Navigating the Inflation Reduction Act (IRA)

What you need to know, how you can prepare, and when you need to take action.

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EBOOK

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The Inflation Reduction Act (IRA) of 2022 allocates federal spending to reduce carbon emissions, lower healthcare costs, provide funding for the Internal Revenue Service, and strengthen taxpayer compliance. 2025 is the year when much of the legislation set forth in the IRA will take effect, including three key provisions that will heavily impact many pharmaceutical manufacturers: the Manufacturer Discount Program (MDP), the Inflation Rebate Program, and the Medicare Drug Price Negotiation Program (MDPNP). This eBook provides important information to help pharma manufacturers gauge the effect of the IRA on their business and develop effective strategies for managing and operating in the sea of regulatory change.

87% **According to the Model N 2025 State of Revenue Report, 87% of pharma leaders say the IRA has already impacted their launch plans for specific diseases or therapeutic areas.[1]**

[1] www.modeln.com/state-of-revenue-2025

Manufacturer Discount Program

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Manufacturer Discount Program

One of the biggest differences pharma manufacturers will see in 2025 is a complete redesign of the Medicare Part D standard benefit, including the replacement of the Coverage Gap Discount Program (CGDP) with a new Manufacturer Discount Program (MDP).

The original Medicare Part D program had a gap in coverage – often called the "donut hole" – where Medicare patients were responsible for paying the full price for prescription drugs. This gap put a significant financial burden on Medicare patients, many of whom live on fixed income from Social Security benefits, causing them to risk their health if they couldn't afford medication while "in the gap." Beginning in 2011, the CGDP reduced the patient burden by shifting costs to pharma manufacturers, ultimately requiring manufacturers to pay 70% of the cost of prescriptions filled in the gap.

The redesign of Medicare Part D coverage finally eliminates the gap and replaces the CGDP with the Manufacturer Discount Program (MDP). Under the new MDP program, manufacturers' rebate rate drops significantly from the peak of CGDP rebates but expands both the number of filled prescriptions to be covered as well as the total Medicare patient population. Invoices for this program will be sent to manufacturers beginning in May 2025.

CGDP versus MDP: Key differences

CGDP	MDP
Retired Q4 2024, 17 quarter tail for unbilled utilization	Effective Q1 2025, first invoice in May 2025
Capped liability for donut hole stage	Uncapped liability (10% in initial phase, 20% in catastrophic phase)
No phase-in plan, same rate for all manufacturers	Small manufacturer and special exclusion statuses available; 10-year phased-in liability rate
Low-income subsidy excluded	Low-income subsidy expansion to increase volume
Billing pattern: Q1 higher costs and ease	Still unknown, but estimated to be slightly lower in Q1 as patients pay deductibles and are within out-of-pocket limits for initial coverage

Changes in cost sharing

The elimination of the donut hole means there are now three phases of Part D coverage, along with changes to the balance of cost-sharing responsibilities in the latter two phases:

1. **Deductible** – Beneficiary is responsible for 100% of their covered prescription drug costs until the deductible is met (unchanged from CGDP).
2. **Initial coverage** – Beneficiary pays 25% (unchanged) with a maximum out-of-pocket (MOOP) cost of $2,000 (down from $5,030). Part D plans (PDPs) pay 65% (down from 75%) and manufacturers pay 10% (up from 0%).
3. **Catastrophic coverage** – Beneficiary pays nothing (unchanged), PDPs pay 60% (up from 20%), manufacturers pay 20% (up from 0%), and Medicare pays 20% (down from 80%).

Phase-in of applicable discounts

Manufacturers who meet specific criteria as defined by the Centers for Medicare & Medicaid Services (CMS) are eligible to gradually increase their required discount percentage in phases. CMS categorizes these manufacturers into two groups:

Specified manufacturers are those that in 2021 had:

- A CGDP agreement in effect
- Total expenditures for CGDP-applicable Part D drugs that represented less than 1% of total expenditures for all Part D drugs
- Total expenditures for specified Part B single-source and biological products that represented less than 1% of total expenditures for all Part B drugs and biological products

Specified manufacturers can phase in discounts for an applicable drug when it is dispensed to an applicable beneficiary who is eligible for a low-income subsidy (LIS) on the date of service.

Specified small manufacturers are those that:

- Qualify as specified manufacturers
- Had total expenditures for any specified small manufacturer drugs covered under the Part D CGDP in 2021 that were greater than or equal to 80% of total expenditures for all specified small manufacturer drugs covered under Part D in 2021

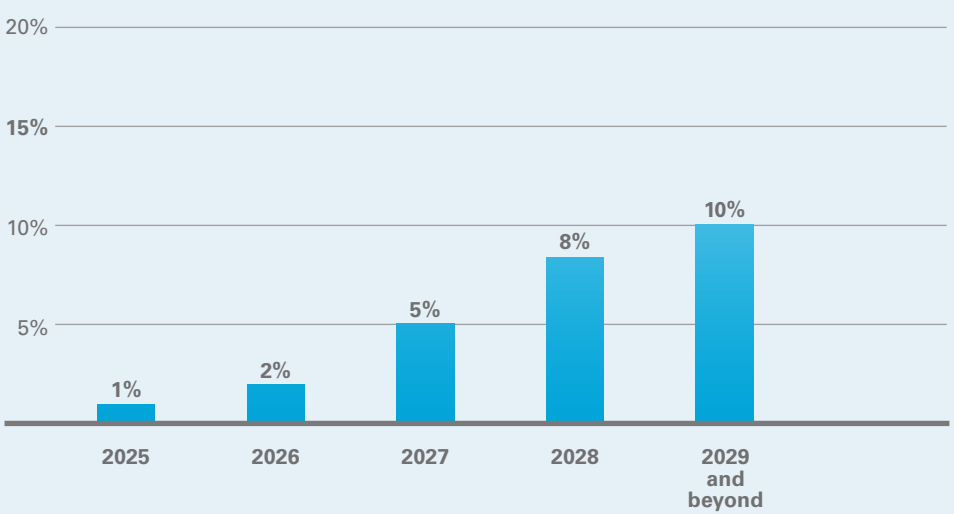
Specified small manufacturers can phase in discounts for an applicable drug when it is dispensed to any applicable beneficiary, regardless of LIS status.

For both groups, the phase-in program only covers applicable drugs that have been in the market as of August 16, 2022.

Phase-in discount timeline

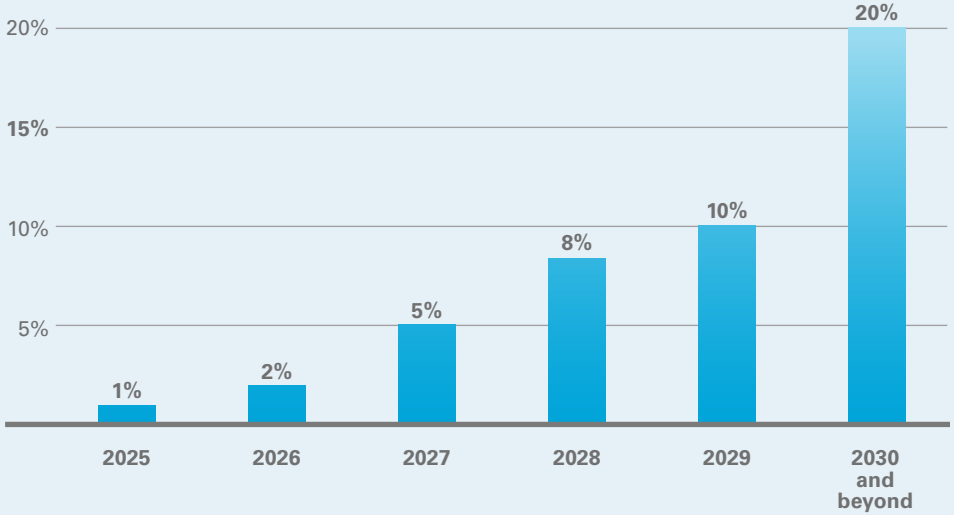
Initial coverage:

Where the beneficiary has NOT satisfied the OOP threshold



Catastrophic coverage:

Where the beneficiary HAS satisfied the OOP threshold



Inflation Rebate Program

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Inflation Rebate Program

In addition to the redesign of Part D drug coverage and MDP, the IRA includes a price-protection provision – similar to what we have seen previously in both Managed Care contracts and in Medicaid's Consumer Price Index for all Urban Consumers (CPI-U) penalty. This Inflation Rebate Program requires manufacturers to pay a rebate on both Part B and Part D utilization if they raise their drug prices faster than inflation. This rebate is paid to Medicare and is calculated and invoiced by CMS.

Part B inflation rebates: Facts and formula

Eligible Part B utilization × | **Rebate payment amount (ASP)** − **– Inflation-adjusted rebate payment amount** |

Inflation-adjusted rebate payment amount

Benchmark quarter payment amount × | **Rebate period CPI-U** / **Benchmark period CPI-U** |

Rebate per unit (RPU) based on average sales price (ASP)

Eligible Part B units excluding 340B volume

Billed quarterly beginning Q3 2025

Part D inflation rebates: Facts and formula

Eligible Part D utilization × | **Volume-weighted annual average manufacturer price (VAAMP)** − **Inflation-adjusted volume-weighted annual average manufacturer price (IVAAMP)** |

VAAMP

Q1 AMP ($/unit) × **Q1 AMP unit** / **Annual AMP unit** + ••• + **Q4 AMP** ($/unit) × **Q14 AMP unit** / **Annual AMP unit**

IVAAMP

Benchmark VAAMP × **Applicable period CPI-U** / **Benchmark period CPI-U**

RPU based on annual weighted average manufacturer price (AMP)

Eligible Part D units excluding 340B volume starting 2026

Billed annually beginning Q4 2025

Medicare Drug Price Negotiation Program

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Medicare Drug Price Negotiation Program

Under the IRA, CMS now has the ability to negotiate directly with drug manufacturers to lower the price of certain high-expenditure, single-source drugs without generic or biosimilar competition. Negotiations for the first set of drugs are in progress, with final negotiated prices scheduled to take effect in 2026. After that, up to 20 new products will be negotiated each year.

The IRA will impose a nondeductible excise tax on manufacturers that fail to enter into negotiated drug pricing agreements and also includes an "anti-abuse" rule under which the Department of Health and Human Services Secretary can treat a sale that was timed for the purpose of avoiding the tax as non-compliance.

Pushback from manufacturers

Many manufacturers feel that the MDPNP isn't a true negotiation but rather a demand for data in exchange for a dictated price. Furthermore, by exposing potential generics and biosimilars to a potential cap at the maximum fair price of the branded product, the IRA depresses the opportunity for manufacturers to earn the initial revenue they rely on and may prevent competition.

Most manufacturers won't be subject to the MDPNP right away, as it targets drugs that are among the highest-spending products in Medicare Part D. However, many anticipate a ripple effect across the industry, including:

- **Decreased revenue:** Many expect that the competitors of the negotiated drugs will be pressured to match or beat the reduced price for their products.
- **Shifts in investment strategies:** Some manufacturers may prioritize research and development (R&D) for drugs that are less likely to be subject to price negotiation.
- **Move to the commercial market:** Some manufacturers may focus marketing efforts more on the non-Medicare commercial market for more flexibility in pricing.
- **Hindered innovation:** Lower prices could potentially discourage R&D efforts for high-cost, novel drugs.

As of January 2025, there are seven ongoing lawsuits filed by pharmaceutical manufacturers against the federal government regarding the IRA.

A new way to pay

In December 2024, CMS introduced a new Third-Party Administrator (TPA) Manufacturer Payment Portal (MPP) to handle invoice distribution, report retrieval, and payments for manufacturers and sponsors across several Medicare programs. In addition to CGDP, the MPP has three new modules for the Discarded Drug Program (DDP) – a recent change to Medicare Part B drug reimbursement, not part of the IRA – the MDP, and the Inflation Rebate Program. Manufacturers are required to have a contracted P number to obtain access. Learn more at https://tpadministrator.com.

Gross-to-net (GTN) impact

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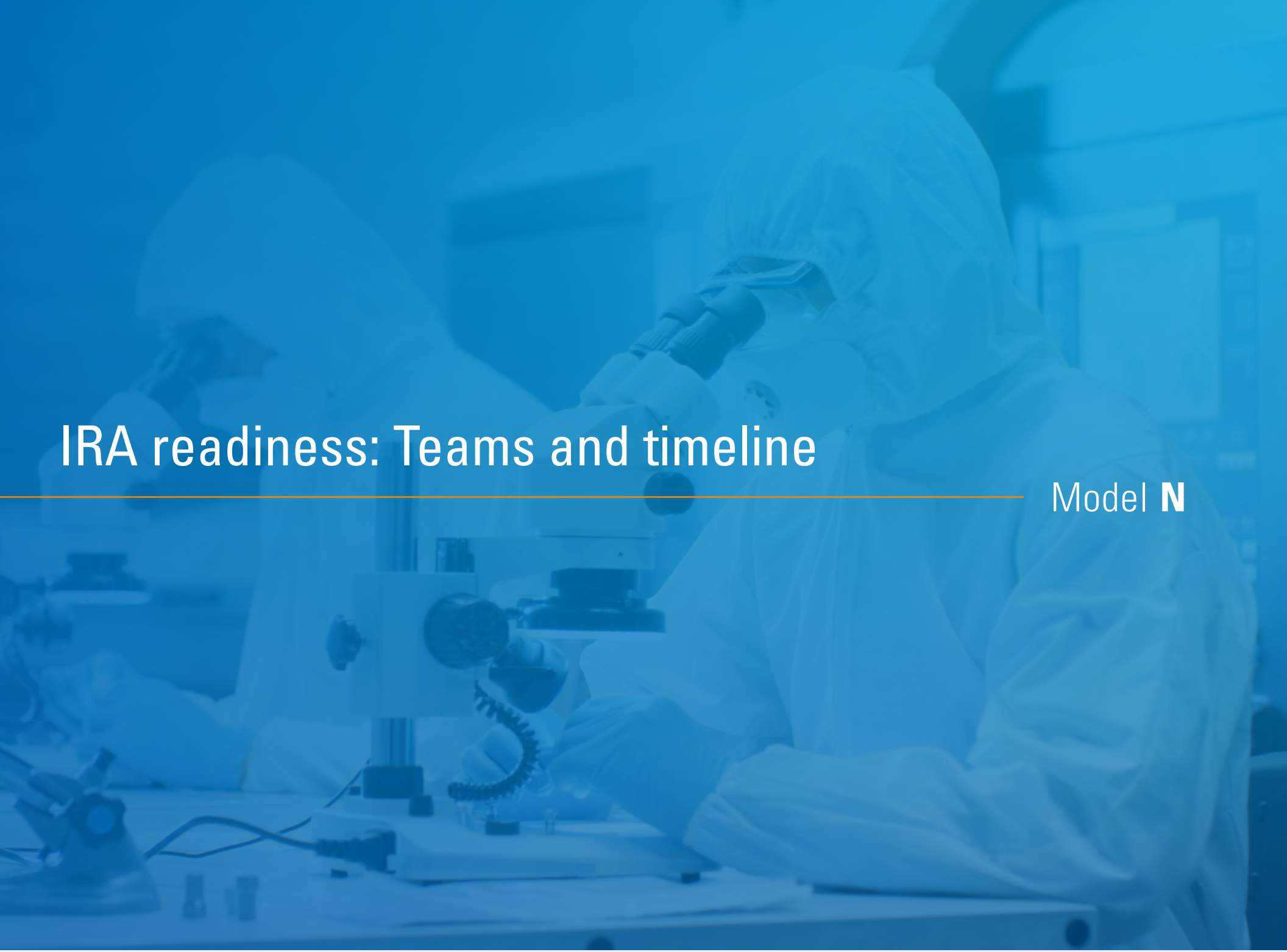
Gross-to-net (GTN) impact

Each of the three pharma-related components of the IRA introduces new challenges, and each has an equally challenging impact on manufacturers' bottom line. As such, they require new components in an already complex GTN calculation. As you address the operational concerns for IRA, consider the following for updating your GTN forecasts and accruals:

- **New categories in your GTN models**
  - MDP for Part D utilization
  - Inflation Rebate Program for both Part B and Part D utilization
  - MDPNP discounts, if applicable
- **Transition away from CGDP**
  - Seventeen quarter look-back for unbilled CGDP utilization – you may need to keep CGDP as a line until the beginning of 2028
- **MDP**
  - New structured manufacturer liability: 10% rebate using a similar model to CGDP; 20% rebate for all additional Part D utilization
  - Expanded coverage includes all previous Medicare Part D utilization, PLUS additional patients eligible through the Low-Income Subsidy expansion
  - Accrual seasonality will change due to the updated rebate model. Depending on your product price, you may expect lower rebates than CGDP early in the year, but an overall increase in rebates due to greater utilization
- **Inflation Rebate Program**
  - New benchmark models are required to establish maximum allowable price increases
  - Plan to assess your initial liability for inflation rebates, recognizing that the first invoices in 2025 may include multiple years of utilization
  - Update forecasts, accruals, and true-up processes to address quarterly rebates on Part B utilization and annual rebates on Part D utilization, where applicable
- **If necessary, create new models for your MFP under the MDPNP**
  - Project costs of data collection in order to comply may be significant



IRA readiness: Teams and timeline

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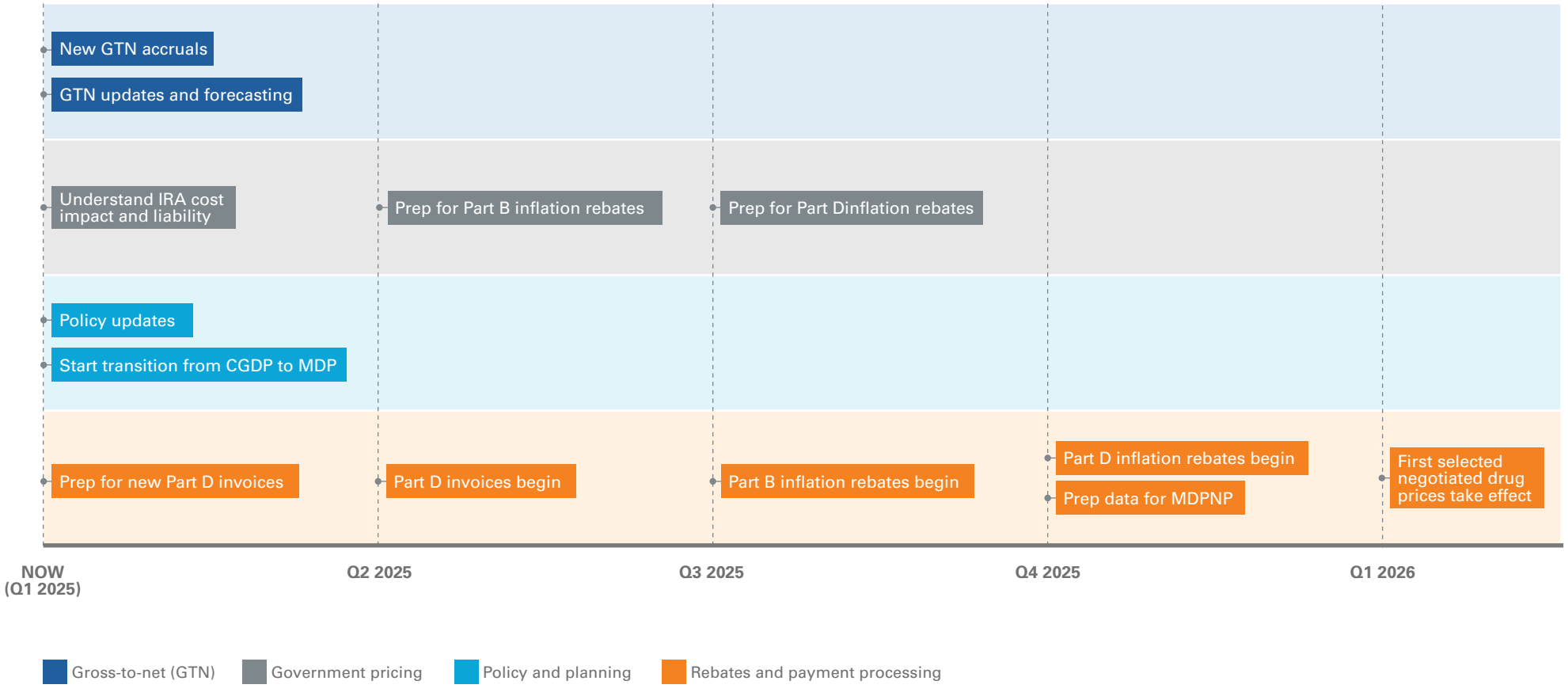
IRA readiness: Teams and timeline

Preparing for effective management and operation under the IRA requires organization-wide education and action. Key responsibilities by department include:

- **Policy and planning**
  - Define clear policies for new Medicare-related government pricing (GP) calculations
  - Develop procedures for GP, rebate processing, accounts payable, and financial planning and analysis to address IRA changes
  - Implement change management and education on IRA for commercial teams
- **Government pricing**
  - Compile inflation penalty benchmark data, weighted-annual AMP, and RPU calculations
  - Calculate expected Medicare MDP quarterly RPU
- **Rebates and payment processing**
  - Implement MDP and MFP-selected rebate validation
  - Enable inflation rebate validation
  - Begin payment processing for MDP, MFP-selected products, and inflation rebates
- **Gross to net**
  - Establish new GTN line items and models for IRA
  - Adjust annual forecasting for MDP in 2025 and reduction in CGDP
  - Conduct updates to monthly accruals, forecasts, and true-ups

IRA readiness timeline



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As pharma leaders prepare for 2025 and beyond, they're faced with the need to overhaul their compliance models to adjust to the many new challenges brought on by the IRA and other regulatory changes.

Through our industry-leading combination of advanced technology and expert services, Model N is committed to helping manufacturers design a new path forward – one that strikes a balance between risk and value.

Recent enhancements to our products and services include:

New Advisory Services

- Consulting services to develop or enhance policy and procedures
- Gross-to-net analysis
- Customized industry training
- Operations and strategy to address IRA and more

Expansion of Business Services

- IRA support for government pricing (GP) calculations, rebate validation, payment processing, and gross-to-net impacts
- Discarded drug refunds support

Product enhancements

- Powered by N support for IRA, including MDP, inflation penalties, and MFP effectuation
- State-specific updates and price threshold reporting in State Price Transparency Management

For more information on how Model N can help your organization develop and execute an IRA readiness plan, reach out to one of our experts.

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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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