

Ensure compliance with government regulations

Regulatory compliance can have an outsized impact on pharmaceutical companies. Government regulations continue to grow more complex and are seemingly ever-changing. According to Model N's industry research, 97% of pharmaceutical executives reported that their teams are preparing their revenue management programs for a host of potential changes – spanning financial controls, new healthcare policies, and increasing price transparency requirements.

Further compounding the challenges associated with government regulations are the impacts that non-compliance, overpayments, and inconsistent and siloed processes can have on pharma revenues and brand reputations.

To mitigate risk and optimize revenue, manufacturers need an end-to-end solution that will give them visibility and control over their government compliance processes. Model N offers the industry's only comprehensive enterprise solution that enables you to remain compliant by accurately and efficiently calculating government prices, paying Medicaid claims, handling state price transparency reporting, and addressing other compliance requirements.

Comply with government price regulations

Model N Government Pricing enables you to manage policies, map accurate data to policy requirements, correctly perform calculations, analyze and validate results, establish audit trails, and generate filing output.

- Incorporate regulations from the Centers for Medicare and Medicaid Services (CMS), Department of Veterans Affairs (VA), U.S. Public Health Service (PHS) programs, and others into one application.



Regulatory update packs (RUPs)

Through our flagship RUP program, we help you ensure compliance by providing current guidance. Each RUP contains the software and documentation necessary to update your process to reflect the latest regulatory changes.

- Efficiently meet monthly, quarterly, and annual requirements for average manufacturer price (AMP), best price (BP), average sales price (ASP/Medicare Part B), 340B prices (PHS), non-federal average manufacturer price (NFAMP), federal ceiling price (FCP), and TRICARE.
- Automatically perform pricing calculations, accurately up to six decimals or more.
- Confidently execute complex contracting strategies while remaining compliant with the Deficit Reduction Act's mandates for bundled drug sales through the Model N Discount Reallocation Management module.

Process accurate and timely Medicaid claims

Model N Medicaid streamlines the processing of claims for Medicaid, state pharmacy assistance programs, and state-specific supplemental programs, so you can avoid overpayments and interest penalties.

- Automatically calculate federal and program-related unit rebate amounts (URAs).
- Import invoices and claim-level data from state portals for processing manually or automatically through Model N Medicaid Automated Invoice Retrieval.
- Perform aggregated and prescription-level utilization data validation tests to identify invoice-level outliers and invalid units through integration with Model N Validata.
- Reduce revenue loss by disputing invalid claims and working with states to resolve disputes.
- Automatically generate required digital and printed versions of Reconciliation of State Invoice (ROSI) and Prior Quarter Adjustment Statement (PQAS) reports.
- Produce consolidated payment packages with all necessary information and reports in a single click.

Efficiently manage state price transparency reporting requirements

Model N State Price Transparency Management delivers the visibility and automation that enable you to comply with the vast, ever-growing set of state regulations.

- Configure legislation rules based on state-specific regulations and easily modify templates as laws are changed or enacted.
- Ensure state-specific reporting requirements and timelines are always met by autogenerating reports based on each state's unique triggering events.
- Simulate potential downstream impacts of future pricing or product events, such as price increases or new product launches.

Monitor Federal Supply Schedule (FSS) compliance

Proactively monitor commercial pricing to ensure your organization does not offer a better price to a commercial entity than FSS prices (e.g., "Big Four," other government agencies [OGA]) based on contract and price negotiation with the VA. You can also manage violations, reporting, and requests for modification (RFM), so you remain compliant with the guidance.

Ensure you pay the right rebates at the right time

Using Model N Validata, you can perform script-level validation to identify duplicate and erroneous claims when processing Medicare, Medicaid, TRICARE, and coverage gap rebates – reducing the risk of non-compliance, overpayments, and duplicate discounting.

Model N Payer Management enables you to accurately validate, calculate, and settle rebates and fees related to your payer and pharmacy benefit manager contracts, including TRICARE and coverage gap.

With Model N Provider Management, you can set up government contracts, such as 340B and FSS (BIG4 and OGA), to ensure the right price is offered to eligible customers. This powerful application enables you to process chargebacks accurately and efficiently, as well as process and pay Industrial Funding Fee (IFF) rebates to the General Service Administration (GSA) as part of the FSS.

Make data-informed decisions about government compliance

Model N Intelligence Cloud provides advanced analytics and scenario modeling tools to help you identify trends, comparative variances, exceptions and outliers, and more, so you can forecast rebate liabilities and make better decisions about future price changes.

Let Model N handle government compliance on your behalf

Model N Business Services is the business process outsourcing solution that's purpose built to help pharmaceutical companies in all stages of commercialization stay ahead of ever-changing regulations. This end-to-end solution combines industry expertise, proven processes, and our purpose-built technology to help you mitigate risk, remain compliant with existing and new regulations, and close knowledge gaps within your organization.

Through Business Services, our advisors and operations team members – each with deep expertise in government programs, commercial contracting, finance, or analytics – can help you with some or all of your government compliance processes:

- Government pricing
- TRICARE and coverage gap
- Medicaid claims processing
- State price transparency reporting
- Government contracts management

Reduce risk of non-compliance

- ✓ **Conduct accurate, auditable, and reproducible methodologies for government pricing policies and calculations.**
- ✓ **Align commercial and government price management.**
- ✓ **Eliminate overpayments within Medicaid claims and TRICARE and coverage gap rebates.**
- ✓ **Manage all government compliance-related data in a centralized repository that cannot be altered or deleted.**
- ✓ **Stay up to date with current guidance through timely releases of regulatory update packs.**
- ✓ **Improve operational efficiency and governance capabilities while decreasing overall IT costs with our SaaS-based applications.**

Address regulatory compliance requirements with one proven partner

Schedule a demonstration to learn how Model N Government Compliance solutions can help you achieve accuracy, reproducibility, and auditability – so you're always compliant and audit-ready.