



WHITEPAPER

CLARITY IN COMPLIANCE

How to efficiently and accurately plan for and comply with aggregate spend, drug price transparency laws, and government price reporting requirements

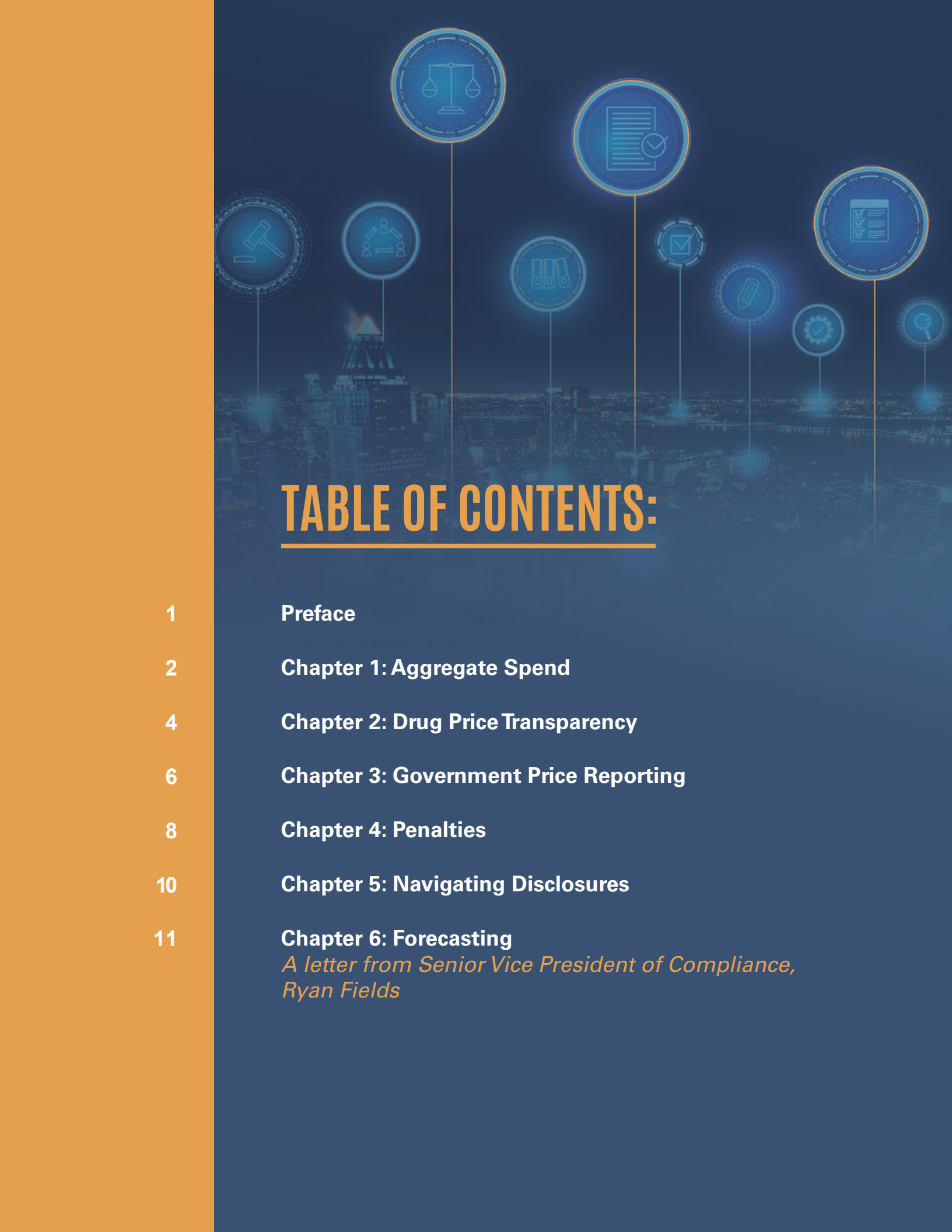


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PREFACE

As the pharmaceutical industry propels forward, it's not just the science evolving at a breakneck pace, but also the regulatory landscape governing it.

For emerging pharma manufacturers, the path to bringing a groundbreaking therapy to market is increasingly complex, punctuated by a maze of federal and state regulations that demand not just attention, but proactive compliance.

Dispelling the myth that compliance is only a concern after a product launch, this ebook will guide you through the complex, pre-launch intricacies of Sunshine Transparency and Aggregate Spend, Drug Price Transparency, and Government Price Reporting. These are not mere regulatory hurdles; they are foundational elements of a successful market entry and sustainable business practice.

Particularly vulnerable are emerging manufacturers who must navigate these waters with often limited resources. This book aims to arm teams like yours with essential knowledge and strategies, highlighting the historical and legislative trends that have led us to this era of unprecedented transparency. By the end of this book, you will gain a comprehensive understanding of how integrated transparency practices not only safeguard against legal repercussions but also bolster your company's commitment to ethical practices and patient-centric care.

When your product is ready to transform lives, the goal is that no compliance hurdle should come as a surprise so that your path to market can remain as clear as the mission that is driving your innovation.



What is Sunshine Transparency and Aggregate Spend?

Federal and state reporting requirements for life sciences manufacturers encompass disclosing the total monetary value of payments and other transfers of value provided to healthcare professionals (“HCPs”), healthcare organizations (“HCOs”), and other related entities and individuals. Reportable transfers of value include but are not limited to consulting and speaker fees, food and beverage, travel expenses, research payments, grants, and charitable contributions.



The spotlight on **HCP and HCO spend disclosure** underscores a new era of mandatory transparency within the life sciences industries. Relationships between manufacturers and healthcare professionals are under unparalleled scrutiny, driven by a broader movement towards transparency to mitigate conflicts of interest in healthcare. However, federal reporting represents only one component of the broader transparency landscape. Many states impose independent requirements, including additional reporting obligations, gift ban restrictions, sample reporting, and sales representative registration often with separate timelines and enforcement standards.

Central to this is the US Physician Payments Sunshine Act (“Sunshine Act” or “Open Payments”), part of the Affordable Care Act, which mandates that manufacturers of pharmaceuticals, medical devices, and biologics annually disclose their financial relationship with HCPs and HCOs. This legislation symbolizes the industry’s shift towards openness, aiming to ensure that healthcare decisions prioritize patient health over financial incentives.

The landscape is complex. Navigating both federal and state requirements requires a structured, proactive approach to transparency and aggregate spend management. Emerging manufacturers must prepare well in advance of commercialization. This includes developing a clear understanding of HCP interactions, identifying all in-scope legal entities, defining internal ownership, and establishing processes for capturing and validating data. Leading organizations begin these efforts at least 6–9 months prior to anticipated launch, aligning systems, processes, and third-party vendors to ensure readiness before reportable activity begins.

Furthermore, the continual evolution of regulatory requirements necessitates advanced data management and internal guidelines to ensure accurate, timely, and complete reporting. Key considerations should include data remediation processes to address inaccuracies and a data source aggregation strategy to ensure comprehensive and reliable transparency reports.

In practice, this means implementing a repeatable, defensible framework that supports data intake, classification, monitoring, and reporting, while maintaining audit-ready documentation.

Navigating Market Entry & Access

Emerging pharmaceutical and medical device manufacturers face a pivotal challenge as they enter the market: managing the complexity of HCP and HCO spend reporting. This challenge extends beyond regulatory compliance—it requires establishing scalable processes, ensuring data integrity, and maintaining alignment across internal teams and external vendors.

Did you hear?

Two Labs recently launched a Sunshine Transparency & Aggregate Spend service with emerging manufacturers in mind.



Learn more on
our website.

CHAPTER 2: DRUG PRICE TRANSPARENCY

The scope of legislative requirements for drug pricing transparency (“DPT”) in the United States has seen considerable momentum in recent years, setting the stage for a cascade of state-level initiatives to clarify the costs of medications through focusing on product launches and price increases.

State-Specific Requirements and Trends

DPT laws require manufacturers to justify their pricing strategies by reporting on various factors, such as clinical trial results, production and R&D expenses, and market analyses. This requirement extends beyond mere cost disclosure; it demands a narrative that explains the rationale for pricing decisions.

The manifestations of these laws range from creating databases that track drug price information to establishing review boards tasked with scrutinizing and offering recommendations on drug costs. Historically, in lieu of capping prices these measures have instead relied on the power of transparency to influence manufacturer pricing strategies – however states such as Minnesota, Illinois, and most recently Connecticut have introduced price increase prohibitions for certain drugs.

Understanding the nuances of state DPT laws is crucial, as each state may have distinct reporting requirements. States like Minnesota and Oregon may demand comprehensive data, while others may have more modest requirements. However, the common thread is the focus on the drug's price and history, with more significant reporting obligations tied to medications with a history of price hikes.



Minnesota mandates comprehensive reporting that includes extensive data on drug pricing and history. In contrast, **Oregon** focuses on capturing significant price increases, demanding detailed information primarily for drugs with a history of price hikes. Despite these differences, both states emphasize transparency in drug pricing to ensure accountability and control over rising medication costs.

Integration, Implications, & Enforcements

While DPT zeroes in on the economic details that justify a drug's market price, and Sunshine Transparency & Aggregate Spend focuses on the totality of expenditures to HCPs and HCOs, both are living and evolving examples of the industry's move toward transparency. Together, they represent critical components of a robust compliance strategy that ensures pharmaceutical companies operate with integrity and accountability.

Noncompliance with DPT laws can carry weighty consequences, from financial penalties to the potential for public "name and shame" campaigns.

States like Vermont and Maine have been forthright in their approach, publishing data that highlights the impact of drug pricing on state expenditures. Others, like Minnesota, have prioritized transparency by detailing the expected versus actual reports submitted by manufacturers.

As DPT laws continue to evolve, it's evident that they are an integral part of the healthcare transparency movement. Pharmaceutical companies are tasked with innovating life-changing treatments and navigating the complex landscape of DPT regulations. Preparation for DPT compliance should begin at least six months before a product launch, with the first reporting requirements triggered by the receipt of the PDUFA date from the FDA. Additionally, post-launch the work is not complete – multiple states have ongoing requirements for reports to be submitted on a quarterly and annual basis (regardless of any pricing actions).

Want to learn more about DPT?

DPT stands for Drug Price Transparency. It includes all our services that help clients navigate the regulatory landscape that awaits them as they determine the appropriate price for their product...



Visit our blog to read more



Vermont publicly highlights the impact of drug prices on state healthcare expenditures, ensuring accountability and transparency. Similarly, **Maine** provides comprehensive reports on drug pricing trends, emphasizing the financial burden on the state and fostering public awareness.

CHAPTER 3:

GOVERNMENT PRICE REPORTING

The goal of every pharmaceutical manufacturer is to ensure their products reach the patients who need it. This includes those underserved patient populations qualifying for Medicaid and Medicare, programs which encompass a market of over 150 million Americans. Manufacturers must participate in programs such as the Medicaid Drug Rebate program, the 340B Drug Discount program, and the VA/FSS contract program in order for their products to be covered.

Encompass a market
of **over 150 million**
Americans



Manufacturers participating in these Government Pricing ("GP") programs are **required to calculate and report** product and pricing data (i.e., average and transactional net price points for their products based on actual sales and discounts in different market segments) to various federal agencies on a monthly, quarterly and annual basis. These data establish the minimum discounts or reimbursement limits for their products under the various GP programs. Reporting accurate product and pricing data requires a deep and nuanced understanding of the ever-evolving regulatory requirements of each GP program, the discount and service fee arrangements with stakeholders in the value chain, and the manner by which different types of transactions are reflected in a manufacturer's revenue management systems.

- Healthcare and drug pricing reforms under the Medicaid Services Investment and Accountability Act, American Rescue Plan Act, Infrastructure Investment and Jobs Act, and the Inflation Reduction Act, introduced new discount programs and amended existing discount programs. These changes obligate manufacturers to provide additional discounts when taking price increases that exceed the CPI-U inflation rate or offering lower commercial discounts, as well as subjecting manufacturers to additional civil monetary penalties for reporting incorrect data.



Given the environment of gross-to-net pressure and enforcement risk, it is increasingly important for manufacturers to be well-equipped with **essential planning tools** for successful product and portfolio management, which include the following:

Change Management Strategy

Adopt a strategy for periodically evaluating changes to the business (e.g., introduction of new contracting strategies, introduction of new products or variations of existing products, new types of contracted entities, etc.) and changes to the regulatory landscape (e.g., new final rule on Best Price stacking).

Fair Market Value/ Bona Fide Service Fee Evaluations

Determine the appropriate cadence of evaluating service fee arrangements to ensure the proper treatment of those fees for the various pricing calculations.

Framework for Analyzing Pricing Strategies

Critically evaluate the gross-to-net impact of contemplated pricing and discounting decisions using predictive analysis supported by well-reasoned assumptions.

CHAPTER 4: PENALTIES

Manufacturers participating in federally funded programs must be cognizant of the inherent risk of penalties for non-compliance, which include fines, civil and criminal judgements, and suspension and debarment for the manufacturer.

Unlike the commercial market, doing business with federal government entities requires manufacturers to certify the accuracy of their data submissions. Inaccuracies in submitted data is therefore not just a mistake, but a violation of the certifications and potential fraud.

The types of action/inaction for participating manufacturers that leads to penalties can be broken into three major categories:

Failure to report on a timely basis

Failure to report required information on a timely basis can result in fines of \$10,000 per day per labeler code. This applies to the required cadence of pricing and product data submissions for the Medicaid Drug Rebate Program (monthly and quarterly), the pricing submissions under the Veterans Health Care (quarterly and annually), and for Medicare Part B (quarterly).

Knowingly providing false information or overcharging for ceiling prices

Knowingly providing false information activates federal false claims and other fraud statutes leading to a penalty of up to \$100,000 per item plus other taxes and fees and potentially criminal penalties including additional fees and in rare circumstances, potential incarceration for certain responsible and knowledgeable personnel. This includes knowingly submitting inaccurate price type calculations or recklessly disregarding the accuracy of submitted price types. Additionally, manufacturers who participate in the programs are also required to contract with the VA through a negotiated Federal Supply Schedule contract. A failure to fully disclose all relevant pricing information during the negotiation (the disclosure also requires certification) or to report a price reduction to an agreed tracking customer during the contract performance activates fraud statutes and carries a fine of \$10,000 per invoice plus damages in the form of a price differential times all units purchased by the government.

Refusal to provide requested information

Refusal to provide government-requested information (or disclosing false information) is similarly considered a false claim and triggers fines of \$100,000 per claim or \$10,000 per invoice submitted and potential criminal charges and fines.



Any of these violations, if determined to be egregious, will also lead to potential suspension or debarment from doing business with the federal government.

Taking the lead from the federal programs, the various States that have drug price transparency laws also motivate compliance through severe fines and penalties. Fines for failure to report on a timely basis range from \$1,000 per day to \$25,000 per day; providing false information or withholding required information also leads to civil penalties and/or criminal prosecution. In contrast to federal GP programs which are voluntary, state price transparency requirements are not contingent on voluntary participation in a state program, but simply having commercial sales in that state.

DPT LAWS

Don't be caught unexpected

Read our article in Pharma Manufacturing about how state drug price transparency laws are here to stay.



Learn more

CHAPTER 5: NAVIGATING DISCLOSURES

Examples of How Two Labs Helps Clients Achieve Compliance through Identifying Reportable Activities, Conducting Spend Inventory Assessments, and Developing Robust Reporting Documentation

Two Labs has supported numerous emerging pharmaceutical and medical device manufacturers in navigating the complex HCP and HCP spend disclosure requirements. Here are some common challenges and how Two Labs has addressed them:

1

Identifying Reportable Vendor Activities

Many emerging clients lack a full understanding of which vendor activities are reportable. With deep knowledge of reportable activities, Two Labs has conducted thorough assessments to identify all potentially reportable vendor activities, mitigating reporting risks associated with vendors working with HCPs and HCOs on behalf of clients.

2

Comprehensive Spend Inventory Assessments

Clients often have only a high-level understanding of reportable activities, focusing on obvious transfers of value like speaker and consulting fees. Reporting requirements, however, extend far beyond these. Two Labs has worked with many emerging manufacturers to conduct comprehensive spend inventory assessments to identify all potentially reportable transfers of value and relevant stakeholders, reducing risk in the reporting process.

3

Developing Reporting Documentation

Many clients struggle to develop necessary reporting documentation, including playbooks, assumptions and methodology documentation, and policies and procedures. Without proper documentation, it's nearly impossible to ensure effective communication, accurate data capture, and consistency in reporting. Two Labs has assisted in creating tailored documents that establish a strong foundation for effective reporting of all transfers of value.

Sunshine Transparency Reporting for Emerging Pharma

In this article for pharmaphorum, Andy Parks and Brian Fittipaldi help first-time pharmaceutical and medical device manufacturers in the US understand the challenges with Sunshine Transparency's unique federal and state reporting requirements.



[Learn more](#)

CHAPTER 6: FORECASTING

Dear Readers,

Embarking on a pharmaceutical product launch is no easy feat, especially if it's your first product. And although the worlds of aggregate spend, drug price transparency, and government reporting are far from straightforward, they don't need to make your launch any harder. With proper planning, you can move through these necessary milestones without adverse effects on your launch readiness.

Looking forward, we anticipate expanding reporting requirements and a focus on enforcement. Similar to the evolving landscape of state licensing, which requires continual adaptation, the domains of transparency and compliance are set to expand under growing regulatory scrutiny. At Two Labs, we are committed to providing proactive and integrated compliance strategies that prepare our clients not just to meet these evolving demands but to excel amidst them.

Many of our clients are small teams bringing their first product to market. They're wearing more hats than they thought they could, and they know these compliance services are essential, but they haven't yet grasped how urgent, interconnected, and increasingly complex they are. They are - understandably, and often at the behest of their investors - laser-focused on their core launch functions and how they might get there by using as little capital as possible. The result is that they haven't thought about the resources needed to support these peripheral yet essential activities.

But our experience has shown that there can be a real threat to launch when it's approached this way. Ensuring robust compliance and transparency is indispensable not only for avoiding legal pitfalls but also for fostering trust and integrity in your operations. And it's also about the success of your launch.

Our commitment to our clients is always to ensure that their launch is approached comprehensively, giving each activity the attention it deserves and connecting the dots to make the process as smooth as possible. Compliance is no exception, no matter what the future holds.



Ryan Fields

Senior Vice President of Compliance

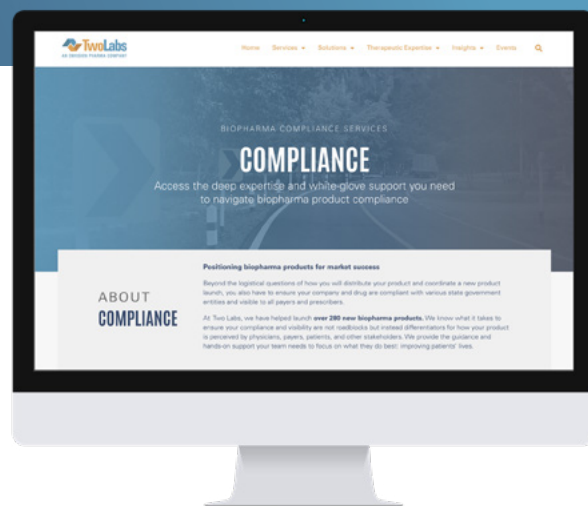
WHY TWO LABS

Two Labs stands apart as a comprehensive solutions provider, uniquely positioned to meet the needs of emerging pharmaceutical companies.

Our expertise spans the entire spectrum of launch activities, including a variety of compliance and transparency services, from aggregate spend to drug price transparency and government price reporting, state licensing, eHRX, compendia, and more.

Choose Two Labs for an expert partner who understands the complexities and nuances of your journey, ensuring compliance, ethical decision-making, and a successful product launch.

We're ready to help. Reach out today.



COMPLIANCE SERVICES



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