

Navigating MFP Effectuation Under the IRA

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EBOOK



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The Inflation Reduction Act (IRA) introduces sweeping healthcare reforms designed to reduce prescription drug costs for Medicare beneficiaries, ushering in a new era of regulatory and financial complexity for pharmaceutical manufacturers. Key provisions now taking effect include the Manufacturer Discount Program (MDP), inflation penalty rebates, the Medicare Drug Price Negotiation Program (MDPNP), and the launch of Maximum Fair Price (MFP) effectuation under the MDPNP.

MFP stands out as a transformative mandate with broad implications. It imposes strict payment deadlines and heightened audit scrutiny while triggering cascading effects across related programs such as Medicaid and 340B, as well as manufacturers' financial forecasting models. These pressures elevate the importance of proactive compliance planning and real-time operational readiness, making MFP more than just a pricing change—it's a systemic shift.

For pharmaceutical companies, the challenge lies in translating this complex policy landscape into concrete action. MFP demands swift, precise execution and a strategic understanding of its ripple effects. This guide offers manufacturers a clear, practical roadmap to navigate MFP effectuation with clarity and confidence, equipping stakeholders to meet regulatory expectations and manage downstream impacts effectively.

What is MFP effectuation?

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What is MFP effectuation?

Under the MDPNP, the Centers for Medicare & Medicaid Services (CMS) now has the authority to negotiate prices for certain high-cost, brand-name drugs and authorized generics (AGs) without generic competition. The outcome is the MFP—a fixed ceiling price that applies to brand drugs and AGs, since AGs are licensed under the original NDA. While the brand manufacturer participates in negotiations, AG manufacturers are still bound by the resulting MFP, despite not being involved in the process.

Beginning with IPAY 2027, drugs will be selected annually, with announcements in February. Manufacturers must submit data within 30 to 45 days, and CMS will set the MFP by the end of November. The price takes effect 13 months later. Beyond Medicare, the MFP can establish Medicaid best price, potentially increasing Medicaid rebate obligations and reducing 340B/Public Health Service (PHS) pricing.

For manufacturers, MFP is a new normal, bringing operational, financial, and compliance challenges:

Tighter payment cycles: After a drug is dispensed, manufacturers must issue MFP-related refund payments within just 14 days—a sprint compared to traditional timelines, placing pressure on cash flow and operations.

Risk of duplicate discounts: MFP interacts with existing obligations under Medicaid and 340B, increasing the chance of overlapping rebates unless systems are carefully coordinated.

Forecasting challenges: Traditional gross-to-net (GTN) and government pricing (GP) models weren't built to accommodate MFP's fixed pricing. Manufacturers must adapt by reworking analytics, scenario planning, and contract assumptions.

¹ Centers for Medicare and Medicaid Services. "Negotiating for Lower Drug Prices Works, Saves Billions." August 15, 2024.

Medicare Drug Price Negotiation: By the numbers¹

\$6B

Estimated Medicare savings in 2023 if negotiated prices had been in effect

\$1.5B

Projected out-of-pocket savings for beneficiaries in 2026

38–79%

Range of discounts off 2023 list prices for the first 10 drugs

9M

Medicare beneficiaries who use at least one of the negotiated drugs

\$100B

Estimated federal savings over 10 years (CBO projection)

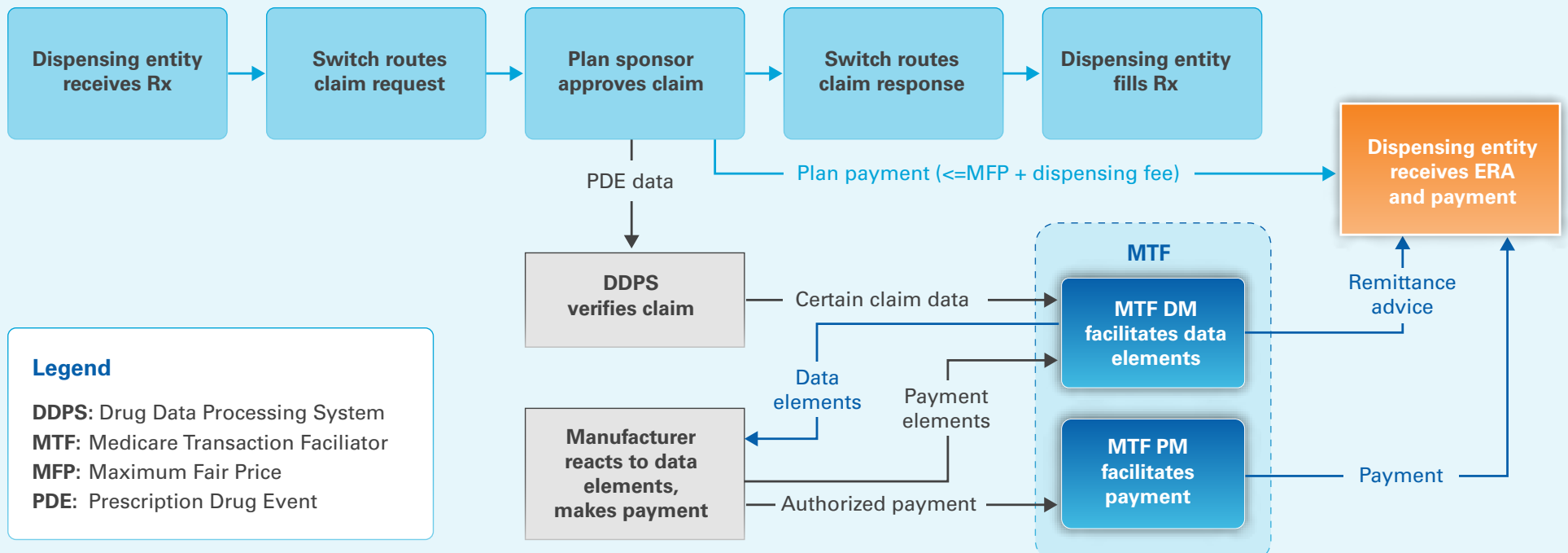
MFP payment processing

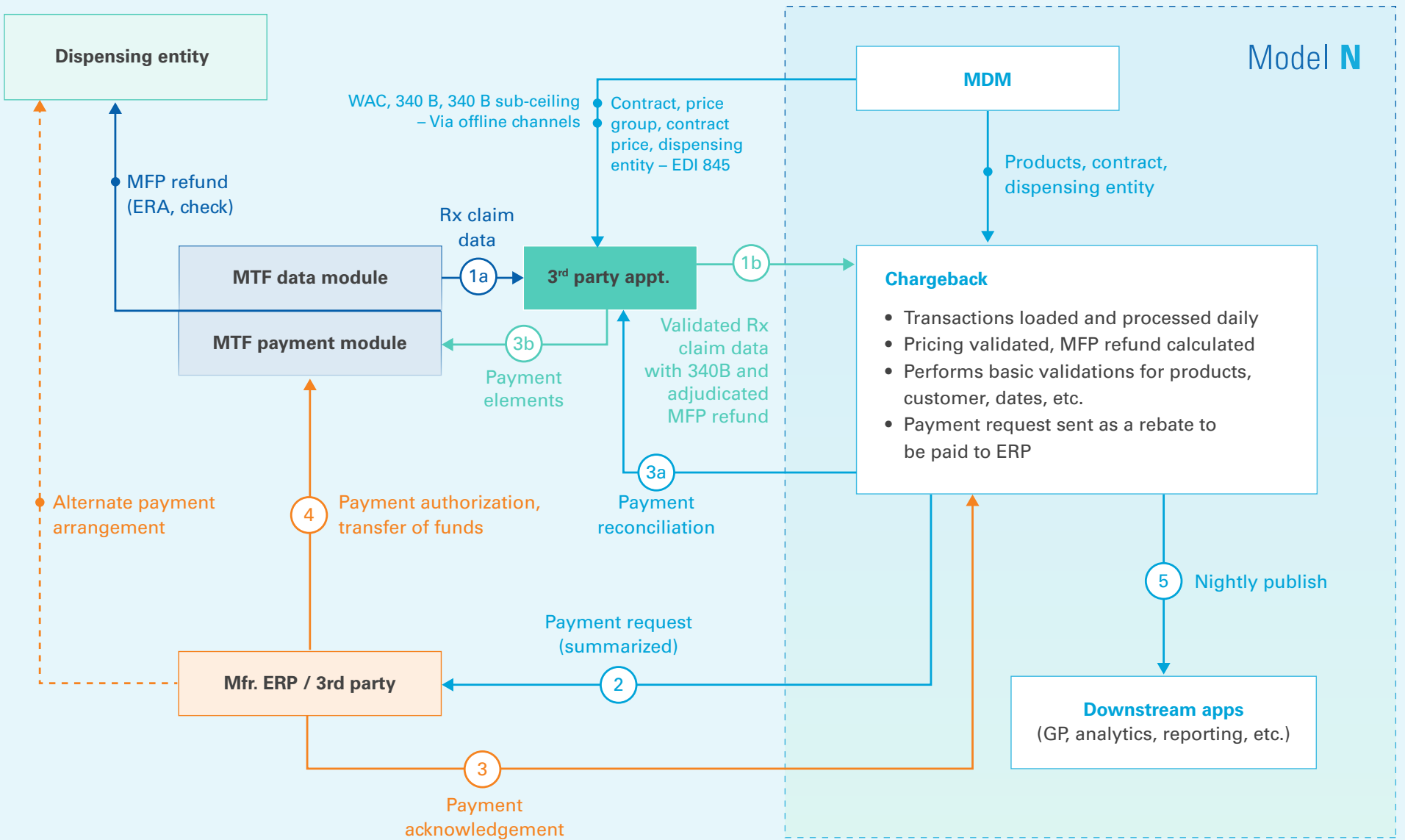
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MFP payment processing

The MFP program introduces a fundamental shift in how manufacturers handle payments, moving from traditional, periodic rebates to a high-frequency, fixed-timeline model. MFP payments must be issued in full within 14 calendar days of a Medicare Part D claim being verified as MFP-eligible. This accelerated cycle requires precise operational alignment and ongoing coordination with the Medicare Transaction Facilitator (MTF), the CMS-designated entity responsible for managing claim-level data exchange and payment validation.

MFP Process Flow and a View of Various Actors Involved





MFP and revenue strategy

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MFP and revenue strategy

Implementing the MFP is not simply a compliance requirement—it represents a fundamental shift in how manufacturers must manage revenue. The financial implications ripple across GTN models, forecasting, and overall pricing strategy. Because the MFP may establish the Medicaid best price, it directly affects key pricing elements such as the unit rebate amount (URA) and 340B ceiling prices. This introduces additional complexity into accrual planning, requiring the development of new models to accurately capture impacts at monthly and quarterly close. Forecasting efforts must also evolve to incorporate the interconnected effects of MFP on Medicaid rebates, PHS pricing, and downstream contract dynamics.

Strategically, companies must revisit and remodel historical revenue assumptions to reflect this new pricing environment. The implementation of MFP affects not just government pricing, but also commercial contracting behavior, discounting strategies, and channel decisions. Organizations will need to build in greater agility to accommodate annual changes in the list of MFP-eligible products, ensuring that pricing and forecasting systems remain responsive. These changes demand close coordination across finance, pricing, market access, and compliance teams.

Harsh penalties for pricing violations:

Up to **10x** the per-unit price, plus excise taxes for prolonged non-compliance



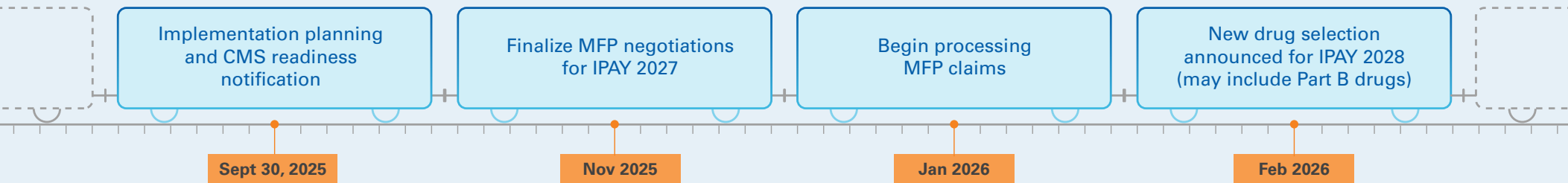
MFP readiness checklist

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MFP readiness checklist

Proactive planning is critical to avoid operational bottlenecks or missed compliance windows.

Key deadlines:



Preparing for MFP effectuation is like laying track for a high-speed train—it requires precision, coordination, and timing. The policy is advancing quickly, and if systems and teams aren’t aligned, the impact will be felt across compliance, finance, and commercial operations. This checklist highlights the critical areas manufacturers must address to stay on course and avoid disruption. Cross-functional teams should use the following questions to pressure-test their readiness and uncover gaps in policy, infrastructure, and planning before key deadlines arrive.



Policy and planning

Before implementation begins, organizations must establish clear internal policies for how MFP rebates will be calculated, validated, and challenged. This ensures consistency and audit readiness. Commercial and compliance teams should be trained on MFP’s unique risks and how it differs from traditional rebates, including the cross-functional coordination required. Without this understanding, new pricing strategies could unintentionally trigger best price implications downstream.

- Are internal policies for calculating, validating, and disputing MFP values clearly documented, and are they audit-ready?
- Are commercial and compliance teams fully trained on how MFP differs from traditional rebates and what cross-functional coordination is required?
- Could any planned pricing strategies unintentionally impact MFP exposure or trigger best price implications downstream?
- Does paying an MFP rebate create a potential duplicate discount for any commercial or government transactions?



Government pricing integration

MFP isn't a standalone process—it must be fully integrated into existing government pricing systems. Manufacturers need to update reporting logic to accommodate MFP transactions alongside Medicaid best price and average sale price (ASP) calculations; without the right foundation, errors and liabilities can follow. If MFP claims aren't processed accurately, manufacturers risk reconciliation issues and underreporting. For instance, when MFP sets a new Medicaid best price, it can reduce URA values and affect rebate payments and 340B pricing downstream.

- Are GP systems configured to process MFP transactions accurately?
- Can MFP claims be traced alongside Medicaid best price and AMP logic?
- How could MFP impact URA, rebates, and 340B pricing?



Rebates and payment processing

Unlike quarterly rebates with flexible timelines, MFP refunds run on a 14-day time clock. That's not a recommendation; it's a mandate. Payment operations teams must adapt to this accelerated rhythm by implementing efficient validation and batching processes. This might involve integrating with the Medicare Transaction Facilitator (MTF) and establishing new workflows for claim-level matching, payment tracking, and exception handling.

- Can the 14-day MFP payment deadline be met without delays?
- Are validation and batching processes tailored for MFP claims?
- Are teams aligned with MTF workflows for claim tracking and exception handling?



GTN adjustments

Financial forecasting doesn't just need a tune-up—it needs a new engine. Accrual models must be redesigned to account for MFP exposures that can shift monthly and affect net revenue across Medicare, Medicaid, and 340B. Missteps in GTN forecasting can ripple into earnings guidance, contract terms, or financial reporting. For instance, if MFP becomes the new Medicaid best price, outdated models could cause accrual shortfalls in the millions.

- Have accrual models been updated to reflect monthly MFP exposure across Medicare, Medicaid, and 340B?
- Does GTN forecasting logic account for the full financial impact of MFP on revenue and rebate liabilities?
- What preparations have been made to adjust financial guidance, pricing strategies, and contract terms based on MFP-driven revenue shifts?

Model N solutions for MFP effectuation

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Model N solutions for MFP effectuation

Model N offers a suite of solutions designed to help manufacturers navigate the operational and strategic demands of MFP effectuation. At the core is support for chargeback-style processing through EDI integrations, enabling timely, compliant payment workflows that align with the 14-day MFP refund requirement. Model N also supports ERP system configuration to accommodate new MFP payment types, ensuring financial systems are equipped to manage evolving compliance standards.

In addition, Model N integrates with key ecosystem partners, allowing customers to streamline data exchange and claims validation. For upstream planning, Model N provides advisory support for MFP policy development and data strategy. At the same time, SaaS tools enable real-time GTN modeling and reporting—critical for tracking MFP impact across GTN metrics.

Wherever you are in MFP preparation, Model N is here to help. To meet different organizational needs, Model N offers scalable options: Business Services for operational outsourcing; Value Realization Services for system configuration and change management; and Advisory Services to support forecasting, pricing analytics, and long-term planning. These combined capabilities help manufacturers ensure they are compliant and financially prepared for MFP’s far-reaching effects.

BUSINESS SERVICES — operational outsourcing	ADVISORY SERVICES – forecasting and pricing impact analysis	VALUE REALIZATION SERVICES – configuration and change management
Model N Business Services provides fully managed, end-to-end business process outsourcing to support MFP effectuation. This offering is available as a standalone service, requiring no additional product subscriptions, and is designed to help manufacturers meet compliance and processing requirements with speed, accuracy, and minimal internal burden.	Model N Advisory Services delivers expert consulting support for MFP-related initiatives. Our industry experts offer guidance across a wide range of strategic areas, including pricing impact analysis, policy and procedure development, GTN model design, IRA compliance strategy, and customized training. This service is designed to help manufacturers navigate regulatory complexity with confidence and agility.	Model N Value Realization Services support the implementation and seamless integration of Model N solutions with third-party MFP service providers, as well as broader enterprise ecosystem applications. This ensures data alignment, operational continuity, and optimized performance across the technology landscape.



Let's get to work

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Let's get to work

As MFP implementation reshapes pricing and compliance strategies, Model N is actively monitoring related developments, including the potential rollout of Most Favored Nation (MFN) pricing regulations. While MFN remains in flux, its potential to influence Medicare, Medicaid, 340B, and Federal Supply Schedule (FSS) pricing structures could introduce further complexity for manufacturers already navigating the demands of the Inflation Reduction Act.

To stay ahead, manufacturers will need to do more than meet compliance deadlines; they must prepare for an evolving regulatory landscape. Model N Advisory Services are designed to help assess and adapt pricing strategies in response to shifting federal policy, ensuring business remains agile and prepared for future reforms.

As MFP takes full effect, success will depend not just on operational execution, but on strategic foresight and integrated planning. This eBook has provided the foundational knowledge needed to manage MFP effectuation and minimize associated risk. The next step is action.

Connect with Model N to explore how our innovative technology platform and expert services can help you execute MFP initiatives quickly, accurately, and confidently.



What to watch: 2026–2028 Outlook

- Possible reintroduction of MFN pricing mandates
- Expanded drug categories under MFP eligibility
- Tighter audit controls and real-time reporting expectations
- Growing alignment across federal pricing programs

For more information on how Model N can help your organization reach IRA readiness, talk to one of our experts.



Our blog offers comprehensive updates on key issues such as MFN policy developments and the ongoing IRA-driven transformation. We explore these trends in depth, providing strategic context beyond the headlines.

About Model N

Model N is the leader in revenue optimization and compliance for pharmaceutical, medtech and high-tech innovators. For 25 years, our intelligent platform has powered digital transformation for pharmaceutical, medtech, and high-tech companies with integrated technology, data, analytics, and expert services that deliver deep insight and control.

Our integrated cloud solution is proven to automate pricing, incentive and contract decisions to scale business profitably and grow revenue. Model N is trusted across more than 120 countries by the world's leading companies, including Johnson & Johnson, AstraZeneca, Stryker, SeagateTechnology and Microchip Technology. For more information, visit modeln.com

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