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Mintz **IRA Update**

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Mintz's **Pharmacy Benefits and PBM Contracting Practice** is pleased to present the 'Fourth Edition: Q1 2025' of our *Mintz IRA Update*, 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 the developments related to the IRA, the *Mintz IRA Update* provides informed and insightful analyses on the issues that directly affect your business. This edition of the *Mintz IRA Update* covers developments through January 2025.

The IRA in 2025: The Future of Medicare Part D

By Stephnie A. John, Abdie Santiago

Last year was a pivotal year for the pharmaceutical industry. Under the IRA's Medicare Drug Price Negotiation Program (the Negotiation Program), the US government negotiated the prices of 10 selected high-expenditure, single- source Medicare Part D Drugs (the Selected Drugs) for the first time in Medicare's history. As we discuss in our article summarizing the litigation challenging the Negotiation Program, manufacturers and stakeholders who filed lawsuits seeking to halt the program's implementation saw a number of losses in federal courts, and the negotiation process proceeded as scheduled in 2024. On August 15, 2024, the Biden administration announced the final negotiated maximum fair prices (MFPs) for the Selected Drugs, which will go into effect on January 1, 2026. We continue our discussion of the uncertain future of the Negotiation Program in light of the transition to the Trump administration and pending lawsuits following the end of *Chevron* deference in a separate article. But as our team looks ahead to 2025, we are paying close attention to the next area of significant reform under the IRA: the major overhaul of Medicare Part D's benefit structure.

Medicare Part D Benefit Redesign

In our last issue, we provided an in-depth overview of the various changes to the Part D benefit design and other program features that went into effect on January 1, 2025. The liability for drug costs paid by Part D beneficiaries and the costs and risks borne by Part D plan sponsors (PDPs), drug manufacturers, and CMS have changed significantly. As a quick recap, the coverage gap in Part D has been eliminated, and the cost-sharing amounts for each Part D benefit phase are now as follows:

- ***Annual Deductible Phase:*** Part D beneficiaries remain responsible for 100% of drug costs during the annual deductible phase.
- ***Initial Coverage Phase:*** Part D beneficiaries continue to be responsible for 25% of drug costs in the initial coverage phase. However, their annual out-of-pocket costs are capped at $2,000 (including what they have paid in the deductible phase). PDPs will be responsible for 65% of the cost of Applicable Drugs, (as defined by 42 CFR § 423.100) and for 75% of the cost of Non-Applicable Drugs (any Part D drug that is not an Applicable Drug and is not a Selected Drug). Manufacturer discounts of 10% are applied to the cost of Applicable Drugs, but manufacturers do not share any responsibility for Non-Applicable Drugs.
- ***Catastrophic Phase:*** In the updated catastrophic phase, PDPs will be responsible

for 60% of the cost of both Non-Applicable and Applicable Drugs. CMS, through reinsurance, will cover 40% of the cost of Non-Applicable Drugs and 20% of the cost of Applicable Drugs. The remaining 20% of the cost for Applicable Drugs will be covered by the manufacturer discount.

Impact of Medicare Part D Redesign

Although the changes only went into effect a few weeks ago, we are already seeing the impact of the shift in stakeholder liability based on data gathered from the CY 2025 PDP bid submission cycle. As a result of the reduction in CMS's liability in the catastrophic phase (from 80% in 2024 to 40% for Applicable Drugs and 20% for Non-Applicable Drugs in 2025), CMS's aggregate reinsurance payments to Part D plans are projected to account for only 17% of total Part D spending in 2025, a substantial reduction from 46% of total Part D spending in 2024. As PDPs take on additional responsibility for drug costs in the catastrophic phase, they also take on an increased amount of risk of losses, especially for beneficiaries who utilize more expensive drugs. However, because the IRA caps year-to-year increases in the base beneficiary premium, such premium for 2025 increased to $36.78, which represents the 6% increase allowed by the IRA. The national average monthly bid amount which impacts the payments that CMS must make to PDPs increased from $64.28 to $179.45 because of the redesign and shifting of final risk away from the government and to the PDPs. As we discuss further below, in 2024, CMS also implemented a voluntary demonstration program to provide additional premium stabilization and risk corridor protection for PDPs.

New Incentives in Formulary Design

As we predicted, the changes to the benefit structure have also shifted priorities for formulary placement between stakeholders. Prior to the IRA's Part D benefit redesign, the structure of the Part D benefit incentivized PDPs to prioritize high–list price brand drugs and biologics with high rebates on their formularies. Under the new benefit structure, with PDPs' increased liability and risk of loss in the catastrophic phase, PDPs are incentivized to cover lower-cost generics and biosimilars. Additionally, the Manufacturer Discount Program's (which replaces the former Coverage Gap Discount Program) mandatory manufacturer discounts applied in the initial and catastrophic coverage phases will likely prompt manufacturers to reduce the rebate amounts manufacturers are willing to offer on their drug products, further incentivizing PDP coverage of generics and biosimilars. Data analyzing the changes between 2024 and 2025 formularies confirms the accuracy of our predictions for a number of drug classes. For example, approximately 50% of Part D beneficiaries lost access to the brand name Humira biologic but gained access to adalimumab biosimilars. Manufacturers decreased the list price of brand-name insulin and inhaler products, thereby decreasing rebate amounts; hence, there are fewer 2025 formularies covering these brand-name products and a corresponding increase in formulary coverage of their generic alternatives.

However, PDPs may still be incentivized to prefer high–list drug products that come with high rebates, as the PDP will be able to apply a higher share of the manufacturer's rebate to the PDP's drug cost obligations in the catastrophic coverage phase. The Manufacturer Discount Program also incentivizes PDPs to shift utilization away from drugs produced by specified manufacturers and specified small manufacturers (i.e., manufacturers of drugs that constitute a negligible amount of Medicare drug expenditures); the Manufacturer Discount Program offers these manufacturers a reduced discount obligation, but the PDP is required to make CMS whole for the difference between the reduced payment amount and the full discount obligation. The effect is evident in formulary changes between 2024 and 2025; drugs manufactured by specified small manufacturers saw a decrease in Part D coverage of their products from 74% to 56%. The IRA's reallocation of liability for drug costs between Part D stakeholders creates nascent tension between each player's preferred formulary design, and we will continue to monitor formulary trends in the wake of the benefit restructure.

What to Watch For in 2025

Voluntary Part D Premium Stabilization Demonstration

As mentioned above, in 2024 the Biden administration implemented a voluntary premium stabilization program to provide additional premium stabilization and revised risk corridors for stand-alone PDPs (including Employer Group Waiver Plans or EGWPs) as they adjust to the increased liability for drug costs under the benefit redesign. The Part D Premium Stabilization Program has three components:

- Reduces the base beneficiary premium for all PDPs by $15 (or less in the event a $15 reduction would result in a plan premium of less than $0, such that the plan premium remains $0).
- Limits the year-to-year total increase in a PDP's total premium to $35 between CY 2024 and CY 2025 (applied after taking into account the $15 reduction in the base beneficiary premium).
- Narrows the upper thresholds of the risk corridors to increase the government's risk sharing for a portion of plan losses from 80% to 90% and reduce the range of spending where PDPs bear full risk for actual costs higher than their bids.

CMS will pay PDPs additional direct subsidy amounts to compensate plans for reduced premium revenue. Despite GOP criticism of the Part D Premium Stabilization Program and its budgetary impact, it is unclear whether the Trump administration will rescind the demonstration program or leave it in place. We will monitor any further development around this program but we note that in 2025, CMS anticipates 99% of PDP enrollees will be covered by a PDP that is participating in the demonstration. So any such rescission will certainly have a sizable impact.

Medicare Advantage and Part D Proposed Rule

On November 26, 2024, CMS released the CY 2026 Medicare Advantage and Part D Proposed Rule (the Proposed Rule). The Proposed Rule sets forth several policies that seek to implement various provisions of the IRA within the Medicare Advantage and Part D programs, including:

- Codifying the requirement that all adult vaccines recommended by ACIP be covered under Part D with $0 cost-sharing requirements for CY 2026.
- Codifying the requirement that Part D cost-sharing amounts for covered insulin products be capped at the lesser of (1) $35, (2) an amount equal to 25% of the MFP, or (3) an amount equal to 25% of the negotiated price under the PDP or Medicare Advantage Part D (MA-PD) plan.
- Require PDPs' network contracts with pharmacies to include a provision requiring such pharmacies to be enrolled in the Negotiation Program's Medicare Transaction Facilitator Data Module to facilitate continued beneficiary access to Selected Drugs, promote access to MFPs, and ensure accurate Part D claims payment.
- Require PDPs to shorten the Prescription Drug Event (PDE) submission timeliness requirement specifically for Selected Drugs; instead of the 30-calendar-day timeframe PDPs have for submission of general initial PDE records, PDPs must submit initial PDE records for Selected Drugs within 7 calendar days to help ensure prompt payments by drug manufacturers to dispensing entities to provide access to the MFP.

The Proposed Rule also includes several policy proposals relating to the Medicare Prescription Payment Program (MPPP), which we discuss further in our article covering the operationalization of the MPPP. While the Biden administration developed and drafted the policies set forth in the Proposed Rule, the Trump administration is tasked with reviewing stakeholders' comments and deciding what aspects of the Proposed Rule will be finalized, what will be rescinded, and what will be paused for further review. We will be watching closely to see which provisions, if any, make it into the Final Rule.

Medicare Part D Coverage of Anti-Obesity Medications

Another key provision of the Proposed Rule is CMS's proposal to reinterpret the statutory exclusion of anti-obesity medications from coverage under Medicare Part D. Historically, drugs used for "weight loss" have been excluded from the statutory definition of a covered Part D drug. Thus, Part D will only cover anti-obesity medications if they are prescribed for a medically accepted FDA-approved indication other than obesity, such as diabetes or cardiovascular disease. State Medicaid programs are also required to cover these drugs for diabetes or cardiovascular disease, but only 13 states currently also cover these drugs for obesity treatment. The proposed reinterpretation would permit Medicare Part D coverage and require Medicaid coverage of anti-obesity medications when used to treat individuals with obesity who do not have another condition pursuant to which Medicare Part D or Medicaid would cover the drug. Despite the recent surge in popularity of GLP-1s, a relatively new class of highly effective anti-obesity medications, CMS has thus far been reluctant to expand coverage of these drugs to include treatment for obesity because of the significant cost; in 2022 alone, Medicare spent $6 billion on GLP-1s for treating medically accepted indications other than obesity. However, the Proposed Rule was closely followed by the Biden administration's selection of Ozempic, Rybelsus, and Wegovy, Novo Nordisk's GLP-1 products, for negotiation under the Negotiation Program in 2025. Notably, the IRA considers products with the same "active moiety" as one product, so despite any difference in dosage strength, formulations, and clinically indicated uses (i.e., whether the drug is used to treat obesity or diabetes), Ozempic, Rybelsus, and Wegovy will be subject to the same negotiated MFP. The Trump administration has signaled that it will continue with negotiating Medicare prices for the 15 drugs selected for the second cycle of the Negotiation Program by the Biden administration, including Novo Nordisk's GLP-1 products. It is unclear yet whether the Trump administration's intention to continue the drug price negotiation also signals that the administration will finalize the proposed coverage for obesity. The administration currently appears focused on finding savings, which the drug price negotiation achieves and the expansion of coverage does not.

Draft CY 2026 Part D Redesign Program Instructions

On January 10, CMS published draft CY 2026 Part D Redesign Program Instructions (Draft Instructions) for implementation of the Part D changes to the benefit structure. The policies set forth in the Draft Instructions only include policies that have been modified or updated from the Final CY 2025 Program Instructions and any new proposed policies for CY 2026 (we covered the Final CY 2025 Program Instructions in our previous edition). Some key highlights of the Draft Instructions:

- *Increase in Beneficiary OOP Cost Maximum.* The annual out-of-pocket cost cap of $2,000 for Part D beneficiaries is increased to $2,100, based on the annual percentage increase (API) in average Part D costs for the previous year.
- *Selected Drug Subsidy Program.* The IRA's redesign of Part D includes a government subsidy program for Selected Drugs, pursuant to which PDPs will receive a 10% subsidy to reduce their liability for Selected Drugs. This subsidy applies to those Selected Drugs that would otherwise be Applicable Drugs eligible for discounts under the Manufacturer Discount Program (Selected Drugs are excluded from the Manufacturer Discount Program). The Selected Drug 10% subsidy is available in the initial coverage phase until the beneficiary reaches the out-of-pocket threshold of $2,100. Afterwards, in the catastrophic phase, CMS will provide 40% reinsurance for Selected Drugs.
- *Inclusion and Substitution of Selected Drugs on Part D Formularies.* Starting in the initial price applicability year 2026, PDPs will generally be required to include Selected Drugs on their formularies. However, the IRA permits PDPs to remove a Selected Drug if the PDP replaces it with a newly available generic (referred to as immediate substitution) that is on the same or lower cost-sharing tier and has the same or less restrictive utilization management requirements (i.e., prior authorization, step

therapy, quantity limits, etc.). Due to changes to Part D regulations, the Draft Instructions designate the codification of the IRA's requirement at 42 CFR 423.120(e)(2)(i) and 423.120(f)(2), (3), and (4). These regulations specify the types of products PDPs may use to replace Selected Drugs on their formularies as well as the circumstances in which a generic or interchangeable biological product may be substituted for a Selected Drug based on the timing of its availability on the market. However, the PDP cannot substitute an authorized generic of a brand-name Selected Drug; the substitution must be with a different generic manufacturer. The Draft Guidance also invites input from stakeholders as to whether CMS should expand the IRA's exception to permit PDPs to remove Selected Drugs within 90 days of adding a corresponding generic drug or interchangeable biological product (referred to as a maintenance change). The Final CY 2026 Part D Redesign Program Instructions will be published by April 7, 2025.

The Future of the Medicare Drug Price Negotiation Program

By Samantha Hawkins, Matthew Tikhonovsky

The Centers for Medicare and Medicaid Services (CMS) and pharmaceutical drug manufacturers are gearing up for the second round of negotiations as part of the Medicare Drug Price Negotiation Program (the Negotiation Program), but the Trump administration and a Republican majority in Congress leaves the future of the Negotiation Program uncertain. As outlined in the Q2 2024 edition of our *Mintz IRA Update*, the second round of negotiations will take place throughout 2025, and the resulting maximum fair prices (MFPs) for the next 15 drugs are slated to become effective on January 1, 2027. In this article, we explore the recent changes made by CMS to the Negotiation Program following the first round of negotiations; manufacturers' reactions to the MFP explanations provided by CMS and the drugs targeted for the second round of negotiations; and the implications of the Trump administration for the future of the Negotiation Program.

Drug Manufacturers React to MFP Explanations and Drugs Targeted for Second Round of Negotiations

On December 20, 2024, months ahead of its March 1, 2025, deadline, CMS released redacted details about how it determined new prices for the 10 drugs it selected in the first round of negotiations. Each MFP explanation contained details that were unique to the specific drug in question, and consistently considered factors focused on R&D costs, relevant patents, net prices, wholesale acquisition costs, and unit volume changes over time. Despite hundreds of pages of information provided by CMS, many industry watchers and manufacturers were disappointed to find that the explanations lacked a systematic and quantitative approach to how CMS arrived at its negotiated prices. Such information, the foregoing parties argue, would have allowed the industry to forecast how selected drugs would be priced in future rounds of negotiation. However, even without such forecasting information, several drug manufacturers have expressed that they are not concerned by the second round of negotiations.

On January 17, 2025, CMS announced the set of 15 drugs for the second round of negotiations under the Negotiation Program — 15 days ahead of its February 1 deadline — and as expected, the popular diabetes drug, Ozempic, and the Huntington's disease medication, Austedo, are among the drugs selected. According to statements made by the CEO at Teva and a top executive at Novo Nordisk, both manufacturers had considered the possibility that their popular drugs, Austedo and Ozempic, respectively, would be selected for negotiation and

began adjusting their growth strategies in advance. Similarly, leaders at AstraZeneca and Pfizer told attendees during the 2025 JP Morgan Healthcare Conference that although their companies would face pressure and be impacted by the Negotiation Program, both manufacturers still predict a strong performance in the coming year.

The full list of the 15 selected drugs is below. Manufacturers with a selected drug will have until February 28, 2025, to decide if they will participate in the second round of negotiations.

Drugs Selected for Medicare Price Negotiation in 2025		
Manufacturer	**Brand Name**	**Generic**
Novo Nordisk A/S	Ozempic, Rybelsus, & Wegovy	Semaglutide
GlaxoSmithKline	Trelegy Ellipta	N/A
Astellas Pharma Inc.	Xtandi	Enzalutamide
Bristol Myers Squibb	Pomalyst	Pomalidomide
Pfizer Inc.	Ibrance	Palbociclib
Boehringer Ingelheim	Ofev	Nintedanib
AbbVie Inc.	Linzess	Linaclotide
AstraZeneca	Calquence	Acalabrutinib
Teva Pharmaceuticals	Austedo; Austedo XR	Deutetrabenazine
GlaxoSmithKline	Breo Ellipta	Fluticasone furoate/vilanterol
Boehringer Ingelheim	Tradjenta	Linagliptin
Salix Pharmaceuticals	Xifaxan	Rifaximin
AbbVie Inc.	Vraylar	Cariprazine
Merck and Co., Inc.	Janumet; Janumet XR	Sitagliptin/metformin
Amgen Inc.	Otezla	Apremilast

Implications of a Trump Administration

The future of the Negotiation Program under this Trump administration remains uncertain. In his prior term as president, President Trump took a hard stance against pharmaceutical prices in the US, and during his re-election campaign, President Trump reiterated that he is committed to lowering the price of drugs for Americans. However, immediately following his inauguration, President Trump revoked a Biden-era executive order aimed at lowering the costs of expensive medications and helping state Medicaid agencies pay for expensive treatments by setting up negotiations between CMS and manufacturers. This revocation may signal that President Trump's priorities have shifted and that he may be less focused on addressing drug costs during his second term.

Many of Trump's advisers appear divided on how and to what extent to regulate the pharmaceutical industry. The future of the Negotiation Program is further muddled by recent statements made by several high-ranking Republicans, such as US Senate Finance Committee Chairman Mike Crapo, who, in September of last year, stated he plans to repeal

and replace the Negotiation Program during his tenure as chairman. Nonetheless, the Trump administration has yet to divulge details of its plans for the future of the Negotiation Program — but as we discuss in this issue's litigation update, there are a number of paths forward available to the administration.

Final Guidance for Second Round Negotiation Cycle

Barring any changes made under the Trump administration, the second round of negotiations will take place throughout 2025, and CMS will be required to publish the new negotiated MFPs by the end of November 2025. The new MFPs will then go into effect in 2027.

The second round of negotiations will largely follow the same process as the first round of negotiations; however, drug manufacturers will now have more time and opportunities to submit counteroffers and to engage with CMS directly. CMS's final guidance for price applicability year 2027 outlines the new requirements and parameters for the Negotiation Program, including, but not limited to:

- **Patient Roundtables and Town Hall:** Up to 15 patient-focused roundtables and one clinically oriented town hall meeting will be held to collect input from patients, patient advocacy organizations, caregivers, and others on the selected drugs for consideration.
- **Negotiation Meetings**: The first optional negotiation meeting between CMS and participating drug companies will be held after the initial offer is announced and before the deadline for the company to submit a counteroffer. If CMS rejects a drug company's counteroffer, CMS will offer the drug company up to two additional negotiation meetings.
- **Data Exchange Parameters**: New guidelines have been established for data sharing between dispensing entities, participating drug companies, and CMS via the Medicare Transaction Facilitator (MTF) Data Module to facilitate access to MFPs of selected drugs.
- **Payment Facilitation**: A voluntary payment facilitation functionality through the MTF Payment Module (MTF PM) has been established to support access to the MFP by passing payment from the drug companies to the dispensing entity.
- **Reporting Requirements**: Drug companies must follow new guidelines and parameters for payments passed to dispensing entities outside of the MTF PM.

A Circuit Win and the End of *Chevron* Deference Could Shift Tides in Drug Price Negotiation Program Challenges

By Xavier G. Hardy, Mitchell J. Clough

As detailed in our previous updates, the IRA's Medicare Drug Price Negotiation Program (the Negotiation Program or Program), which enables the federal government to negotiate prices for some of the costliest Medicare Part D drugs, has been subject to several legal challenges from manufacturers and trade associations over the last year. Since CMS selected the first ten drugs subject to negotiation in late August 2023, four chambers of commerce, two trade associations, and all but one of the affected manufacturers have filed a total of nine lawsuits challenging the constitutionality and legality of the Negotiation Program on several grounds.

Since our last update, there have been developments in several cases as well as a significant Supreme Court ruling in an unrelated case that may create new avenues for manufacturer challenges to the Negotiation Program. Specifically with respect to the Negotiation Program lawsuits:

- In September 2024, the US Court of Appeals for the Fifth Circuit reversed a Texas federal court's decision tossing on procedural grounds a suit brought by Pharmaceutical Research and Manufacturers of America (PhRMA), the National Infusion Center Association (NICA), and the Global Colon Cancer Association (GCCA), sending the case back for consideration of the merits.
- In late October 2024, the US Court of Appeals for the Third Circuit heard oral argument in appeals from decisions dismissing suits brought by AstraZeneca, Bristol Myers Squibb, and Johnson & Johnson.
- In July and October 2024, a federal district court judge in New Jersey ruled against two manufacturers, granting summary judgment in favor of the government in both cases. Both manufacturers, Novo Nordisk (Novo) and Novartis, have since appealed the decisions to the Third Circuit, and Novo has requested that the court expedite oral arguments and a decision.
- In August 2024, a federal district court judge in Ohio granted the government's motion to dismiss based on lack of standing and improper venue in a lawsuit led by the Dayton Chamber of Commerce. The plaintiffs have since appealed the ruling to the Sixth Circuit.
- In August 2024, Boehringer Ingelheim (BI) appealed the July 2024 district court ruling granting summary judgment in favor of the government to the Second Circuit.
- In January 2025, Teva Pharmaceuticals USA, Inc. and Teva Branded Pharmaceutical Products R&D, Inc. (Teva) filed a complaint against the US Department of Health and Human Services (HHS) in the US District Court for D.C.

Additionally, in late June, the Supreme Court overruled its landmark 1984 *Chevron* decision in the consolidated cases *Loper Bright Enterprises v. Raimondo* and *Relentless, Inc. v. Department of Commerce* (*Loper Bright*). For the last 40 years, *Chevron* directed courts to defer to a federal agency's "reasonable" interpretation of ambiguous statutes. While the *Loper Bright* decision was unrelated to the ongoing Negotiation Program lawsuits, the fact that the ruling reduces judicial deference to administrative agencies may provide a new pathway to block negotiation and implementation of maximum fair prices (MFPs).

Further, on January 20, 2025, President Donald Trump was sworn in for his second term in office. The change in administration has obviously raised questions about the future of the Negotiation Program.

National Infusion Center Association

Months ago, an Austin, Texas-based federal court dismissed the lawsuit brought by PhRMA and two other associations, NICA and GCCA, on procedural grounds. In short, the district court concluded that it lacked subject-matter jurisdiction over NICA's constitutional claims because those claims had to be "channeled" through HHS before a suit could be brought in court. And without NICA's claims, the court concluded that the venue in Texas (which is within the jurisdiction of the conservative-leaning Fifth Circuit) was improper.

In September, the Fifth Circuit reversed the lower court action, scoring the first victory for manufacturers in the ongoing Negotiation Program lawsuits. The Fifth Circuit concluded that the constitutional claims did not have to be channeled through HHS. A majority of the court concluded that because NICA did not challenge specific reimbursement rates, but instead challenged whether an unconstitutional process was created to set the price for the drugs for which its members are reimbursed, the claims did not need to be channeled. (One judge penned a dissent.) Importantly, the court also concluded that NICA lacked standing based on its claims that the Negotiation Program violated the non-delegation doctrine and that it levies excessive fines, sowing doubt as to whether those claims can be considered by the district court on remand. Though the court did not comment on the merits of the claim, the majority opinion also provides some hints that at least two judges on the Fifth Circuit align with the manufacturers' view of the Negotiation Program as a "gun to the head" rather than a true negotiation.

The government has the option to petition for further review from either the *en banc* Fifth Circuit or the Supreme Court. If it does not, then the case will return to the district court for further proceedings on the merits. That merits decision may make its way to the Fifth Circuit in the not-so-distant future.

Third Circuit Hears Argument in AstraZeneca, J&J, and BMS Cases

As we previously reported, federal judges in New Jersey and Delaware rejected constitutional challenges brought by AstraZeneca, Bristol Myers Squibb Company (BMS), and Janssen Pharmaceuticals, Inc., a division of Johnson & Johnson (J&J). Each manufacturer appealed, and the Third Circuit, on October 30, 2024, heard oral argument on the appeals. The arguments before a panel of three judges considered the plaintiffs' constitutional claims, including violations of the Fifth Amendment Takings Clause, the First Amendment right against government-compelled speech, the unconstitutional conditions doctrine, and procedural due process (which we have previously summarized). The court also considered AstraZeneca's Administrative Procedures Act claims challenging CMS's interpretation of "qualifying single source drug" and "bona fide marketing," as well as the government's procedural arguments that AstraZeneca lacked standing to bring those claims and, in any event, those claims were subject to the IRA's judicial-review bar with respect to those interpretations. The judges hurled difficult questions at counsel for both parties, showing no clear inclination of which way the court would rule on the various claims.

A decision is expected by the spring of 2025. That decision, regardless of its outcome, will likely be appealed to the Supreme Court.

Novo Nordisk and Novartis

On July 31 and October 18, respectively, a New Jersey federal judge rejected constitutional challenges from Novo and Novartis. As we detailed in our last update, on April 29, 2024 Judge Zahid N. Quraishi of the District of New Jersey, who has overseen four of the manufacturer lawsuits, issued a joint ruling against BMS and J&J. The four cases involved many overlapping claims and arguments, and Judge Quraishi's rulings in the Novo and

Novartis decisions largely mirror his earlier ruling against BMS and J&J.

Novo filed its lawsuit against the government on September 29, 2023, after CMS selected two of its products, NovoLog (NovoLog, NovoLog FlexPen, and NovoLog) and FIASP (FIASP, FIASP Flextouch, and FIASP Penfill), for negotiation. The Novo case is notable because CMS controversially aggregated the three NovoLog and three FIASP products as a single selected drug. Novo alleged that the IRA violated the separation of powers, the Fifth Amendment's Due Process Clause, and the First Amendment's prohibition on compelled speech (together, Constitutional Claims), as well as the APA and Security Act (SSA) by imposing new legal obligations without complying with notice-and-comment rulemaking procedures, and the express mandate of the IRA by combining the NovoLog and FIASP products as a single drug (together, Statutory Claims).

Consistent with his ruling against BMS-J&J, Judge Quraishi rejected each of the manufacturer's Constitutional Claims based on the conclusion that participation in Medicare is purely voluntary. The court rejected the Statutory Claims as well, reasoning that because the IRA precluded administrative or judicial review of the selection of drugs, the court lacked subject matter jurisdiction to consider challenges to CMS's underlying determinations that led to it selecting Novo's drugs. Further, in considering Novo's argument that CMS had effectively identified 15 products for 2026, the first year of the Program, (rather than the 10 drugs permitted by the IRA) by combining the NovoLog and FIASP products into a single drug, the court concluded that Novo failed to demonstrate it had standing. To establish standing, a plaintiff must demonstrate that it suffered a concrete injury, that the injury was likely caused by the defendant, and that the injury would likely be redressed by judicial relief. Instead of seeking judicial relief on each of its statutory claims, however, Novo had provided "a ten-paragraph general prayer for relief based on all of their claims," which the court concluded was "overbroad" because it sought not just to enjoin the injury that Novo suffered, but also "to enjoin the IRA program as a whole and to declare invalid CMS's entire guidance."

On September 1, 2023, shortly after CMS selected the company's heart failure medication, ENTRESTO, for negotiation, Novartis filed suit alleging that the Negotiation Program violated the Fifth Amendment's Takings Clause and the First Amendment's prohibition on compelled speech. Novartis also argued that the Program's "excise tax" was an excessive fine in violation of the Eighth Amendment Excessive Fines Clause. The court rejected each of Novartis's claims, citing to and reiterating the analysis of these claims in its BMS-J&J and Novo rulings.

Novo and Novartis appealed to the Third Circuit. On January 27, 2025, after three of Novo's drugs (Ozempic, Wegovy, and Rybelsus) were selected for negotiation for 2027, Novo requested that the court expedite the oral arguments and its decision in the matter.

Dayton Chamber of Commerce

One of the first challenges to the Program was filed by the Dayton Area Chamber of Commerce, the Ohio Chamber of Commerce, the Michigan Chamber of Commerce, and the US Chamber of Commerce (together, the Chambers). As we've previously written, on September 29, 2023, the district court denied the Chambers' motion for a preliminary injunction and the government's first motion to dismiss, which gave the Chambers the opportunity to amend their complaint and to elaborate on the facts establishing standing. Because each of the Chambers did not have standing to sue in their own right, they asserted standing under the theory of associational standing, which allows associations in some circumstances to sue on behalf of their members who have standing.

After the plaintiffs filed an amended complaint, the Ohio federal court recently ruled in favor of the

government's latest motion to dismiss, dismissing the case on procedural grounds before reaching the merits of the constitutional challenges.

The court concluded that three of the Chambers (Dayton, Ohio, and Michigan) did not have associational standing, while the fourth (US Chamber of Commerce), had it filed the case alone, would have needed to file suit in a different venue. The Chambers had argued that they had associational standing to sue on behalf of members that suffered injury, naming AbbVie (located in Illinois, California, Massachusetts, and the District of Columbia) and Pharmacyclics (based in California). The court concluded that the Chambers had failed to provide information directly connecting the interests of Pharmacyclics or AbbVie to the business climate in the Dayton area, and as such, the interests at stake in this lawsuit were not germane to Dayton's interest. The court similarly concluded that the Ohio and Michigan Chambers of Commerce had not explained how any named members have interests in Ohio or Michigan. The court reasoned that the US Chamber of Commerce's purpose — improving business conditions in the US — was sufficiently related to the interest in the lawsuit to satisfy the requirements for associational standing. However, the court agreed with the government's argument that if Dayton's claims were dismissed, venue would not be proper in the Southern District of Ohio where the case was filed. As such, the court granted the government's motion to dismiss with respect to the US Chamber of Commerce as well.

The Chambers appealed the district court's ruling to the Sixth Circuit, which is not expected to rule for several months.

Boehringer Ingelheim Appeals to the Second Circuit

As detailed in our last update, on July 3, the federal district court in Connecticut overseeing the lawsuit brought by Boehringer Ingelheim (BI) granted the government's motion for summary judgment, concluding that the Program passed constitutional muster. Resting largely on the conclusion that participation in the Medicare program is purely voluntary, the court rejected BI's claims, which overlapped with those brought by several of the other manufacturers (including the First Amendment, Takings Clause, and Unconstitutional Conditions claims considered and rejected by other courts). BI has since appealed the ruling to the Second Circuit. A decision from the Second Circuit is not expected for several months.

Teva Files Lawsuit Related to its Drug Austedo

In January 2025, Teva filed a lawsuit against HHS related to its drug Austedo. The lawsuit appears to mirror the arguments advanced by the other lawsuits, including the assertion that CMS's definition of a Qualifying Single Source Drug and the bona fide marketing standard set forth in CMS's implementing guidance violate the Administrative Procedures Act (APA), and that the CMS guidance violates the Fifth Amendment's Due Process Clause. Notably, the Teva lawsuit is the first manufacturer challenge related to the drugs selected for 2027. While Teva filed the lawsuit two days prior to the HHS announcement of the 15 drugs selected for negotiation for 2027, HHS included Austedo on its list of drugs for 2027.

Loper Bright and the End of *Chevron* Deference

In late June, the Supreme Court issued a ruling in the high-profile *Loper Bright* case, overturning its long-standing doctrine of *Chevron* deference. While *Loper Bright* was not specifically related to the Negotiation Program lawsuits, the ruling is expected to have (and in some cases, already has had) a significant impact on various areas of administrative law. As we discussed in a blog post in August, *Loper Bright* could breathe fresh life into APA challenges to the Program.

For context, *Chevron* deference was primarily a product of the Court's 1984 decision in *Chevron USA, Inc. v. Natural Resources Defense Council*, which

established a two-step test that federal courts were mandated to follow when reviewing whether a federal agency's interpretation of a statute was permissible. In the first part of the test, courts were required to examine whether Congress had directly spoken to the precise question at issue. If there was an underlying statute that was unambiguous and clear, courts would review whether an agency's interpretation adhered to the statute. The second step, which is typically referred to as *Chevron* deference, provided that if the statute was silent or ambiguous on the issue in question, then the court would analyze whether the agency's interpretation was based on a "permissible construction" of the statute, regardless of whether a court felt that there was a more accurate interpretation of the law.

Long considered a "bedrock" of federal administrative law, *Chevron* deference essentially gave federal agencies wide latitude to issue federal regulations and administer federal programs based on congressional legislation that often (and sometimes intentionally) has left specific details about how a particular law is supposed to function unaddressed. For many years, the impact of *Chevron* deference has had a considerable effect on lawsuits challenging agency action. There is also some empirical evidence that *Chevron* resulted in agency rule drafters adopting more aggressive interpretations of federal statutes.

Subsequent Supreme Court decisions narrowed the scope of *Chevron* deference so that courts were only required to defer to an agency's interpretation if supported by formal proceedings, including adjudication and notice-and-comment rulemaking. Opinion letters, policy statements, agency manuals, and other subregulatory guidance were thus afforded lesser judicial deference under *Skidmore v. Swift & Co.* Along with similar rulings issued by the Supreme Court around the same time, including *Corner Post, Inc. v. Board of Governors of the Federal Reserve System* and *Securities and Exchange Commission v. Jarkesy*, *Loper Bright* is expected to open federal agencies such as CMS up to more scrutiny and increase the number of lawsuits filed against agencies when a statute underlying agency action is ambiguous.

Loper Bright will potentially strengthen the APA claims that manufacturers and other plaintiffs have brought, although it is unclear how much of an immediate impact the Court's ruling will have on the current Negotiation Program litigation. There is evidence that courts have been deferring to agency interpretations less and less in recent years, and *Chevron* has not appeared to factor into the Negotiation Program lawsuits, some of which only include constitutional claims that are unaffected by *Loper Bright.* Even for those lawsuits that include APA claims, the litigations appear to be more focused on the constitutional issues raised. In part, the focus of manufacturers and other plaintiffs on constitutional claims over APA and other statutory claims may be strategic. The constitutional claims, if successful, would be more successful in gutting the Negotiation Program completely, whereas success under the APA claims would likely only affect certain specific aspects of the Program, such as CMS's subjective determinations in selecting negotiation-eligible drugs and the calculation of MFPs.

It's also unclear how *Loper Bright* will help manufacturers and other plaintiffs (some of which have taken issue with the fact that CMS implemented the Negotiation Program primarily through subregulatory guidance) overcome the fact that the IRA expressly allows the Secretary of HHS (which CMS is a subagency of) to implement the Program for 2026, 2027, and 2028 "by program instruction or other forms of program guidance." Manufacturers and other plaintiffs must also overcome the IRA's bar on judicial review; the IRA also precluded judicial review for many of the aspects of the Negotiation Program that are most concerning manufacturers and other plaintiffs, such as the factors used to determine which drugs are negotiation eligible.

The Teva lawsuit filed in January 2025 includes a single reference to *Loper Bright* in support of the manufacturer's assertion that courts "may not defer to an agency interpretation of the law simply

because a statute is ambiguous." It is unclear whether *Loper Bright* will play a larger role in Teva's argument as the litigation progresses. It would not be surprising if other manufacturers and plaintiffs — including those that bring claims in the future related to CMS's selection of drugs for 2027 and onward — will attempt to center *Loper Bright* in their arguments that parts of CMS's implementing guidance, to the extent not supported by a clear delegation of authority in the IRA, are invalid. In that sense, *Loper Bright* may breathe new life into challenges to the Negotiation Program.

Looking Forward: The Trump Administration and the Negotiation Program

The election of President Trump has raised questions about the future of the Negotiation Program and the IRA more broadly. Congressional Republicans, who gained control of the Senate and maintained control of the House of Representatives, have been critical of the Negotiation Program since the IRA was passed. Unsurprisingly, the US pharmaceutical industry appears to be aggressively lobbying the new administration, which has various mechanisms to either repeal or undermine the Program.

The most substantial action the Trump administration could take would be to outright repeal the Negotiation Program via legislation. While Republicans only hold 52 seats in the Senate, short of the 60-vote filibuster-proof majority that would typically be needed to repeal a major law like the IRA, they would only need a simple majority in the Senate to repeal the law because it was passed under a Budget Resolution. Repeal of the Negotiation Program would arguably render the existing lawsuits moot.

The Trump administration is also now responsible for defending the law in federal court against the manufacturer lawsuits and could simply choose not to defend challenges to the law. However, the fact that the lawsuits involve constitutional claims that, if successful, could undermine the government's ability to carry out other measures means the Trump administration has a broader incentive to continue aggressively defending the lawsuits against manufacturers. Further, the administration abandoning the government's defense of the Negotiation Program would not necessarily result in a different outcome — federal courts can appoint *amicus curiae*, or "friends of the court," to argue in favor of a law's constitutionality. As we've noted, federal courts have thus far rejected the manufacturers' claims on the merits, and the federal government removing itself from the defense of the Program would not necessarily change how courts have analyzed the claims.

Finally, the Trump administration could also modify the Negotiation Program via agency guidance. Under President Biden, HHS has entirely implemented the Negotiation Program via subregulatory guidance, a decision that has been challenged (unsuccessfully) by manufacturers. While implementing the Negotiation Program via guidance had the benefit of expediency for the Biden administration, it also means that the Trump administration now has broad discretion to modify the Program to address manufacturer complaints about how drugs are deemed eligible for negotiation.

If recent history is a guide, speculating on the future of the Negotiation Program with any certainty is an exercise in folly. However, reporting by news organizations (which is consistent with what Mintz's consulting group, ML Strategies, has heard) indicates the new administration's approach to the Negotiation Program is more likely to involve modifications to certain aspects of the Negotiation Program rather than outright repeal or abandoning the defense of the lawsuits. For one, while President Trump has made broader statements about repealing portions of the IRA, notably, he has not publicly addressed how his administration's approach to the Negotiation Program will differ from the Biden administration's. Instead, his criticisms of the IRA have focused on the environmental provisions of the law. Further, on

January 29, CMS published a short statement indicating that the new administration will continue the Negotiation Program. The statement also notes that CMS is "considering opportunities to bring greater transparency in the Negotiation Program" and would give stakeholders an opportunity to provide specific ideas to improve the Negotiation Program. The same day CMS released the statement, President Trump's nominee to lead HHS, Robert F. Kennedy Jr., stated during his nomination hearing that the White House had issued an executive order on the Negotiation Program — although it appears he was mistakenly referring to the CMS statement. Otherwise, Mr. Kennedy did not provide substantive responses to the various questions on the Negotiation Program he received from several senators.

The new administration's apparent reluctance to attach the Negotiation Program may be explained by the fact that it is broadly popular among the general public. One recent Kaiser Family Foundation poll shows that 65% of Democrats, 54% of Independents, and even 48% of Republicans support *expanding* the number of drugs the federal government negotiates. There are obvious parallels to previous attempts to repeal the Affordable Care Act during the first Trump administration, which appear to have failed in part due to the ACA's growing popularity at the time.

There are also indications from Trump's first term in office that are informative. The first Trump administration's rhetoric and proposals related to lowering drug prices were surprisingly aggressive. For example, prior to leaving office, the Trump administration's HHS proposed a Most Favored Nation (MFN) Model that would have capped the price of Medicare Part B drugs and biologics at the lowest price that a drug could receive in other similar countries. Senator Bernie Sanders (I-VT) has championed the broader use of MFN pricing for years, including most recently in a bill proposed in 2023.

Another signal that the Negotiation Program will be subject to tweaks rather than outright repeal comes from the reporting on pharmaceutical industry lobbying of the Trump administration. By all indications, drug lobbyists have focused on delaying the timeline (i.e., bona fide marketing standard) and formula (i.e., Qualifying Single Source Drug) used for determining a drug's eligibility for negotiation rather than outright pushing for the Trump administration to eliminate the Program.

As noted, however, anything short of outright repeal will not necessarily address the broader constitutional challenges to the Negotiation Program. As such, the litigation over the Negotiation Program will likely continue.

Duplicate Discounts Between the 340B Program & Medicare Drug Price Negotiation Program

By Lauren Moldawer, Abdie Santiago

The 340B Drug Pricing Program (340B Program) is no stranger to controversy. We have previously covered the ongoing contract pharmacy legal battles and the new alternative dispute resolution process. And now, a new 340B hurdle is on the horizon for drug manufacturers whose drugs were selected for the Medicare Drug Price Negotiation Program (Selected Drugs): duplicate discounts with the Maximum Fair Price (MFP).

Under the IRA, manufacturers of Selected Drugs do not need to provide covered entities with both the 340B discounts and the MFP (which would result in "duplicate discounts"). Rather, manufacturers must provide covered entities with the lesser of the 340B price or the MFP. This requirement presents the same challenge that the 340B program has been dealing with for well over a decade under the duplicate discount prohibition between the Medicaid Drug Rebate Program and the 340B price. Central to this issue is: how do manufacturers identify when a drug is dispensed to a 340B eligible patient (a 340B Drug) and thus eligible for the 340B price?

Compounding the risk that manufacturers will potentially pay duplicate discounts to covered entities for Selected Drugs, is the fact that CMS is enacting a 14-day prompt pay requirement, requiring manufacturers to reimburse dispensing entities (including covered entities) the difference between the amount the covered entity paid for a Selected Drug and the MFP within two weeks of the drug's identification as MFP-eligible. As pointed out in comments to this proposal, due to the difficulties in identifying when a drug is a 340B Drug, this timeframe may result in manufacturers carrying millions in excess payments.

The remainder of this article discusses how CMS is (or more accurately, is not) addressing this risk of duplicate discounts through its October 2, 2024 Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act (MFP Guidance), as well as manufacturers' responses.

CMS Offers Limited Solutions for Duplicate Discounts between the MFP and 340B Price

To effectuate the MFP, CMS will establish the Medicare Transaction Facilitator Data Module (MTF DM) and the MTF Payment Module (MTF PM), which will facilitate the exchange of claims data and payments between manufacturers and dispensing entities. The idea is that the MTF DM would provide manufacturers with information regarding when a claim is an MFP-eligible claim and when the dispensing entity is entitled to the MFP. Manufacturers must then reimburse the dispensing entity if it paid more than the MFP within the 14-day requirement discussed above.

While the MTF modules play an important role in the Medicare Drug Price Negotiation Program, they do little to address 340B duplicate discounts. Critics of the MTF modules argue that the MTF DM will not contain data elements necessary to assist in the nonduplication of MFP and 340B claims. For example, CMS refused to implement proposals to include a mandatory data field identifying when a Selected Drug was dispensed to a 340B patient, thus making it eligible for the 340B price. In fact, CMS disavowed responsibility for deduplicating discounts, stating: "CMS is not charged with verifying or otherwise reviewing whether a particular drug claim is a 340B-eligible claim and will not, at this

time, assume responsibility for deduplicating discounts between the 340B ceiling price and MFP." This leaves the responsibility of nonduplication on the manufacturer and/or the covered entity.

Manufacturer Potential Solution – J&J's Proposed Rebate Model

A controversial solution put forth by manufacturers participating in the 340B Program is the utilization of rebates to effectuate both the 340B price and the MFP. In a recent lawsuit filed against HRSA, Johnson & Johnson (J&J) argued that the use of rebates to effectuate both the 340B ceiling price and the MFP could alleviate some of the administrative burdens associated with both programs and would ensure that 340B covered entities serving Medicare patients would receive the appropriate drug prices with respect to the patient served. Rather than providing covered entities with the 340B ceiling price upfront, as is current practice, the rebate model proposed by J&J, and others, would allow manufacturers more time to confirm utilization of the drug under the 340B Program or some other government program (e.g., Medicare) and thus allow the manufacturer to avoid duplication of discounts. HRSA did not approve J&J's proposed rebate model and instead threatened enforcement against the drug maker, thus leading to the lawsuit.

2025 Nonduplication Outlook

As stakeholders ponder solutions for nonduplication of the MFP, 340B ceiling price, and Medicaid drug rebates, we expect to see continued friction in the industry. Following J&J's lawsuit over the proposed rebate model, four other drugmakers have since sued HRSA over its denial of similar proposed rebate models. In a letter to CMS, the American Hospital Association (AHA) urged CMS to take a more prescriptive approach in requiring drugmakers to standardize payment across pharmacies dispensing on behalf of Medicare patients. Further, AHA argued that silence from CMS on the duplicate discount issue "appears to have been perceived by drug companies as a 'green light' to pursue a 340B rebate model whereby drug companies will make the 340B price available in a retrospective manner similar to the agency's process for making the negotiated MFP available through the MTF DM and PM."

If CMS and HRSA decline to provide additional guidance on the subject of duplicate discounts, then manufacturers, covered entities, and contracted pharmacies will each develop independent processes for compliance with Medicare, Medicaid, and the 340B Program. Such a fragmented approach could lead to claims duplication, payment delays, and disputes amongst parties, and would not only affect the financial stability of entities operating within the pharmaceutical supply chain but could also impact patient access to their prescription medicines at accurate prices.

Operationalizing the Medicare Prescription Payment Plan and Medicare Inflation Rebate Program

By Madison M. Castle

Medicare Prescription Payment Plan

In addition to the Part D Benefit Redesign, the IRA's Medicare Prescription Payment Plan (MPPP) went into effect beginning January 1, 2025. The MPPP requires Part D Sponsors (PDPs) to allow Part D beneficiaries to pay for their out-of-pocket prescription drug costs in monthly capped payments over the course of a given plan year instead of at the pharmacy point-of-sale. The MPPP's requirements apply to all Part D Sponsors, including Medicare Advantage plans (MA-PDs), stand-alone Part D plans, Employer Group Waiver Plans (EGWPs), cost plans, and demonstrations plans, but notably do not apply to Retiree Drug Subsidy plans. In our previous blog posts covering the MPPP's Part One Guidance and Part Two Guidance for CY 2025, we summarized the guidance CMS has provided to PDPs with respect to the operational and functional updates they must make to offer and run the MPPP, as well as the outreach, communication, and education the PDP must provide to Part D beneficiaries, network pharmacies, and contracted providers. Below, we note additional clarifications that CMS has provided as PDPs roll out the MPPP.

Interaction Between the Medicare Prescription Payment Plan and Other Forms of Payment Assistance

In a Health Plan Management System (HPMS) memo released by CMS in December 2024, CMS acknowledged that Low Income Subsidy (LIS) enrollees in PDPs are generally unlikely to benefit from the MPPP since they already have the benefit of low and stable drug costs. While there are limited circumstances in which a LIS enrollee would benefit from MPPP enrollment, CMS requires PDPs to tailor their support to all enrollees based on their individual situation. PDPs should advise LIS enrollees when MPPP participation is not practical or when LIS enrollment is more advantageous than MPPP participation. CMS also notes that the MPPP has no practical implication for plans that exclusively charge $0 cost-sharing for Part D drugs. As such, PDPs offering such plans are not expected to provide informational and educational materials about the MPPP to their beneficiaries because it would only cause confusion. Finally, in another HPMS memo issued on November 15, 2024, CMS confirmed that Part D beneficiaries participating in the MPPP could continue to receive assistance with payment for covered Part D drugs or payments to PDPs from appropriate charitable assistance programs. However, any drugs that are covered through a manufacturer's patient assistance program are **not** eligible for the MPPP.

PDP Reporting and Claims Processing Requirements

In order to monitor the MPPP's efficiency, CMS modified its Medicare Advantage and Prescription Drug system (MARx) to allow PDPs to report data elements related to their MPPP, both at the beneficiary-level and the plan benefit package level. As of January 1, 2025, all PDPs must:

- Submit beneficiary-level data related to MPPP participation into the MARx system via a MARx Batch Input Transaction Data File.
- Adopt an MPPP-specific bank identification number (BIN) and processor control number (PCN) for certain MPPP transactions. Federal regulations already require the use of a BIN and PCN; however, MPPP-specific BINs and PCNs will be used to process out-of-pocket amounts for beneficiaries. The PDPs must also supply this BIN and PCN to network pharmacies.

Medicare Advantage and Part D Proposed Rule

On November 26, 2024, CMS released the CY 2026 Medicare Advantage and Part D Proposed Rule (the Proposed Rule). In the Proposed Rule, CMS proposes to codify the Part One and Part Two Guidance requirements for CY 2026 and future years of the MPPP, including modification of the list of PDP-required content to include the model and standardized materials as well as website content requirements for the MPPP. The Proposed Rule also includes several proposed modifications and new program requirements, including:

- Allowing PDPs to follow its normal processes for Part D claim adjustments and issuing refunds, but when adjustments increase the beneficiary's balance owed, PDPs must include the additional costs in the revised out-of-pocket balance.
- Modifying the start date for the grace period to start the first day of the month following the date the initial notice of non-payment is sent.
- Creating an automatic renewal process that automatically renews a Part D beneficiary's participation in the MPPP for the next calendar year unless the enrollee opts out.
- Requiring the effective date of voluntary termination in the MPPP to be within 24 hours of receipt of a beneficiary's voluntary termination request.
- Requiring PDPs to ensure pharmacies can easily access information on a PDP's enrollee's costs incurred for prescriptions under the MPPP at the point-of-sale.

Medicare Prescription Drug Inflation Rebate Program

On December 9, 2024, CMS issued the CY 2025 Physician Fee Schedule final rule (the Final Rule) effective January 1, 2025, which included a number of policies implementing the Medicare Prescription Drug Inflation Rebate Program (the Inflation Rebate Program) under the IRA. As we discussed in a previous IRA Update, the Inflation Rebate Program aims to tackle high drug prices for Medicare Part B and Part D beneficiaries by requiring drug manufacturers to pay a rebate to CMS for drugs with prices that increase faster than the rate of inflation (on a quarterly basis and annual basis, respectively). The Final Rule codified policies that were established in the revised guidance for the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program and finalized several new policies to implement the Inflation Rebate Program, including:

- *Removal of 340B Units.* CMS finalized its proposal to exclude 340B units of Part B rebatable drugs purchased by 340B covered entities from Part B inflation rebate calculations to prevent any duplicate discounts. However, based on stakeholder criticism and objection, CMS declined to finalize its proposed 340B estimation methodology to remove 340B units of Part D rebatable drugs from calculations for Part D inflation rebates. CMS notes that it will explore establishing a claims data repository in the future to comply with this IRA requirement, but does not articulate a timeline, leaving manufacturers in the dark as to how to prevent 340B duplicate discounts with respect to Part D drugs.
- *Rebate Reconciliation.* The Final Rule establishes the method and process for reconciling rebate amounts for Part B and Part D rebatable drugs to account for revised information, calculation errors, or misreporting by manufacturers, including specifying the circumstances under which automatic and discretionary reconciliations will occur. CMS also confirmed that it will exclude Part B units of single-dose container or single-use package drugs subject to discarded drug refunds during reconciliation.
- *Penalties for Non-Compliance.* The Final Rule establishes the process by which CMS will impose civil monetary penalties (CMP) on manufacturers of Part B or Part D rebatable drugs that fail to pay the inflation rebate amount in full by the payment deadline for the applicable calendar quarter or applicable

period, including the appeal process for manufacturers. The CMP will be equal to 125% of the rebate amount.

- *Part B Payment Benchmark Quarter.* For Part B rebatable drugs that were approved by the FDA on or before December 1, 2020, but marketed after that date, the benchmark quarter against which CMS will measure future price changes to determine whether a rebate is owed is the third full calendar quarter after the drug's first marketed date. For Part B rebatable drugs billed using a not otherwise classified (NOC) code in the calendar quarter starting July 1, 2021, or the third full calendar quarter after the drug's first marketed date, whichever is later, the benchmark quarter is the third full calendar quarter after the drug is assigned a non-NOC code.
- *Part D Payment Benchmark Quarter:* For Part D rebatable drugs without manufacturer-reported average manufacturer price (AMP) data, CMS indicates that the benchmark quarter against which CMS will measure future price changes to determine whether a rebate is owed is the first calendar year, starting from the calendar year 2021 or later, in which at least one quarter of AMP was reported.
- *Coinsurance Adjustment Criteria.* As we've previously discussed, the IRA requires beneficiary coinsurance for a Part B drug to be reduced when its price increases faster than inflation. The Final Rule codifies the existing policy requiring CMS to compare the payment amount in its quarterly pricing files to the inflation-adjusted payment amount to determine whether the beneficiary coinsurance must be reduced.

FROM THE DESK OF ML STRATEGIES

The Medicare Drug Price Negotiation Program under the Second Trump Administration

By Alexander Hecht, Matthew Tikhonovsky

The start of Donald Trump's second presidency and Republican control in the 119th Congress raises questions about the future of the IRA's Medicare Drug Price Negotiation Program (the Negotiation Program), which could be significantly modified by the Trump administration and by Republicans in Congress.

President Trump himself has been silent about the future of the Negotiation Program. On the campaign trail, Trump did not discuss the program, nor has he since released a policy plan related to the program. While Project 2025 did call for a repeal of the Negotiation Program, Trump during his first term was largely supportive of efforts to reduce drug prices and is unlikely to repeal the program unless he has a replacement for it. The first Trump administration did advance a most favored nation drug model for drug pricing, which would tie drug prices to those paid in other high-income countries. Stakeholders are keeping close eyes and ears on whether President Trump will once again advocate for this plan during his second administration.

During his first week in office, President Trump issued an executive order (EO) repealing several Biden administration executive orders on healthcare, but this EO did not touch the Negotiation Program. Trump revoked a Biden EO that had directed the Center for Medicare and Medicaid Innovation (CMMI) to lower drug costs through three experimental pricing models, an initiative that was still in its early phases. He also withdrew another EO that had extended the open enrollment period for Obamacare and signed an EO to withdraw the U.S. from the World Health Organization (WHO). The early actions show that Trump is willing to undo parts of Biden's legacy on health care, but it remains to be seen just how far the new president is willing to go.

President Trump's picks to lead the US Department of Health and Human Services (HHS) and Centers for Medicare & Medicaid Services (CMS) are Robert F. Kennedy, Jr. (RFK Jr.) and Dr. Oz, respectively, who will both oversee the IRA's drug price negotiation process. Neither RFK Jr. nor Dr. Oz has publicly commented on the negotiation program. However, RFK Jr. has supported capping drug prices and following a European drug pricing model. Dr. Oz has been critical, yet financially supportive, of Big Pharma, criticizing the industry for high insulin prices despite his personal investments in numerous drug companies. The drugs subject to negotiation in the second year of the Negotiation Program were selected by the Biden administration in early January. Yet how Dr. Oz and RFK Jr., if confirmed, run the negotiations, and whether they push for lower price reductions for drug manufacturers, will provide the first insights about the future of the Negotiation Program under the Trump administration.

During his recent confirmation hearing with the Senate Finance Committee, RFK Jr. did not discuss specifics about the drug price negotiation program, but he did vow to lower drug prices. "President Trump was very aggressive during his first term about negotiating drug prices," RFK Jr. said during his hearing, and "he has instructed me… that we need lower prices for seniors in this country." When pressed by Senator Sanders (I-VT) if he would defend the IRA, which enacted the Negotiation Program, RFK Jr. said, "I'm going to comply with the law." On February 4, 2025, the Senate Finance Committee voted to advance RFK Jr. to the full Senate floor, which likely clears his path for confirmation. Dr. Oz's confirmation hearing is expected to be held in early February.

In Congress, where the fate of the Negotiation Program really lies, some Republicans have been outspoken about their desire to repeal the program entirely. In September, Senator Mike Crapo (R-ID), who is now the Chair of the Senate Finance Committee, along with other Republicans in the House and Senate stated that they would try to repeal the negotiation program in the next Congress. On the first day of the new Congress, House Republicans introduced a bill to repeal the entire IRA, which would include the Negotiation Program. However, a straight repeal of the entire IRA would bring a number of political complexities, including the fact that a repeal of the drug negotiation provisions would incur a cost to the government—the current Negotiation Program is expected to save the government about $100 billion over the next 10 years, according to the Congressional Budget Office. Rep. Brett Guthrie (R-KY), who is the Chairman of the House Energy and Commerce Committee, has indicated that he is supportive of a most favored nation model for drug pricing, but it is not clear how widely supported this plan is among Republicans.

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