

Ensure compliance with government regulations



Regulatory compliance can have an outsized impact on pharmaceutical companies. According to Model N's industry research, 60% of pharmaceutical executives believe expanding and evolving government pricing programs have increased gross-to-net complexity. Challenges with non-compliance, overpayments, and inconsistent or siloed processes can substantially impact revenue and brand reputation.

To mitigate risk and optimize revenue, manufacturers need an end-to-end solution that provides 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, including the provisions of the Inflation Reduction Act.

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.
- 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.
- Accurately perform pricing calculations, up to six decimals or more.



Regulatory update packs (RUPs)

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

- 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.
 - Unify master data, commercial sales management, rebate calculations, and government program requirements (Medicaid, Medicare, government pricing, and discount reallocation management) in one integrated platform, eliminating data silos and enabling coordinated compliance modeling across all channels.
 - Navigate the complexity of best price initial (BPI) calculations by analyzing all eligible contracted rebates and discounts and projecting rebates for the BP calculation.
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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).
 - Use agentic AI automation through Model N Medicaid Invoice Retrieval to import invoices and claim-level data from state portals for processing.
 - 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 numerous reports, including 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.
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Efficiently manage state price transparency reporting requirements

Model N State Price Transparency Management delivers the visibility and automation you need 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 met by automatically generating 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 [OGAs]) as a result of contract and price negotiations 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 Services Administration (GSA) as part of the FSS.

Let Model N handle government compliance on your behalf

Model N Revenue Management Services is the business process outsourcing solution that helps 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 innovative technology to help you mitigate risk, remain compliant with existing and new regulations, and close knowledge gaps within your organization.

Through Revenue Management 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 revenue management and compliance processes:

- Government pricing
- TRICARE and coverage gap
- Medicaid claims processing
- State price transparency reporting
- Government and commercial 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 in 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.

[Schedule a demo](#)modeln.com