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Spring/Summer 2026

# Inflation Reduction Act Update

## What's Changing in Drug Pricing

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Mintz's **Managed Care, PBMs & Pharmacies Practice** is pleased to present the "Spring/Summer 2026" edition of our *Inflation Reduction Act Update - What's Changing In Drug Pricing*, a regular publication that delves into developments of the Inflation Reduction Act of 2022 (IRA) and their impact on pharmaceutical supply chain stakeholders.

To help our clients track and stay up to date with developments related to the IRA, the *Inflation Reduction Act Update* provides informed and insightful analyses on the issues that directly affect your business.

# Inflation Reduction Act Update: What's Changing in Drug Pricing

*By Madison Castle, Theresa Carnegie, Stephanie John, Hassan Shaikh*

The Inflation Reduction Act (IRA) continues to reshape the US drug-pricing landscape as federal implementation accelerates and market responses evolve. In 2025, regulators advanced core IRA programs affecting Medicare negotiation, inflation rebates, and benefit redesign, while litigation, executive action, and agency rulemaking clarified, and in some cases expanded, the federal government's role in pharmaceutical pricing and access.

This update reviews key drug-pricing developments from 2025 and examines regulatory, enforcement, and market trends shaping 2026. With negotiated prices now taking effect, new payment and rebate models under consideration, and continued scrutiny of manufacturers, Pharmacy Benefit Managers (PBMs) and their stakeholders face a period defined less by statutory uncertainty and more by operational execution, compliance risk, and strategic adjustment.

## Medicare Drug Price Negotiation Program

The Medicare Drug Price Negotiation Program has moved from planning to execution, significantly expanding federal control over drug pricing. With negotiated prices now being implemented, additional drugs entering negotiation, including Part B drugs for the first time, and firm timelines in place, stakeholders must adjust contracting, operations, and compliance systems to operate within a maximum fair price–based reimbursement model.

### Expansion of Negotiated Drugs and Pricing Authority

In 2025, CMS advanced multiple phases of the IRA's Medicare Drug Price Negotiation Program (the "Negotiation Program"), including:

- **CMS selected 15 additional Part D drugs for the second negotiation cycle**, including Ozempic, Wegovy, and other chronic disease therapies. In November 2025, CMS released the negotiated prices, referred to as maximum fair prices (MFPs), which will take effect in January 2027.
- **CMS developed the Medicare Transaction Facilitator (MTF)** to implement MFPs for the first 10 negotiated drugs, starting January 1, 2026.
- **CMS issued Final Guidance for IPAY 2028**, bringing Part B drugs into the negotiation process for the first time.

Collectively, 2025 saw an increase in federal control of drug pricing, where stakeholders now need to adapt their contracting practices, operational systems, and compliance programs to function within the new MFP-based reimbursement model.

### Next-Phase Negotiations and Part B Entry

CMS is entering a pivotal phase of implementation for the Medicare Drug Price Negotiation Program. With the rollout of MFPs for the initial 10 Part D drugs (IPAY 2026) on January 1, 2026, the Negotiation Program is now operational for the first time.

In January 2026, CMS also announced the 15 additional drugs selected for the third cycle of negotiations. The third-cycle negotiations will include drugs payable under Part B for the first time, along with one drug, Tradjenta, selected for renegotiation. Third-cycle negotiations are slated to occur in 2026, and prices will take effect in 2028. On March 13, 2026, CMS announced that manufacturers for all 15 selected drugs agreed to participate in negotiations. CMS plans to issue initial MFP offers in June 2026, with manufacturers given 30 days to accept or counter. Negotiations will continue into mid-September, after which CMS will issue final offers by September 30. Manufacturers will then have until October 31 to accept or reject those offers, and CMS plans to publish the agreed-upon prices by November 30, 2026.

## Litigation Challenging the IRA Negotiation Program

*By Theresa Carnegie, Mitchell Clough, Xavier Hardy*

Legal challenges have largely failed to derail the Medicare Drug Price Negotiation Program, allowing negotiated prices to take effect and signaling that the program is on firm legal footing. While some residual litigation remains, the Supreme Court's refusal to hear challenges significantly reduces near-term uncertainty, shifting stakeholder focus away from constitutional risk and toward compliance and operational execution.

### Constitutional Challenges and Early Court Outcomes

Throughout 2025, the government secured a series of victories against manufacturer challenges to the Negotiation Program. Manufacturers have raised a smattering of theories seeking to upend the program. The Second and Third Circuits rejected constitutional attacks, emphasizing that Medicare participation is voluntary, and therefore refusing to block the reduced pricing. District courts likewise ruled for the government, including a Texas district court case brought by PhRMA and the DC district court's rejection of Teva's challenge.

With no successful challenge to block the program, the first round of IRA negotiated prices took effect on January 1, 2026, with CMS reporting an average discount of 63% off list price.

### Residual Litigation Risk

Cases continue to wind their way through the courts, including PhRMA's appeal in the conservative-leaning Fifth Circuit and Teva's appeal of its trial-court loss in the DC Circuit. Significantly, six manufacturers, including AstraZeneca and Novartis, asked the Supreme Court to weigh in on the issue. Even with the change in power in the executive branch, the Trump administration has still stepped in to defend the Negotiation Program's constitutionality.

On May 18, 2026, the Supreme Court denied all six petitions for certiorari filed by drug manufacturers challenging the IRA's Medicare Drug Price Negotiation Program, bringing much of the first wave of constitutional challenges to a close. This is effectively the end of the road for the first wave of challenges. There remain just two cases from the first wave pending — one in the Fifth Circuit and one in DC federal court. There have also been recent filings as the second and third waves of Negotiation Program drugs have been identified, with one already on appeal in the DC Circuit. A ruling in the manufacturers' favor in either circuit would create a live circuit split and could give the Supreme Court a reason to step in.

# Executive Action on Drug Pricing, MFN, and Tariffs

*By Grace Callander*, Theresa Carnegie, Xavier Hardy, Hassan Shaikh

Executive action has become a primary lever for drug-pricing policy, using MFN pricing and the threat of tariffs to pressure manufacturers on pricing and domestic production. While implementation remains unpredictable, these actions have already driven manufacturer investments, pricing negotiations, and accelerated decisions around US onshoring and participation in MFN agreements.

## MFN Pricing as Policy Leverage

Throughout 2025, the Trump administration issued multiple executive orders targeting drug pricing and access. In May 2025, the Trump administration issued the "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" Executive Order (the "MFN Executive Order"), aiming to align US drug prices with the lowest price offered to any "comparably developed" foreign country. By September, the administration escalated with a proposed "100% tariff" US-based production presence, while also pushing for greater supply, through efforts such as securing manufacturer commitments to a Strategic API Reserve.

## Tariffs as Industrial and Pricing Policy

While the 2025 Section 232 tariffs were at first delayed, then narrowed, and ultimately not enforced, the threat advanced the administration's priorities: Manufacturers announced investments in US production and came to the table to negotiate pricing deals with the administration.

## Implementation Uncertainty and Manufacturer Response

The threat and actual implementation of tariffs on pharmaceutical products has remained unpredictable in 2026 as drug manufacturers rush to comply with the ever-changing landscape.

While the Supreme Court ruled that the International Emergency Economic Powers Act (IEEPA) doesn't authorize the president to issue emergency declarations in order to impose broad import taxes without a clear authorization from Congress, pursuant to authority under Section 232 of the Trade Expansion Act of 1962, President Trump issued a presidential proclamation on April 2, 2026, "Adjusting Imports of Pharmaceuticals and Pharmaceutical Ingredients into the United States," outlining a plan to impose 100% tariffs on certain patented pharmaceutical products and ingredients. These tariffs are scheduled to take effect July 31, 2026 for most manufacturers, with a later date of September 29, 2026 for the 17 manufacturers originally targeted by the manufacturer letters.

The tariff structure includes:

- **Baseline:** A 100% tariff applies to imports of patented drugs and related ingredients.
- **Onshoring Incentive Option:** Companies with approved (or imminent) US manufacturing plans face a reduced 20% tariff, rising to 100% in April 2030.
- **Country-Specific Rates:** Rates for patented products coming from Japan, the EU, South Korea, Switzerland, and Liechtenstein.
- **Carve-outs:**
    - Orphan drug and high-need specialty drugs will have a zero tariff carve-out
    - Companies with Onshoring Incentive + MFN agreement

These proposed tariffs reflect the administration's goal to pressure smaller manufacturers' participation in MFN negotiations. On May 13, 2026, the Department of Commerce issued a notice announcing the procedures for pharmaceutical

manufacturers to apply for company-specific agreements with the Department "to onshore manufacturing of pharmaceutical products and their ingredients" in order to avoid the tariffs. Applications are requested by June 12, 2026.

## TrumpRx, Direct-to-Consumer Drug Sales, and Manufacturer Agreements

*By Grace Callander, Theresa Carnegie, Hassan Shaikh*

The administration is using MFN agreements and direct-to-consumer (DTC) strategies to reshape drug pricing outside of traditional legislative channels. While these deals have driven significant pricing commitments and US manufacturing investments, questions around transparency, sustainability, and the real-world value of TrumpRx signal ongoing uncertainty for manufacturers, payers, and patients.

**MFN Deal Architecture**

Following letters issued to 17 pharmaceutical manufacturers starting in September 2025, the administration has struck MFN agreements with many targeted drugmakers. These agreements consistently rested on three pillars:

- MFN pricing commitments for federal programs
- Promise to offer discounted medication(s) through a direct-to-consumer platform
- Investment pledges tied to US manufacturing and R&D

Several agreements focused specifically on GLP-1 therapies, creating a potential pathway for lower-cost access for federal program beneficiaries who meet the proposed covered indications.

At the same time, the Trump administration announced a federal DTC platform, "TrumpRx.gov," intended to serve both as an access point and as a reference for drug-pricing benchmarks. By promoting DTC platforms, the administration effectively blurred the lines between policy and market competition, signaling its intent to use DTC discounting as leverage against PBMs and other intermediaries.

***2026 Snapshot.*** In early 2026, the Trump administration accelerated efforts to finalize additional MFN agreements.

- **January 8, 2026: J&J announcement**
  - Agreed to offer MFN pricing to state Medicaid programs and through TrumpRx
  - Reaffirmed a $55 billion, four-year US manufacturing and R&D investment
  - Announced plans for new US-based manufacturing facilities
- **January 12, 2026: AbbVie announcement**
  - Committed to lower Medicaid prices and expand DTC access to four widely used medications via TrumpRx
  - Announced a $100 billion, 10-year commitment to US manufacturing and R&D, the largest tied to an MFN agreement to date
- **April 23, 2026: Regeneron announcement** (the final MFN agreement among the originally targeted 17 manufacturers)
  - Committed to comparable MFN pricing provisions
  - Pledged $27 billion in US R&D and manufacturing by 2029
  - Announced that as part of the agreement, a "new gene therapy for a

rare type of genetic deafness . . . will be given to U.S. patients at no cost," though eligibility and distribution details remain unclear

**Oversight, Transparency, and Sustainability Concerns**

Despite these developments, the administration continues to face scrutiny from Congress over the confidentiality of MFN agreement terms, a challenge that has thus far prevented securing the legislative support needed to codify the framework. As previously discussed, the administration has pivoted, aiming to obtain legislative and industry support for codification of the MFN deals by hosting discussions with pharmaceutical companies to brainstorm proposed legislation. Underwhelming reviews on early performance of TrumpRx has also been seen: Three months after its February 2026 launch, users and industry stakeholders report that discounts on many drugs mirror existing manufacturer coupons, and that insured patients often pay less through their health plans than via the platform. On May 18, 2026, the White House announced that TrumpRx will now "feature more than 600 generic medications."

**CMS Innovation Center and Pilot Models Affecting Drug Prices**

CMS is signaling a clear shift toward international reference-based drug pricing across Medicare and Medicaid, creating potential new rebate obligations and pricing pressure for manufacturers. While these Innovation Center models are still early and evolving, they point to increased scrutiny of US drug prices and set the stage for future debates over access, affordability, and sustainability for high-cost therapies.

In late 2025, the CMS Innovation Center announced several proposed rules to implement models aligned with the administration's MFN pricing initiatives:

- **GLOBE (Global Benchmark for Efficient Drug Pricing)** would impose mandatory rebates for certain Medicare Part B drugs when US prices exceed those paid in comparable OECD countries
- **GUARD (Guarding US Medicare Against Rising Drug Costs)** would apply a similar rebate mechanism to high-cost Medicare Part D drugs
- **GENEROUS (Generating Cost Reductions for US Medicaid)** seeks to align Medicaid net prices with international benchmarks through CMS-led negotiations and supplemental manufacturer rebates for participating states

These models reflect the administration's commitment to embedding international reference-based drug pricing into the Medicare and Medicaid programs, signaling continued scrutiny of US drug prices and the risk of substantial rebate obligations for manufacturers.

***2026 Snapshot.*** These models remain in the early stages of development and implementation but reflect a clear federal move toward international-based drug-pricing benchmarks and set up future debates on how to balance access to high-cost therapies with the realities of chronic disease management — particularly in therapeutic categories where large portions of the beneficiary population may meet clinical indications for therapy. The comment period for the GLOBE and GUARD models closed in late February 2026, with only a limited number of public comments. The deadline for manufacturer participation in the GENEROUS model is July 17, 2026. These developments have sparked concern from pharmaceutical industry stakeholders, especially over the expanding role of international drug-pricing benchmarks in the US.

**340B Drug Pricing Program Developments**

The 340B program continues to expand faster than oversight mechanisms can keep pace, increasing scrutiny around compliance, spending, and program integrity. While a proposed shift to rebate-based pricing was halted by the courts, federal and state activity signals that reform efforts

are not over — leaving stakeholders facing continued uncertainty, legal risk, and the likelihood of future structural changes.

***6(a) Growth Without Guardrails: 340B Program in 2025***

***2025 Developments.*** Throughout 2025, debate over the rapid expansion of the 340B Program intensified as various federal reports detailed how the current scale of the program stretches far beyond its original intended structure. These analyses discuss how contract pharmacy networks, substantial revenue flow through hospitals and FQHCs, and increasingly complex third-party administrator arrangements have fueled the increase. At the same time, oversight has not kept pace. A report by the CRS detailed how courts have seemingly narrowed HRSA's enforcement reach, states have adopted inconsistent contracting protections for pharmacies, and HRSA lacks the broad rulemaking authority needed to keep pace with a much larger system.

Budget and oversight agencies, including the CBO, have concluded the current 340B program may drive higher federal spending. The GAO similarly links growth to oversight limits, noting covered entity sites more than doubled from 2013 to 2023 and identifying persistent weaknesses in HRSA's compliance tools, including gaps in duplicate discount oversight and eligibility verification. As a result, debates over rebates, distribution models, and program integrity are unfolding against a backdrop where the program keeps expanding and where participants forge ahead with new initiatives, all while the program's guardrails remain fragmented.

***2026 Snapshot.*** With no new comprehensive federal reports issued in 2026, recent state activity is helping shape the next phase of the 340B debate. The Minnesota Department of Health's latest statewide 340B transparency report added new empirical context to long-standing concerns about the program's growth and concentration among hospital participants. At the same time, states such as Washington continue to join the growing ranks of states that have enacted broad 340B contract pharmacy and reporting laws. Washington's effort has already sparked litigation in federal court and further highlights the limits of resolving these issues through state action alone.

***6(b) HRSA Pauses 340B Rebate Model Pilot After Court Injunction***

***2025 Developments*.** In late 2025, HRSA approved a voluntary 340B Rebate Model Pilot that would have replaced upfront discounts with post-sale manufacturer rebates for a limited set of drugs. On December 29, 2025, the US District Court for the District of Maine enjoined the program, finding that HRSA likely failed to address covered entities' reliance interests and operational impacts in violation of the Administrative Procedure Act. HRSA subsequently ended its appeal and formally rescinded the pilot approvals in February 2026. The litigation underscored the legal and operational risks of converting 340B from an upfront discount program into a rebate framework, particularly with respect to cash-flow strain, administrative burden, and decades of program reliance by covered entities.

***2026 Snapshot.*** Although the pilot has been withdrawn, the rebate concept remains under active federal review. In February 2026, HHS submitted a revised rebate concept to the Office of Management and Budget for pre-rule review, and HRSA issued both a Request for Information and an Information Collection Request to rebuild the administrative record. These steps signal a methodical reset rather than abandonment of rebate-based pricing, with any future pilot or rulemaking likely delayed until HRSA completes stakeholder consultation and establishes a more defensible process.

## GLP-1 Therapies, Obesity Coverage, and Affordability

*By Grace Callander, Theresa Carnegie, Madison Castle, Hassan Shaikh*

GLP-1 therapies remain a major focus of affordability and access efforts, but progress is uneven across programs. While Medicaid access is expanding and short-term Medicare pathways are in place, coverage delays, rising utilization, enforcement against compounded products, and increased regulatory scrutiny mean patients, plans, and manufacturers face a rapidly evolving and more tightly regulated GLP-1 landscape.

**GLP-1 Coverage Expansion Efforts**

Access to GLP-1s for obesity remained a focal point of health care policy in 2025:

- While the Trump administration did not move forward with the Biden-era proposal for Medicare Part D and Medicaid GLP-1 coverage for weight management, CMS launched the BALANCE model allowing state Medicaid programs to cover GLP-1s for weight management if manufacturers agree to negotiated net prices.
- CMS also announced a short-term initiative, the Medicare GLP-1 Bridge Program, designed to provide access to these therapies by July 2026.
- Outside of the federal health care programs, GLP-1s were also a focus in MFN deals with manufacturers, resulting in discounted cash prices available through DTC platforms. Some manufacturers are also developing direct-to-employer models.

**GLP-1 Market Growth and Manufacturer Strategy**

GLP-1 use continues to surge. Approximately 1 in 8 adults currently take a GLP-1, and total spending has increased by more than 500% from 2018 to 2023, promoting commercial plans and employers to reassess coverage strategies.

Manufacturers also intensified scrutiny of compounded GLP-1s, with Novo Nordisk and Eli Lilly filing multiple lawsuits against compounding pharmacies alleging, among other things, trademark infringement, false advertising, and potential safety risks associated with compounded products.

Following a headline-heavy 2025, the focus in 2026 is shifting toward implementation, enforcement, and market response.

After major Part D sponsors declined to participate in the BALANCE model, in late April 2026 CMS announced that it would delay the Medicare Part D component of the model, originally slated for a 2027 launch. Meanwhile, CMS also moved to extend the Medicare GLP-1 Bridge Program to run for an additional year, through the end of 2027, positioning the Bridge Program as the primary near-term access pathway for Medicare beneficiaries seeking GLP-1 therapies, with a $50 monthly copay for eligible beneficiaries. Despite the setback on the Medicare side, the Medicaid component of the BALANCE model is still moving forward, with state application open through July 31, 2026 and participation beginning between May 2026 and January 2027.

The administration has also highlighted the "historic price reductions" for Ozempic and Wegovy following the launch of TrumpRx in February. Regulatory scrutiny of compounded GLP-1s has also intensified. In February, the FDA released a statement of its intent to restrict the dissemination of non-FDA-approved GLP-1s as shortages ease, followed by an April 1, 2026 Drug Alert clarifying the conditions under which compounding pharmacies may produce GLP-1 therapies under the Federal Food, Drug, and Cosmetic Act.

As regulatory enforcement and litigation continue to escalate, some compounding pharmacies may consider scaling back or discontinuing their compounded GLP-1s offerings altogether.

# Medicare Part D Redesign and Part B Changes

*By Madison Castle, Tara Dwyer, Stephanie John*

The IRA's Part D redesign and heightened Part B oversight are shifting both financial responsibility and compliance expectations across the Medicare program. As new cost-sharing limits, liability structures, and subsidies take effect alongside negotiated prices, plans and manufacturers must update systems and processes, while manufacturers also face increased documentation and enforcement risk under tighter Part B oversight.

**Structural Changes to the Part D Benefit**

After the initial announcement of the Part D redesign for CY 2026, on April 7, 2025 CMS released the Final CY 2026 Part D Redesign Program Instructions implementing the IRA's major updates to Medicare Part D. Key changes include:

- **Annual out-of-pocket (OOP) cap set at $2,100**, reflecting an inflation adjusted increase from the $2,000 cap established for 2025.
- **Revised liability structure** across beneficiaries, plan sponsors, manufacturers, and CMS to account for the introduction of negotiated drug prices for selected drugs beginning in 2026 under the Medicare Drug Price Negotiation Program.
- **Creation of the Selected Drug Subsidy Program**, which provides a 10% subsidy to Part D plans for selected drugs to reduce plan liability on negotiated prices for beneficiaries (1) enrolled in a standalone PDP or MA-PD plan and (2) who have not incurred costs that are equal to or exceed the annual OOP threshold of $2,100.
- **Revision of the Creditable Coverage Simplified Methodology**, requiring non-retiree drug subsidy group health plans to cover at least 72% of participants' prescription drug expenses (up from 60%) to align with the IRA-enhanced Part D benefit; for CY 2026 only, plans may use either standard.
- **Formulary substitution flexibility guidance**, affirming that Part D plan sponsors may substitute a selected brand-name drug with its generic equivalent, or a selected reference biological product with an interchangeable biosimilar, during the price applicability period.
- **Heightened Part B Compliance Expectations.** On November 5, 2025, CMS finalized a CY 2026 Physician Fee Schedule rule covering key Part B Program changes effective January 1, 2026. CMS declined to finalize proposed changes to Bona Fide Service Fees (BFSFs) definitions but did finalize new requirements: Manufacturers must now submit reasonable assumption letters documenting FMV methodology and certification letters from BFSF recipients confirming that the fees are not passed through to affiliates, clients, or customers.

***2026 Snapshot.*** In 2026, stakeholders have focused on operationalizing the redesigned Part D benefit by updating systems to apply the new $2,100 OOP cap, revised liability structure, formulary substitution flexibilities, and the Selected Drug Subsidy Program as negotiated drug prices take effect. At the same time, manufacturers are navigating heightened Part B oversight, as CMS will begin enforcing new documentation requirements for BFSFs, including FMV assumption letters and recipient certifications confirming that fees are not passed through to third parties.

# FDA Importation of Prescription Drugs from Canada

*By Theresa Carnegie, Elizabeth Dennis, Hassan Shaikh*

The FDA's push to revive prescription drug importation from Canada reflects renewed efforts to lower drug costs, but meaningful impact remains uncertain. While federal agencies are streamlining approvals and encouraging state participation, delays, supply-chain challenges, and likely legal opposition continue to pose significant barriers to implementation.

**Program Evolution and Policy Objectives**

President Trump issued the "Lowering Drug Prices by Once Again Putting Americans First" Executive Order (the "Americans First EO"), directing HHS to "streamline and improve" the Section 804 Importation Program (SIP) of the Federal Food, Drug, and Cosmetic Act. Congress enacted SIP in 2000 to allow importation of prescription drugs from other countries, though a 2003 amendment limited the SIP to Canadian imports. The program was not implemented until the first Trump administration issued the SIP 2020 Final Rule.

In January 2024, Florida became the first state to receive SIP proposal approval, though the program has yet to launch despite its third extension as of November 2025 and approximately $82 million in state spending. Following the Americans First EO, the FDA announced enhancements to the SIP, including plans to pre-review proposals, collaborate with applicants, and develop tools and materials to streamline the required cost savings analysis.

***2026 Snapshot.*** In March 2026, the FDA met with several states interested in submitting SIP proposals to make it easier for them to obtain authorization. If launched successfully, SIPs could impact the pharmaceutical supply chain. Moreover, this program could potentially reduce the cost of certain prescription drugs.

**Implementation Barriers and Legal Risk**

However, the program faces strong opposition from the Pharmaceutical Research and Manufacturers of America (PhRMA). In 2023, PhRMA challenged the 2020 Final Rule, though the case was dismissed for lack of standing as no SIP had been authorized at the time. If the administration's push for SIPs in 2026 is successful, similar legal challenges are likely to arise. In the context of the Florida SIP delays in implementation, it remains unclear as to whether Florida will be able to get Canadian manufacturers to export drugs to the US.

**IRA Inflation Rebate Program**

The IRA Inflation Rebate Program is now fully operational, creating ongoing financial and compliance exposure for manufacturers whose drug prices outpace inflation. With CMS actively invoicing rebates, refining methodologies, and expanding reporting infrastructure, manufacturers must closely monitor pricing strategies, rebate calculations, and 340B interactions to manage enforcement risk and avoid penalties.

**Rebate Mechanics and CMS Enforcement**

Throughout 2025, the IRA's Medicare Prescription Drug Inflation Rebate Program (the "Rebate Program") became fully operational, allowing CMS to invoice manufacturers for rebates on certain Medicare Part B and Part D drugs whose prices increased faster than inflation. As previously discussed, the program's central premise is to lower drug prices for Medicare Part B and Part D beneficiaries. CMS's 2023 implementation guidance for Part B and Part D established the core rebate framework for the Rebate Program:

- **Part B Rebates.** CMS determines inflation rebate liability for manufacturers based on the extent to which a drug's "specified amount" exceeds the inflation-adjusted payment amount. For single-source drugs, the specified amount is 106% of the lesser of average sales price (ASP) or wholesale acquisition cost (WAC); for biosimilars, it is 100% of the biosimilar ASP plus 6% of the ASP of the reference product ASP. Coinsurance for certain Part B drugs and biologicals with above-inflation increases is capped at 20% of the inflation-adjusted payment amount in certain circumstances.
- **Part D Rebates.** CMS assesses whether a manufacturer owes rebates by comparing the drug's annual manufacturer price to its inflation-adjusted payment amount, with CMS given nine months to invoice manufacturers for rebates.

As previously discussed, CMS also issued the CY 2025 Physician Fee Schedule Final Rule, implementing key policies, including rebate reconciliation, penalties for noncompliance, benchmark quarters, and removal of 340B units from Part B rebate calculations. CMS also launched the "Manufacturer Payment Portal" in 2025, allowing for online rebate reporting and payments.

**Methodological Refinements and 340B Interaction**

On January 1, 2026, the CY 2026 Physician Fee Schedule Final Rule took effect. It describes Part B benchmark quarter identification and rebate calculation in certain circumstances; finalizes the Part D methodology for 340B removal from rebates; establishes a voluntary 340B data repository for Part D claims for testing purposes; and expands on numerous sections of the 2025 Final Rule.

**PBM Regulation, Antitrust, and Rebate Reform**

Pharmacy Benefit Managers (PBMs) have experienced an increasing amount of targeted legislation, regulation, and lawsuits. Mintz carefully monitors the PBM industry and our updates are regularly available in blogs, articles, podcasts, webinars, and the *PBM Policy and Legislative Update*.

Notable 2026 PBM reform includes the Consolidated Appropriations Act of 2026, Department of Labor–proposed PBM transparency rules, FTC lawsuits, and federal drug-pricing initiatives.

## Frequently Asked Questions

**What is the focus of the Inflation Reduction Act (IRA) Update?**

This biannual update reviews key drug-pricing developments and examines emerging regulatory, enforcement, and market trends as shaped by the IRA and other industry changes.

**What major developments occurred in the Medicare Drug Price Negotiation Program in 2025?**

In 2025, CMS advanced multiple phases of the IRA's Medicare Drug Price Negotiation Program, including selecting 15 additional Part D drugs for the second negotiation cycle, releasing negotiated prices in November 2025, developing the Medicare Transaction Facilitator (MTF), and issuing Final Guidance for IPAY 2028 bringing Part B drugs into the negotiation process for the first time.

**When do negotiated drug prices take effect?**

The negotiated prices for the second negotiation cycle will take effect in January 2027, while maximum fair prices (MFPs) for the first 10

negotiated drugs take effect starting January 1, 2026.

**Did the Supreme Court take up challenges to the Negotiation Program?**

On May 18, 2026, the Supreme Court denied all six petitions for certiorari filed by drug manufacturers challenging the IRA's Medicare Drug Price Negotiation Program, bringing much of the first wave of constitutional challenges to a close.

**What is TrumpRx?**

The Trump administration announced a federal direct-to-consumer platform, "TrumpRx.gov," intended to serve both as an access point and as a reference for drug-pricing benchmarks.

**What drug-pricing models has the CMS Innovation Center proposed?**

The CMS Innovation Center announced proposed models including GLOBE, GUARD, and GENEROUS, which would impose rebate mechanisms or align US drug prices with international benchmarks.

**Why was the 340B Rebate Model Pilot halted?**

On December 29, 2025, a federal district court enjoined the program, finding that HRSA likely failed to address covered entities' reliance interests and operational impacts. HRSA formally rescinded the pilot approvals in February 2026.

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