Utilizing Technology to Overcome Pharma Compliance Challenges in 2024

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WHITE PAPER

Ensuring regulatory compliance has become increasingly complex as the life sciences industry evolves. Pharmaceutical manufacturers across the globe are facing unprecedented challenges and heightened scrutiny, causing many to reexamine their approach to compliance management.

This is particularly true in the United States. Manufacturers whose products are participating in government drug pricing programs, including Medicaid, the 340B Drug Pricing Program (340B), and Medicare Parts B and D, must navigate an ever-evolving legislative landscape to strike a balance between risk and value. Failure to comply can be profoundly costly in terms of fines, remediation costs, and reputational damage.

Manufacturers must not only stay abreast of changes in compliance but also have solutions in place to ensure they can meet these requirements, both now and in the future. This guide highlights the four key challenges that will impact compliance in 2024 – state drug price transparency, 340B, the proposed rule CMS-1793-P, and the Inflation Reduction Act – and explores how technology can help pharma manufacturers reduce risk and protect revenue for the long term.

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37.5%

Approximately 37.5% of the U.S. population is covered by Medicare (18.7%) or Medicaid (18.8%), according to the U.S. Census Bureau.[1]

94%

94% of pharma executives are concerned about governmental changes, according to the Model N 2024 State of Revenue Report.[2]

[1] "Health Insurance Coverage in the United States: 2022." U.S. Census Bureau, 2023.

[2] "2024 State of Revenue Report." Model N, 2024.

Four key developments impacting compliance in 2024

1. State drug price transparency

The challenge

As of October 2023, more than 20 states have enacted drug price transparency laws. In general, these laws require drug supply chain entities such as manufacturers, pharmacy benefit managers, health plans, and/or others to report information explaining high price increases, high-priced new drugs, and other price changes to existing drugs.

Requirements differ from state to state, however, with variances in reporting formats, data to include in each report, timelines, definitions for qualifying events, and more. Additionally, states are proposing and passing new legislation regularly, in addition to tweaking existing laws.

Navigating the disparate pricing regulations on a state-by-state level is complicated and time consuming. Many manufacturers lack the dedicated resources to constantly monitor and interpret these developments. What's more, for many state submissions there is no single group within a manufacturer that has all the information required to be reported. This then requires interdepartmental understanding and communication, which can make it difficult to maintain consistent processes and documentation, leading to errors.

Manufacturers must address these challenges or face severe consequences: Late, missing, or incomplete reporting can result in costly fines – up to $25,000 per violation in most states.[3] They must also consider how state price transparency reporting requirements may affect current and future pricing strategies, as well as the reputational and competitive impact of some pricing information becoming public.

17.5M

In 2020, California's Office of Statewide Health Planning and Development fined more than a dozen drug makers a total of $17.5 million for drug pricing reporting violations, with one company receiving a total accrued penalty of $2.6 million.[4]

[3] "2023 State Drug Transparency Law Development Update." Goodwin Law, 2023.

[4] "California fines more than a dozen drug makers for not providing drug pricing data." STAT, 2020.

The solution

Deploying an automated state price transparency solution will help manufacturers:

- Reduce risk of non-compliance with state-specific price transparency requirements by providing all necessary reporting on time and in the correct format.
- Translate current and future legislative activity into tasks that can be configured and triggered based on each state's laws and regulations.
- Streamline cross-departmental visibility and collaboration with approval workflows and scheduled reporting calendars.

2. 340B Drug Pricing Program

The challenge

Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to healthcare organizations that care for many uninsured and low-income patients. The program has been growing more rapidly since 2010 with little oversight, making it increasingly difficult to ensure that the medications purchased at the 340B price go to the proper patients.

Calculating the 340B price and managing who is eligible to purchase at that price is a complex process that requires extensive, accurate, real-time data. However, the growing number of covered entities participating in the program – as well as an increase in contracted pharmacies filling the prescriptions – makes it difficult to track who is using what product for what facility under what price. Inefficient management of inventory and contractual relationships increase the risk of duplicate discounts, ineligible claims, and chargeback disputes, which can cause considerable revenue loss.

$100B

In 2022, 340B sales exceeded $100 billion in wholesale acquisition cost (WAC) dollars.[5]

[5] "The 340B Drug Discount Program Exceeds $100B in 2022." IQVIA, 2022.

Making matters worse is the fact that federal rules and judicial guidance governing the program are ever-changing, putting an immense burden on resources and increasing the likelihood of confusion and mistakes. For example, a recent court ruling[6] broadens the definition of the word "patient" so that potentially, a patient who ever used a covered entity could be considered 340B-eligible well into the future.

In response to these challenges, many manufacturers are revising their contract pharmacy policies and restricting ship-to arrangements, raising questions about liability within the supply chain and subsequent potential financial implications. The financial advantages for entities participating in 340B will continue to increase as the program expands, which may significantly impact the bottom line for manufacturers.

The solution

Deploying a tech-based 340B compliance tool will help manufacturers:

- Calculate the accurate 340B price and share with wholesalers.
- Properly pay or reject 340B chargebacks based on a contract pharmacy policies.
- Evaluate rebate submission data to identify prescription transactions with a high likelihood of being dispensed with 340B-priced product.
- Perform script-level validation to identify duplicate and erroneous claims.
- Continuously monitor compliance with the 340B Drug Pricing Program.
- Avoid revenue loss resulting from double or triple dipping.

[6] "What Makes a Patient a "Patient"? Court Rejects Restrictive 340B Definition." McDermott, Will, & Emery, 2023.

3. CMS-2434-P Proposed Rule

The challenge

In May 2023, the Centers for Medicare & Medicaid Services (CMS) proposed a change to best price (BP) determination that could have a substantial impact on Medicaid rebate liabilities. The rule, "Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program" (MDRP), changes the definition of BP to require manufacturers to "stack" all discounts on unit(s) sold of a specific product – even the discounts that were given to different entities in different companies.

This could require manufacturers to report a lower BP than they do today, potentially resulting in higher Medicaid rebates that could be greater than the cost of the drug.

The solution

Regardless of whether CMS-2434-P is ultimately passed, manufacturers can utilize technology to ensure compliance with government price regulations by:

- Aligning commercial and government price management processes through integrations with other systems.
- Constructing auditable, reproducible, version-controlled methodologies for government pricing policies.
- Accurately calculating every transaction, price, rebate, and adjustment that could impact monthly and quarterly reporting.
- Performing data analysis to support decision-making.

4. Inflation Reduction Act

The challenge

The Inflation Reduction Act (IRA) of 2022 provides Medicare the ability to negotiate directly with drug manufacturers to lower the price of certain high-expenditure, single-source drugs without generic or biosimilar competition. Additionally, the IRA requires drug companies that raise their drug prices faster than the rate of inflation to pay Medicare a rebate.

The IRA will impose a nondeductible excise tax on manufacturers that fail to enter into negotiated drug pricing agreements. The law also includes an "anti-abuse" rule under which the Health and Human Services Secretary can treat a sale that was timed for the purpose of avoiding the tax as noncompliance.

While the IRA authorizes the negotiation of drug prices directly with participating manufacturers, many in the industry feel the process isn't a true negotiation, but rather a demand for data in exchange for a dictated price. Furthermore, by exposing potential generics and biosimilars to a potential cap at the maximum fair price of the branded product, the IRA depresses the opportunity for manufacturers to earn the initial revenue they rely on and may prevent competition.

Language in the IRA implies netting Medicare's cost down to the maximum fair price must happen very quickly, but there are doubts whether the standard payer method will be fast enough or if the pharmacy will need an immediate chargeback from the manufacturer.

94%

According to the Model N 2024 State of Revenue Report, 94% of pharma manufacturers expect the IRA to impact their revenue management programs, and 50% are expecting it to have a significant impact.[7]

The solution

A scalable, tech-based pricing platform can help manufacturers:

- Calculate and pay the inflation-based rebates for Medicare Parts B and D.
- Support Medicare negotiation with enhanced reporting capabilities for specified drugs.
- Ensure regulatory and operational compliance with full reproducibility, an audit trail, reporting, and analysis.

[7] "2024 State of Revenue Report." Model N, 2024.

Getting prepared

As pharma companies prepare to face compliance challenges in 2024, the need to modernize outdated, manual systems will become more urgent than ever. A comprehensive compliance platform powered by advanced technology – and backed with robust data and analytics capabilities – can help manufacturers:

Automate core functions such as report generation, reviews, and approvals to improve efficiency, control compliance-associated costs, enable scalability, limit the burden on strained resources, and lower the risk of human error in manual processes.

Trigger updates when state and federal policies change, ensuring consistent compliance with the latest laws.

Access and validate real-time data to ensure accurate pricing calculations and reduce the likelihood of over- or underpaying claims and rebates.

Create a single source of truth for government regulations, legal interpretations, and supporting documentation.

Leverage accurate, auditable, reproducible methodologies for government pricing policies and calculations.

Put our technology and expertise to work for you

Model N helps you accelerate digital transformation with cloud-integrated technology and expert services, so you can respond with agility to market and regulatory changes while mitigating risk and growing your revenue.

Our intelligent platform integrates technology, data, and analytics to deliver deep insight and control over the complexities of compliance. Not ready to implement an enterprise-level SaaS solution? Leverage our expertise to handle some or all your compliance functions through our business process outsourcing service.

To learn more or talk with one of our compliance experts today, visit **modeln.com** or email us at **info@modeln.com**.

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