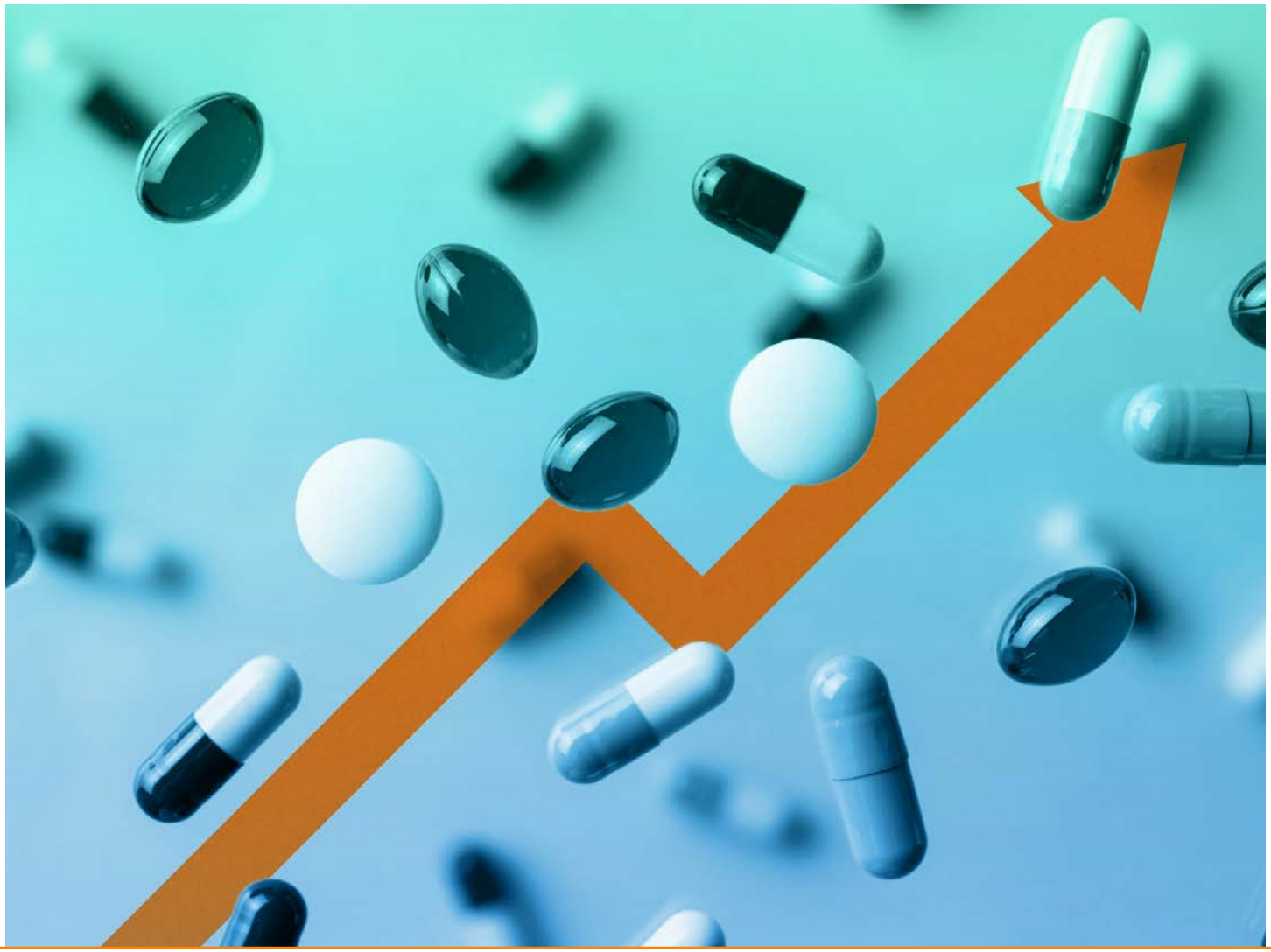

Guide to Revenue Execution for Pharmaceutical Manufacturers

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WHITE PAPER

Model **N**

Facing complex and challenging market dynamics, the global pharmaceutical industry must consider impactful changes to revenue strategy and execution. This guide explores these market pressures and associated impact on how pharmaceutical manufacturers price, sell, and distribute their products. We also share our perspective on how manufacturers can gain a competitive advantage by automating their revenue execution to maximize profitable revenue and ensure contract and regulatory compliance.

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Market landscape for pharma revenue execution

One of the most significant market dynamics impacting drug manufacturers is uncertainty related to the regulatory environment. Governments worldwide, driven by consumer pressure, are seeking to contain healthcare costs. Regulatory proposals across the globe come and go, but with each proposal, manufacturers need to evaluate the potential impact and changes required to comply with new regulations – which is often a time-consuming and costly effort.

Already, many regulations must be considered when manufacturers make decisions about drug pricing and distribution. Failing to consider any one of these regulations puts them at risk for penalties and fines. The added burden of an unpredictable, dynamic regulatory landscape means manufacturers must adapt quickly to new regulations. Even simple non-compliance scenarios under current laws can lead to substantial penalties. For example, when a hospital is overcharged, manufacturers typically must do a credit and rebill, investing additional time and resources with no incremental return.

Consequences can be dramatically more severe if non-compliance happens with a VA hospital. In that scenario, penalties can include revocation of the manufacturer's ability to treat government patients. And in cases of extreme and repeated non-compliance, the government may delist the manufacturer's products, causing massive revenue impact and turmoil. Monitoring and complying with existing regulations, while looking ahead to potential future legislation, makes regulatory compliance a significant burden.

One driver for changing regulations is the increasing demand for price transparency. Governments, consumer advocacy organizations, and consumers are demanding to understand how drugs are priced and why some drugs are more expensive in some regions than others. This demand is unlikely to go away, and drug manufacturers must prepare for how they will increase visibility into their pricing strategies. This is difficult, given the complexity of global pricing and tendering; however, it is critical to maintaining public trust and credibility, in addition to regulation adherence.

At the same time, pharmaceutical research, production, and distribution costs will likely rise. Manufacturers must account for these cost increases, while figuring out how to handle the pressure to reduce out-of-pocket costs to patients.

83%

of adults believe prescription drug costs are unreasonable.[1]

$83B

was spent on pharmaceutical R&D in 2019 – 10x what was spent in the 1980s.[2]

[1] Kaiser Family Foundation. "Public Opinion on Prescription Drugs and Their Prices." October 18, 2021.

[2] Congressional Budget Office. "Research and Development in the Pharmaceutical Industry." April 2021.

Additional market forces impacting pharmaceutical manufacturers include:

- Market consolidation through mergers and acquisitions resulting in revamped systems, processes, and contracts
- Broader adoption of contract manufacturing to meet rising global demand, which increases supply chain complexity
- Demand for value-based contracts, which drives new business models that must be implemented across the selling process

Together, these factors increase the complexity and cost of doing business in the pharmaceutical industry. The process of manufacturing, selling, and distributing drugs is already complicated; market pressures only add to the intricacies involved in success and market leadership.

Organizations that expertly employ people, processes, and technology to address these challenges efficiently have a distinct competitive advantage. These elite organizations can confidently comply with new regulations, successfully manage margins through a complex matrix of pricing requirements and contracts, and meet transparency requirements.

Organizational evaluation

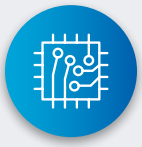
What is the appropriate way to create the capabilities needed to respond to this dynamic market? The first step is evaluating the current state of your organization by answering a series of questions related to your existing people, processes, and technology to determine your true capabilities.

To assess your people, consider:

- *Are your employees trained and organized well enough to respond to these challenges?*
- *How disruptive is it when key individuals leave?*
- *Do you have the right skills for market analysis and implementation of changes?*

For processes, ask:

- *What repeatable processes are currently in place?*
- *Are current processes adaptable to the challenges of the market?*
- *How will you comply with proposed regulations?*
- *What do you need to do differently? How will you ensure those changes are successfully adopted?*



And finally, for technology, examine:

- *What percentage of your processes is automated today, and what is still manual?*
- *Are current systems adaptable to changes?*
- *How long will it take and how much will it cost to change systems to comply with new regulations?*
- *Is there an end-to-end system of record? If not, how are siloed systems integrated into the process? How much room is there for error?*
- *How do you test custom integrations?*
- *How quickly can you roll out new pricing strategies?*

The list of questions is extensive and may include more areas to explore that are unique by company. Only through judicious and thorough evaluation of your current state can you minimize your risk and maximize your revenue.

Once these questions have been adequately answered, you should develop a plan to address problem areas and create an approach that puts you on a path to success. Without taking a dispassionate look at your organization, you will not be able to respond to the challenges you're facing. By going through this process, you will be best positioned to lead the market.

6%

Pharmaceutical manufacturers unknowingly leak as much as 6% of their revenue due to ineffective systems. **That's $60 million for every billion dollars of revenue.**

The desired state

It can be daunting to envision solving issues at the nexus of people, processes, and technology to address market dynamics. With the right end state in mind, you can systematically build an approach that will streamline processes, enable people, and leverage end-to-end software designed specifically to help the pharmaceutical industry meet the challenges of the changing market landscape.

In this desired state, you can:

- Easily create new pricing that meets regulatory requirements and is integrated into business systems like ERP and CRM.
- Roll out new pricing globally that enables your sales staff to increase market share while maximizing profits.
- Ensure that every customer is charged correctly and receives the lowest price to which they are entitled.
- Improve accuracy of rebates and chargebacks to ensure compliance and avoid overpayments.

A strategic and unified solution to establish accuracy, confidence, compliance, and a single version of truth is critical in today's environment. By removing the silos of management in global pricing, global tenders, payers, providers, government pricing, and Medicaid you can gain clarity. This vision includes actionable strategies to prevent as much as 6% of revenue from leaking due to ineffective systems and processes.

Model N's view

Managing revenue across the pharmaceutical supply chain is a critical capability in today's dynamic market. Each aspect of revenue execution can be highly specialized, but taken together, they are highly strategic to an organization. Model N empowers pharmaceutical manufacturers to grow net revenue and market share, pay exactly what they owe the first time, and reduce regulatory compliance risk. Our software platform automates processes within and across each function to become the system of record used to manage global pricing and tenders, contracts, chargebacks, and regulatory compliance.

Maximizing global revenue

Global Pricing Management

With an array of global market access challenges and several revenue growth drivers, you must be able to continuously adjust pricing by region throughout the entire product lifecycle and increase the speed of information exchange. Cost containment initiatives by payers, governments, and healthcare insurance organizations have created a challenging business environment with controlled pricing, promotion of generic alternatives, and greater obstacles to bringing innovative drugs to market. Achieving global pricing excellence is now more important than ever if the industry is to remain viable while providing patients affordable access to medicines.

Model N Global Pricing Management supports a variety of pricing simulations and controls to prevent price erosion. Along with a validated price and reimbursement database that is 100% accurate, Global Pricing Management includes capabilities to automate and track multi-country launches and conduct pricing and sales forecasting. By unifying all divisions and systems into one end-to-end platform built specifically for pharma, you can execute innovative pricing strategies more effectively, enabling revenue optimization and price protection globally.

Global Tender Management

As the complex bidding process becomes more competitive, global tenders must be managed efficiently to allow for planning and prioritization of tender response activities. Departments can shape and respond to tenders with limited resources – acting locally, but coordinating globally – by streamlining auditable approval workflows, tracking and analyzing tenders for continuous improvement, and developing best practices as the number of tenders grows.

Utilizing a unified solution to help plan, create, execute, track, and analyze global tenders has been proven as the key to winning more bids. Our integrated Global Tender Management solution gives teams visibility into global opportunities and the ability to generate winning strategies proactively. With a centralized view, clear workflows, and organized approval processes, silos are removed, and efficiencies fall into place. Furthermore, by integrating a tender marketplace search directly into the platform, tender managers can easily search public marketplaces for new publications and convert them into tender opportunities. This solution offers enhanced controls and insights to streamline the bidding process, promote cross-functional collaboration, reduce risk, and increase top-line revenue.

Managing payers and providers

Payer Management

On average, pharmaceutical organizations pay 25-31% of their revenue in rebates with heavy penalties for late payments. This makes accurate and timely chargeback validation, calculation, and settlement crucial to success.

As rebates become more innovative and value-based, they become more difficult to model and execute. It is no longer enough to prove a new product is safe and effective; manufacturers must also demonstrate outcomes-based price justification. Outcomes-based contracts include clauses for reimbursement for the cost of care based on the value or outcome received by the patient.

Our cloud-based Payer Management solution offers a comprehensive approach to navigating the complex requirements for formulary, market share, and price protection calculation. This solution keeps structured contract documents in a single repository to reduce manual effort, leverages preapproved templates and clauses (value-based and traditional), automates workflows and approvals, rejects invalid claims, and reduces rebate overpayments. To offer value beyond pricing, Payer Management supports flexible contracts, includes configurable data fields, and has robust analytics for payments and reporting.

Validata for configurable, script-level validations

Managing the complex and fast-changing payer pricing and contracting landscape is an ongoing challenge. Manufacturers often have tens of hundreds of contracts in place with various payers, for both commercial and Medicare Part D. Without consistent, accurate, and reliable data, it can be nearly impossible to clearly determine which prescriptions are eligible for rebates.

By developing an automated workflow that allows contract, validation, and rebate analysts to monitor, investigate, and identify suspect claim lines in a timely and efficient manner, you can significantly reduce incorrect payments, streamline claim validation activities, and remain compliant. Model N Validata utilizes our SaaS technology to offer automated script-level validation tools that enable you to enforce terms of agreements and ensure that rebates are only paid on eligible prescriptions. When coupled with Validata Intelligence Cloud, Model N Validata helps you not only improve rebate and payment accuracy but also gain visibility into competitive insights and effectiveness of key programs.

Provider Management

Managing group purchasing organizations (GPOs), integrated delivery networks (IDNs), health systems, and local hospital agreements is often a cumbersome, manual process comprising spreadsheets and aging systems. Model N Provider Management proactively eliminates overpayments of fees and chargebacks and provides visibility into customer commitment tracking. There is power in using the massive amounts of data available to address customer purchasing behaviors and manage price-tier commitments. With clean and accurate data in a single solution, you can reach greater than 98% clean first-pass rates in processing chargebacks, in accordance with HDA best practices.

To optimize your provider management processes, our solution integrates:

- Contracting and pricing
- Channel management
- Incentives, fees, and accruals
- Federal Supply Schedule compliance
- Membership management
- Tiered-pricing compliance

Real-time visibility and insights into your chargebacks, contracts, pricing, and compliance enable you to interact seamlessly with providers. These tools also help you make informed decisions and reduce revenue leakage.

Mitigating revenue risk

Government Pricing

There is a growing demand for price transparency in the supply chain for drugs and biologics. Changes to the safe harbor rule may have been tabled, but the cry for price transparency continues, and most industry thought leaders expect new rules and mandates to come soon. In the meantime, complying with current regulations is imperative to avoid increased fines and preventable revenue loss. To manage risk and prepare for the unknown, consider proven systems, tools, and processes that deliver flexibility, agility, and innovation.

Cloud-based and data-driven revenue management solutions, comprised in a single system of record, will play an integral part in helping you transition to a new set of industry rules and standards and deal with the possible changes on the horizon. Model N Government Pricing, a SaaS-based solution, offers regular and automated updates to incorporate changes to government pricing and reporting regulations so you can stay in compliance while supporting every transaction, price, rebate, and adjustment.

State Price Transparency Management

While the federal government has been unable to curb the trend of wholesale acquisition cost (WAC) increases, many states have taken action. Numerous states have passed legislation on price transparency, and others have proposed similar laws. While designed to help control pharmaceutical spend and generate a better understanding of the rationale for price increases, these rules differ greatly from state to state, creating administrative challenges.

Model N State Price Transparency Management is a highly configurable solution that helps you manage and meet the unique reporting needs of the vast set of state price transparency regulations. With a single legislation repository, you can configure rules based on state-specific regulations and update those rules as changes occur or new laws are enacted. Visibility and automation help ensure compliance with reporting rules, formats, and timelines.

Medicaid

To help you navigate shifting regulations, all Medicaid data should live in a single source. Data managed in silos is error-prone and no longer reliable. A clear view into accurate data ensures immediate chargeback claim processing, thus reducing costly interest and government penalties. In the age of digital transformation, you cannot afford to rely on disparate legacy systems and integrations that can be slow and produce inaccuracies.

Our cloud-based and automated Medicaid solution helps you reduce overpayments in Medicaid rebates through aggregated or prescription-level utilization data validation. The system can differentiate Medicaid and commercial transactions, automating correct validations and further reducing revenue leakage and potential for human error.

This automated solution ensures accurate, timely claim remittances to federal and state governments by offering:

- Medicaid claims movement
- Automated disputes and adjustments
- Preloaded unit rebate amount (URA) formulas
- Regulatory update packs to stay current
- Formula builders
- Validations and reasonability tests

End-to-end revenue execution

Integrated and transparent contract management, revenue operations, and risk mitigation functions are table stakes in today's dynamic pharmaceutical industry. It is no longer sufficient to knit together point solutions or rely on cumbersome spreadsheets. Errors and lost opportunities abound. Instead, an end-to-end system for revenue execution across all functions in the revenue lifecycle is required. This system must be robust, trusted, and designed for the unique challenges of the pharmaceutical industry.

With Model N Revenue Cloud for Pharma, you can automate and streamline people, processes, and technology across many functional areas, including:

- Global Pricing Management
- Global Tender Management
- Payer Management
- Validata
- Provider Management
- Government Pricing
- State Price Transparency Management
- Medicaid

This end-to-end revenue execution system of record reduces compliance risk and maximizes revenue. Model N Revenue Cloud for Pharma has helped customers prevent billions of dollars in revenue leakage and liabilities from non-compliance.

Visit **modeln.com** for more information or contact us at **info@modeln.com** to receive a complimentary revenue execution assessment and ROI analysis from a pharmaceutical revenue management expert.

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