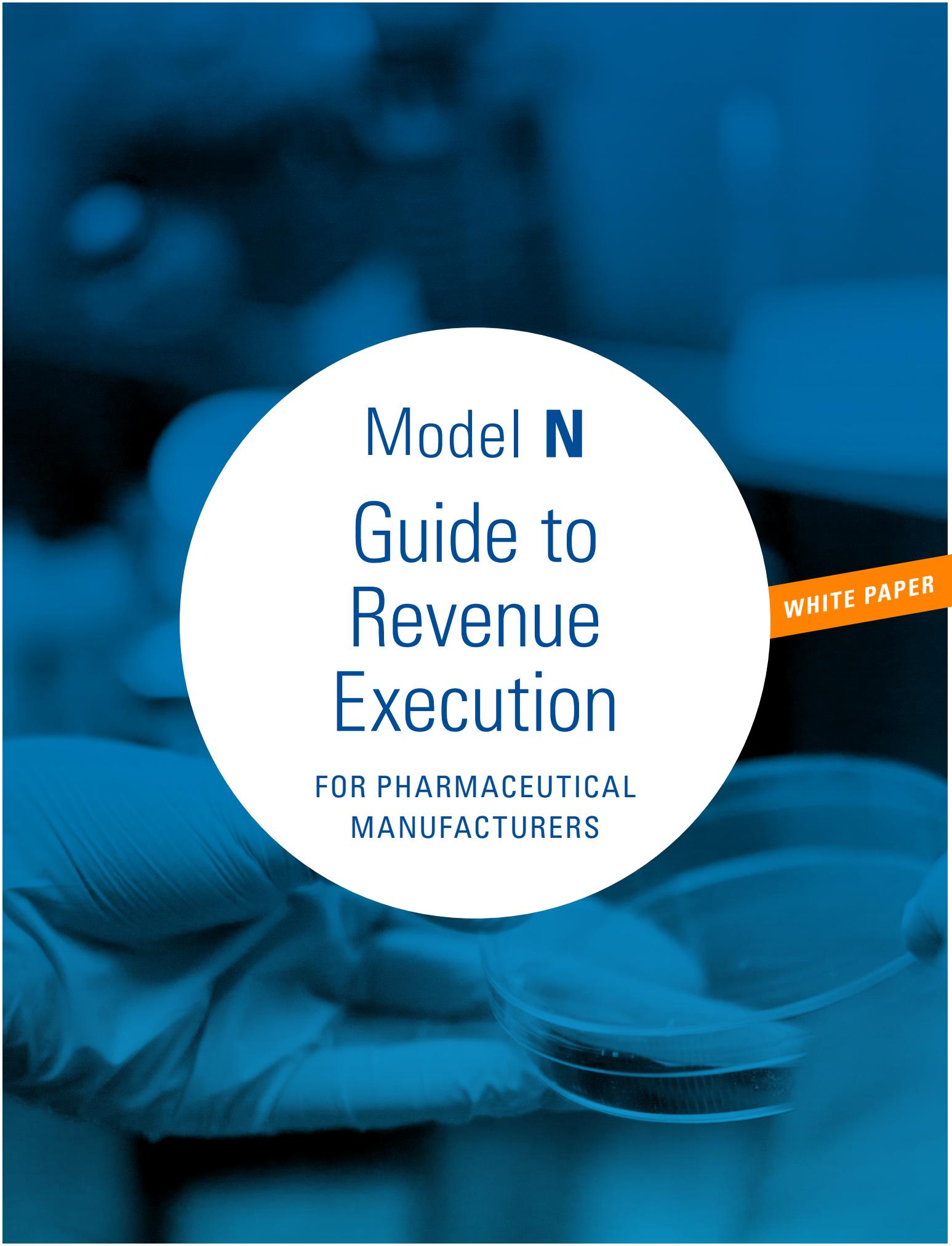

Model **N**

Guide to Revenue Execution

FOR PHARMACEUTICAL MANUFACTURERS

WHITE PAPER

Guide to Revenue Execution for Pharmaceutical Manufacturers

INTRODUCTION

The global pharmaceutical industry is facing complex and challenging market dynamics that are forcing the industry to consider impactful changes to its revenue strategy and execution. In this guide we will explore these market pressures and the impact they are having on how pharmaceutical companies price, sell, and distribute their products. We will 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.

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 and other stakeholders need to evaluate the potential impact and the necessary changes that are required to comply with the new regulations. Assessing the potential impact of each new proposal is often a time-consuming and costly effort.

Already, there are many regulations that must be considered when manufacturers make decisions about pricing and distributing their drugs. Failing to consider any one of these regulations puts pharmaceutical manufacturers at risk of being penalized and fined. The added burden of an unpredictable and dynamic regulatory landscape means pharmaceutical manufacturers need to adapt quickly to new regulations. Even simple non-compliance scenarios under current laws can lead to substantial penalties, such as when a hospital is overcharged. Under usual circumstances, manufacturers must do a credit and rebill, investing additional time and resources with no incremental return.

Further, 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 even delist the manufacturer's products causing massive revenue impact and turmoil. Monitoring and complying with existing regulations, while simultaneously looking ahead to potential future legislation, makes regulatory compliance a significant burden on pharma companies.

One of the drivers for changing regulations is increasing demand for price transparency. Governments at all levels, consumer advocacy organizations, and consumers themselves are demanding to understand how drugs are priced and why some drugs are much more expensive in some regions than others. This demand is unlikely to go away and drug manufacturers must prepare specifically 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, it is likely that pharmaceutical research, production, and distribution costs will rise. Pharma companies must account for these cost increases while also figuring out how to handle pressure to reduce out-of-pocket costs to patients.

Additional market forces impacting pharmaceutical companies include:

- Shortages in generic drugs, which fuels the price transparency conversation
- Market consolidation through mergers and acquisitions resulting in revamping systems, processes, and contracts
- Broader adoption of contract manufacturing to meet rising global demand, increasing the complexity of the supply chain
- 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 pharma industry. The process to manufacture, sell, and distribute drugs is already extremely complex; market pressures are only adding to the intricacies involved in success and market leadership.

What does this mean for today's pharmaceutical manufacturers? Organizations that can expertly employ people, processes, and technology to address these challenges efficiently will have a distinct competitive advantage. These elite organizations will be able to confidently comply with new regulations, successfully manage margins through a complex matrix of pricing requirements and contracts, and meet transparency requirements. The result is a significant reduction of risk exposure to legal requirements, an ability to maintain healthy margins, and success in delivering on price transparency requirements.

ORGANIZATIONAL EVALUATION

What is the appropriate way for organizations to create the capabilities needed to respond to this dynamic market? The first step is an evaluation of the current state of your organization. Pharmaceutical manufacturers must answer a series of questions related to their existing people, processes, and technology to determine their true capabilities.

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

It is useful to ask a series of questions for each of the three areas.

To assess your people, you may consider these questions:

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

For processes, you may ask:

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

And finally, for technology, you may ask:

- What percentage of our processes is automated today and what is still manual?
- Are the current systems adaptable to changes?
- How long will it take and how much will it cost to change the systems to comply with new regulations?
- Is there an end-to-end system of record, and 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 the above questions have been adequately answered, organizations need to develop a plan to address problem areas and create an approach that puts them on a path to success. Without taking a dispassionate look at themselves, organizations will not be able to respond to the challenges they are facing. Those that go through this process will be best positioned to lead the market.

THE DESIRED STATE

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

In this desired state, pharma manufacturers 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 includes enabling 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

Pharma companies have determined that a strategic and unified solution to establish accuracy, confidence, compliance, and a single version of truth is absolutely critical in today's environment. By removing the silos of management in global pricing, global tenders, contract lifecycles, payers, providers, government pricing, and Medicaid, organizations are gaining clarity. This vision includes actionable strategies to eliminate as much as 6% of their revenue from leaking due to ineffective systems and processes.

Model **N**

Model N's View

Model N views manufacturers' need to manage revenue across the pharmaceutical supply chain as a critical capability in today's dynamic market. Each aspect of revenue execution can be highly specialized and seem niche, but taken all together, they are highly strategic to the organization. In the past, some may have specialized in individual operations without addressing cross-functional operations. Model N empowers pharmaceutical companies to grow net revenue and market share, pay exactly what they owe the first time, and reduce regulatory compliance risk. It does this with software that automates processes within each function, as well as across functions, 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, manufacturers must have the ability 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. With changing dynamics in the industry, achieving global pricing excellence is now more important than ever in order to continue having a viable industry while providing patients affordable access to medicines.

It is crucial that manufacturers utilize Global Pricing Management (GPM) solutions that support a variety of pricing simulations and controls to prevent price erosion. This includes capabilities to automate and track multi-country launches, the ability to conduct pricing and sales forecasting, and a validated price and reimbursement database that is 100% accurate. By unifying all divisions and systems into one end-to-end GPM platform built specifically for pharma, companies can execute innovative pricing strategies more effectively, enabling revenue optimization and price protection globally.

Global Tender Management

As the complex bidding process only becomes more competitive, global tenders must be managed efficiently to allow planning and prioritization of tender response activities. Departments can shape and respond to tenders with limited resources, acting locally, but coordinating globally, to execute efficiently by streamlining auditable approval workflows, tracking

and analyzing tenders for continuous improvement, and developing best practices as the number of tenders grows.

Just like Global Pricing Management, utilizing a unified solution to help plan, create, execute, track, and analyze global tenders has been proven as the key to winning more bids. An integrated Global Tender Management solution allows for teams to have visibility into all 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. Today's technology offers enhanced controls and insights to streamline the bidding process, promote cross-functional collaboration, reduce risk, and increase top line revenue.

MANAGING CONTRACTS, PAYERS, AND PROVIDERS

Contract Management

Organizations that integrate contract creation, management, and renewal with revenue operations realize greater returns. A smoothly functioning contracting and pricing group that is operating at the highest levels can not only optimize organizational processes, but, in fact, can add real dollars to the top line.

By eliminating disjointed and manual contracting processes, sales and legal teams are able to close more business faster, increase margins, and streamline operations. The digital revolution has brought solutions to market that automate contracting between payers and providers, and guide the negotiations that result in contract execution. This includes price and rebate programs and their complex measurement and discounting terms. Additionally, critical operational information, such as real-time prices and eligible contracts, are easily accessible during contract authoring. It is

recommended that contract management solutions are tightly integrated into payer and provider management solutions to also ensure the correct price, rebates, and complex measurement and discount terms are adhered to.

Payer Management

To support pharma manufacturers in navigating the complex requirements for formulary, market share, and price protection calculation, pharma companies are implementing cloud-based payer management solutions that offer a comprehensive approach. On average, pharma organization pay 25-31% of revenue in rebates with heavy penalties for late payments. This makes accurate and timely chargeback validation, calculation, and settlement crucial to success.

Rebates are becoming more innovative and value-based, and with that complexity, it is increasingly more difficult to model and execute. It is no longer enough to prove a new product is safe and effective; manufacturers also need to 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. True payer management solutions keep structured contract documents in a single repository to reduce manual effort, leverage pre-approved templates and clauses (value-based and traditional), automate workflows and approvals, reject invalid claims, and reduce rebate overpayments. To offer value beyond pricing, the right solution must support flexible contracts, configurable data fields, and have robust analytics for payments and reporting.

Provider Management

Managing group purchasing organizations (GPOs), integrated delivery networks (IDNs), health systems, and local hospital agreements is often a cumbersome and manual process utilizing spreadsheets and aging systems. In order to proactively eliminate overpayments of fees and chargebacks, and to provide visibility into customer commitment

tracking, manufacturers are implementing cloud-based SaaS provider management solutions. There is power in using the massive amounts of data we now have to address customer purchasing behaviors and manage price-tier commitments. With clean and accurate data in a single solution, manufacturers are able to reach greater than 98% clean first-pass rates in processing chargebacks, in accordance with HDA best practices.

When building a strategy and solution to optimize your provider management processes, consider solutions that integrate the following:

- Contracting and pricing
- Channel management
- Purchase-based incentives
- Federal Supply Schedule compliance
- Membership management
- Contract compliance
- Accruals management

A key aspect of a provider management solution is intelligence and analytics. Real-time visibility and insights into your chargebacks, contracts, pricing, and compliance enables pharma companies to interact seamlessly with providers. These tools also allow teams to 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, biologics, and medical devices. The changes to the safe harbor rule may have been tabled, but the cry for price transparency continues, and most industry thought leaders are expecting new regulatory rules and mandates to come soon. In the meantime, it is imperative that pharmaceutical manufacturers comply with current regulations to avoid increased fines and preventable revenue loss. To manage risk today as well as prepare for the unknown tomorrow, consider systems, tools, and processes that are currently in place as well as the level of flexibility, agility, and innovation that can be achieved through them.

Cloud-based and data-driven revenue management technologies, comprised in a single system of record, will play an integral part in helping manufacturers transition to a new set of industry rules and standards, and in dealing with the many possible changes that are on the horizon. SaaS solutions offer regular and automated updates to incorporate changes to government pricing and reporting regulations so that manufacturers can stay in compliance while supporting every transaction, price, rebate and adjustment.

Medicaid

Changing dynamics in the pharma and government landscape have also made it vital that all Medicaid data lives in a single source so that manufacturers can navigate shifting regulations. 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, manufacturers

can no longer afford to rely on disparate legacy systems and integration that can be slow and produce inaccuracies.

Today's cloud-based and automated technology enables pharma organizations to reduce overpayments in Medicaid rebates through aggregated or RX-level utilization data validation. Systems are able to differentiate Medicaid and commercial transactions, automating correct validations, and further reducing revenue leakage and potential for human error.

An automated solution that ensures accurate and timely claim remittances to Federal and State governments should offer:

- Medicaid claims movement
- Automated disputes and adjustments
- Pre-loaded URA formulas
- Regulatory update packs to stay current
- Formula builders
- Validations and reasonability tests

By implementing Global Pricing Management and Medicaid solutions that are robust and cloud-based, manufacturers are reducing fraud, minimizing risk, ensuring compliance, and maximizing revenue.

END-TO-END REVENUE EXECUTION

Integrated and transparent contract management, revenue operations, and risk mitigation functions are table-stakes in today's dynamic pharmaceutical manufacturing industry. It is no longer sufficient to knit together point solutions, manage through spreadsheets, or outsource the work. 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.
Pharma companies using Model N Revenue Cloud for Pharma are able to automate and streamline people, processes, and technology across many functional areas, including:

- Global Pricing Management
- Global Tender Management
- Contracting and Chargebacks
- Payer Management
- Provider Management
- Medicaid
- Government Pricing

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

VISIT US

at **modeln.com** for more information or contact us at **info@modeln.com** to receive a complimentary Revenue Execution Assessment and ROI Analysis with a Pharma Revenue Management expert

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