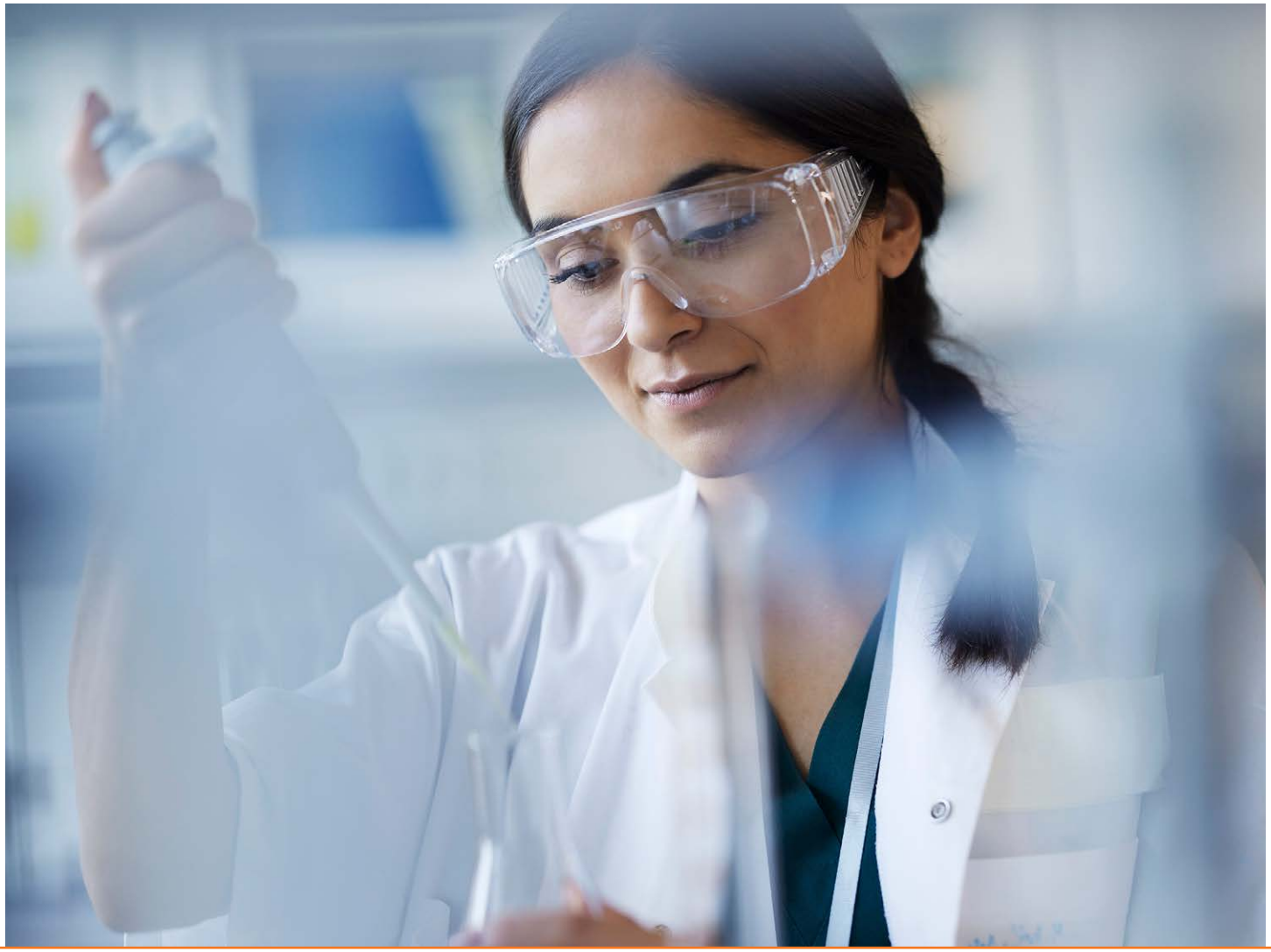

Overcoming three key pharma compliance challenges in 2025

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WHITE PAPER

Ensuring regulatory compliance has become increasingly complex as the life sciences industry evolves. Pharmaceutical manufacturers across the globe face 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 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.

In 2025, manufacturers are entering a new era in which compliance is less about following mandated protocols and more about mitigating government program liability.

This guide covers:

- The latest developments in three key compliance challenges that will continue to impact pharma companies this year – the Inflation Reduction Act (IRA), the 340B Drug Pricing Program, and state drug price transparency laws
- How some U.S. manufacturers are pushing back on regulatory demands
- Expert insight for staying compliant and protecting revenue in this dynamic landscape

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According to the Model N 2025 State of Revenue Report:[1]

87%

of pharma leaders say the **IRA has already impacted their launch plans** for specific diseases or therapeutic areas

+1/3

are keeping a close eye on the **expansion of the 340B program**

75%

are concerned about the **impact of state drug pricing mandates and affordability boards**

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[1] www.modeln.com/state-of-revenue-2025

Concerns with the Inflation Reduction Act

2025 is the year when much of the legislation set forth in the Inflation Reduction Act (IRA) of 2022 will take effect, including three new Medicare rebate programs:

1. **Manufacturer Discount Program (MDP)** – The IRA redesigns Medicare Part D, eliminating the "donut hole" for patients. It replaces the Coverage Gap Discount Program (CGDP) and its 70% discount on utilization in the gap with the MDP – a new tiered 10% to 20% rebate on all Medicare Part D utilization. Invoices for this program will be sent to manufacturers beginning in May 2025.
2. **Inflation penalty rebates** – With a new discount similar to Medicaid's Consumer Price Index for All Urban Consumers (CPI-U) penalty, the IRA requires manufacturers that raise their drug prices faster than inflation must pay a rebate on this utilization. Manufacturers will see invoices for Part B utilization in Q3 2025 and for Part D utilization in Q4.
3. **Medicare Drug Price Negotiation Program (MDPNP)** – Centers for Medicare & Medicaid Services (CMS) now has the ability to negotiate directly with drug manufacturers to lower the price of certain high-expenditure, single-source drugs without generic or biosimilar competition. Negotiations for the first set of drugs are in progress, with final negotiated prices scheduled to take effect in 2026. Up to 20 new products will be negotiated each year.

> *"This statute is unlike anything that we've ever seen in this country – the attempt to institute price controls outside of wartime. And the means by which the IRA achieves this are suspect constitutionally."*
>
> John Shakow, Partner, King & Spalding

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

Pushback from manufacturers on the IRA is plentiful. Many feel that the MDPNP 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.

As of January 2025, there are seven ongoing lawsuits filed by pharmaceutical manufacturers against the federal government regarding the IRA.

Staying compliant

- Evaluate liability for inflation rebates back to 2023.
- Get ready to pay MDP rebates.
- Prepare and deliver data to CMS for maximum fair price (MFP) negotiation of any selected products; plan for processing and payment of MDPNP rebates payable on the specified timeline.
- Update the gross-to-net impact of replacing CGDP with MDP, as well as lines for inflation rebates and, optionally, MDPNP.

How Model N can help

Model N is rapidly updating our software to handle the provisions of the IRA as they become effective. This functionality will be rolled out to all SaaS customers and Model N Professional, Advisory, and Business Services to help customers rapidly adapt their compliance policies, processes, and methodologies.

- **Model N's new inflation rebate functionality** empowers customers to calculate Medicare Part D inflation rebate-per-unit, ensuring compliance with IRA regulations.
- **Model N Government Pricing, Payer Management, Provider Management, and Validata** provide customers with a unified, end-to-end process for managing pricing strategy, calculating fees, and issuing rebate payments in compliance with IRA guidance.

Expansion of the 340B Drug Pricing Program

340B was introduced as a section within the Veterans Health Care Act of 1992. Today, it's the second largest drug program in the U.S. – right behind Medicaid. 340B continues to expand rapidly, making it increasingly difficult to ensure that the medications purchased at the 340B price go to the proper patients. This year, pharma manufacturers need to watch the following developments closely:

- **Attempts to impose a rebate mechanism** – Many manufacturers are pushing for a point-of-purchase model similar to the one used by AIDS Drug Assistance Programs (ADAPs) – a move strongly opposed by the U.S. Health Resources and Services Administration (HRSA). Manufacturers argue this model will give them more control over the integrity of the 340B program by instituting controls over patient eligibility, entity eligibility, contract pharmacies, misuse, and abuse. Several manufacturers have filed suit against HRSA, claiming its prohibition of a rebate model for 340B drugs violates both the 340B statute and the Administrative Procedure Act.
- **Interaction with IRA on non-duplication** – One of the key drivers for the attempted adoption of a rebate mechanism is manufacturers' responsibility to enforce the MFP requirement of the IRA. 340B dictates that manufacturers need not extend duplicate discounts on the same drug, and currently, the rebate model is seen as the only way to ensure non-duplication. Because the CMS is requiring manufacturers to submit their plans for instituting and effectuating MFP by September 2025, resolution of this rebate question must happen soon.
- **State litigation results** – Eight states have currently passed contract pharmacy protection laws that essentially require manufacturers to facilitate the use of contact pharmacies (CPs), despite the fact that 340B states they are not obliged to do so. While recent legal battles between the federal government and two states – West Virginia and Kansas – have resulted in outcomes that favor manufacturers, 2025 will likely see additional states passing CP laws, presenting major challenges for the industry.

> *"With the Republican takeover of both houses of Congress, it will be interesting to see if the covered entity community really pushes for the legislative reform that it sought in 2024 when the Democrats held the Senate."*
>
> Shakow

Staying compliant

- Ensure good processes and policies regarding government pricing calculations that drive your Public Health Service (PHS) price: average manufacturer price, best price, CPI-U for urban consumers penalties, and your final unit rebate amount.
- Publish your prices consistently and in a timely manner to the Department of Health and Human Services (HHS) and your wholesalers and distributors, honoring your prices for indirect sales.
- Monitor covered entities' eligibility and their relationships with commercial providers and contract pharmacies to ensure only eligible customers receive this heavily discounted price.
- Understand how this pricing impacts your revenue and cash flow, which requires attention outside the distribution channel and pricing calculations:
  - Analytics and gross-to-net calculations must address both the immediate pricing and utilization and forecast the anticipated PHS sales.
  - Evaluate crossline utilization – particularly against Medicaid claims-level data – to identify and mitigate the risk of duplicate discounts.

How Model N can help

Model N handles the entire 340B ecosystem end to end:

- **Model N Government Pricing and Medicaid modules** accurately calculate the final 340B price.
- **Model N Provider Management** efficiently publishes the final price to wholesalers and leverages membership management and Syndicated Customer Master to ensure only the correct customers receive the discounted price.
- **Model N Validata and the 340B Vigilance modules** scrub utilization data to ensure units already sold at the 340B price do not receive duplicate discounts in Medicaid or payer contracting.

Evolving state price transparency laws

State price transparency 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. However, requirements differ from state to state, with variances in reporting formats, required data, timelines, definitions of qualifying events, and more. Additionally, states are proposing and passing new legislation and regularly tweaking existing laws. As of January 2025:

21 states have enacted **drug price transparency reporting requirements**.

11 states have established **prescription drug affordability boards** (PDABs), tasked with assessing the affordability of selected drugs sold in the state.

13 states have **pending legislation** to establish or expand existing PDABs.

Manufacturers must stay on top of developments in state legislation, particularly where PDABs are concerned: For drugs found to be unaffordable to state consumers or the state healthcare system, some PDABs have the authority to set upper payment limits (UPLs), creating a maximum rate at which the drug can be purchased in the state.

Thanks in large part to PDABs, state price transparency – like 340B – is becoming an increasingly litigious subject for manufacturers. In a recent example, Amgen filed a lawsuit claiming Colorado PDAB's actions were unconstitutional because they conflict with federal laws and violate rights to due process. The state has yet to file a response.

Staying compliant

- Document clear reporting instructions for each state.
- Monitor for changes to current legislation and any new states introducing laws for the first time.
- Understand what triggers a price change report in each state and set up an alerting mechanism to notify you when you need to report – ideally before your price change occurs.
- Know your pricing thresholds to help inform your pricing committee of what price increase will trigger state reporting.
- Consider how state price transparency reporting requirements may affect current and future pricing strategies and the reputational and competitive impact of some pricing information becoming public.

How Model N can help

Model N State Price Transparency Management, a module of the industry-leading Model N SaaS platform, helps customers manage compliance on their own.

- 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.

Or, customers can leverage our **Model N Business Services** to handle all filings on their behalf, keep them up to date on new and changing regulations, or both.

Model N outlook

The three regulations discussed in this guide present implications that will heavily impact legacy compliance processes and strategies. Unlike simply altering their assumptions to deal with these changes, pharma companies are now faced with overhauling their models to adjust to many net-new challenges.

Model N is actively working with customers to design the path forward so manufacturers can effectively manage and operate in the sea of regulatory change. Recent enhancements to our products and services include:

New Advisory Services

- Policy and procedures
- Gross-to-net analysis
- Customized industry training
- Operations and strategy

Expansion of Business Services

- IRA support for gross profit calculations, rebate validation, payment processing, and gross-to-net impacts
- Discarded drug refunds

Product enhancements

- Powered by N support for IRA including MDP, inflation penalties, and MFP effectuation
- State-specific updates and price threshold reporting in State Price Transparency Management

Prepare for 2025 and beyond

Ready to future-proof your compliance management strategy?

CONTACT US