction.

## **Staying Abreast of Regulatory Updates**

Staying informed about regulatory updates is critical. Companies should implement strategies for monitoring changes in transparency reporting requirements across all jurisdictions they operate in. This may involve subscribing to regulatory newsletters, joining industry associations, or engaging with regulatory consultants.

# LEVERAGING TECHNOLOGY SOLUTIONS

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Technology can play a pivotal role in helping to lift the burden of spend transparency reporting. Powerful tools are available that can aid in data collection, validation, and reporting and also provide expertise to help guide your team. These tools automate many of the manual tasks associated with data management, reducing the risk of human error and increasing efficiency. Companies should consider investing in flexible technology and services that can easily scale to meet evolving compliance needs.

One such tool is our own RLDatix Life Sciences Global Spend Transparency platform. The only transparency system built by compliance professionals for compliance professionals, it helps users generate reports in compliance with US and global transparency regulations, laws, and codes. Through the platform's comprehensive aggregation technology, dashboards, and analytics, you can monitor and audit engagements and transfers of value to ensure compliance with HCP interactions. This cloud-based system supports reporting in 40+ countries, 40+ languages, and 40+ currencies and is secure, accessible anywhere, and compliant with GDPR.

RLDatix Life Sciences also provides a suite of professional services to support your Global Spend Transparency — from compliance advice or risk analysis to full-service compliance data tracking, management, and reporting.

By addressing these challenges with best practices and leveraging technology, pharmaceutical companies can navigate the complexities of spend transparency more effectively. Preparing for future changes and maintaining scalable, efficient systems will position companies to remain compliant and uphold their commitment to ethical practices and public trust in an ever-evolving regulatory environment.





LET'S WORK  
**TOGETHER**

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