MINTZ

Third Edition: Q2 2024

Mintz **IRA Update**

TABLE OF CONTENTS

Mintz's **Pharmacy Benefits and PBM Contracting Practice** is pleased to present the 'Third Edition: Q2 2024' 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.

The IRA is the most significant legislation relating to prescription drug pricing and coverage since the creation of Medicare Part D — and has the potential to fundamentally change the drug pricing landscape with provisions that impact manufacturers, PBMs, payers, pharmacies, and plan beneficiaries. To help our clients track and stay up to date with the impacts of the IRA, the *Mintz IRA Update* analyzes current pharmacy supply chain related developments and provides informed and insightful analyses on the issues that directly affect your business. This edition of the *Mintz IRA Update* covers developments through July 1, 2024.

Learning From Experience: Medicare Drug Price Negotiation Program Updates

By Stephnie John, Samantha Hawkins, Madison Castle

Since our last edition of the ***Mintz IRA Update***, the Medicare Drug Price Negotiation Program (the "Negotiation Program" or "Program") and related maximum fair price (MFP) negotiation process for each of the 10 high-expenditure Medicare Part D drugs selected for negotiation (the "Selected Drugs") has gone into full swing. After the Centers for Medicare and Medicaid Services (CMS) sent initial offers to the manufacturers participating in the first cycle of the Negotiation Program, the Biden administration confirmed that **it had received counteroffers** from each of the Selected Drugs' manufacturers. The Biden administration later **confirmed** in April that it had sent subsequent counteroffers to manufacturers for the Selected Drugs. Pursuant to the **Draft Guidance for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the MFP in 2026 and 2027** (the Draft Guidance), each manufacturer may meet with CMS up to three times to further negotiate the MFP before CMS announces the final MFP for each Selected Drug on September 1, 2024.

Despite an initial outcry from many manufacturers, including litigation challenging the program filed in six judicial circuits, some manufacturers have since conceded that the negotiations have not proven to be as disparaging to their businesses as anticipated, which we discuss further below. Nevertheless, as we detail in this article, CMS is already considering changing the structure and format of the negotiation meetings for 2027.

Changes to the 2027 Negotiation Process and Potential Drugs for Selection

CMS released the Draft Guidance on May 3, 2024. CMS outlined new requirements for the second cycle of negotiations, which begin in 2025 and will result in negotiated MFPs that go into effect in 2027.

A key focus under the Draft Guidance is CMS's invitation for public comment regarding how CMS may change the format and number of negotiation meetings with manufacturers. Currently, CMS invites manufacturers to meet up to three times to negotiate the MFP for a Selected Drug before CMS announces a final price. However, as the number of drugs selected for negotiation increases each year (e.g., 15 additional Part D drugs in 2027, and an additional 15 Part B and/or Part D drugs in 2028),

CMS acknowledges that holding three meetings for each drug selected for negotiation will prove overly burdensome and difficult to schedule.

Some additional updates to the Negotiation Program since publication of the **Revised Guidance for Initial Price Applicability Year 2026** (the "Initial Guidance") include:

- Changes to the requirements and parameters for data exchange among dispensing entities (e.g., pharmacies) and participating manufacturers via a Medicare Transaction Facilitator (MTF) to provide data needed to facilitate access to MFPs of Selected Drugs for dispensing entities;
- Use of an MTF to facilitate the provision of claim-level data elements to manufacturers when a Selected Drug is dispensed to a person verified to be MFP-eligible;
- Requirement that participating manufacturers must make the MFP available at the point of sale to MFP-eligible individuals (and dispensing entities with respect to such MFP-eligible individuals) who are dispensed that Selected Drug during a price applicability period; and
- Proposed changes to the process and format for the MFP offer and counteroffer process between CMS and manufacturers, such as replacing one or more of the meetings with a written offer.

Response to Draft Guidance Across Industry

CMS solicited public comment and feedback on the Draft Guidance, with comments due to CMS by July 2, 2024. According to an **article from *Endpoints News***, the Draft Guidance has received negative feedback from various pharmacy supply chain stakeholders for a lack of transparency.

Representatives from trade associations PhRMA and **BIO** have reported that they found certain aspects of the Draft Guidance — specifically the proposal to reduce the format and number of industry-CMS negotiation meetings — to be an attempt by CMS to limit opportunities for manufacturer input with respect to the negotiation of the MFP. According to the trade associations' representatives, the Draft Guidance fails to address patient and provider concerns regarding the process through which CMS sets prices and how information gathered by negotiation meetings with manufacturers will be utilized. Representatives also found that the Draft Guidance did not address concerns offered in public comments to the **Initial Guidance**, in which many commenters were wary that price negotiations, combined with changes in interested party liability following a redesign of Part D, could impact the structure of Part D and in turn decrease patient access to medications.

Additionally, the American Hospital Association (AHA) **submitted a letter** to CMS on July 2, 2024, expressing concern over CMS's proposal to retrospectively effectuate the negotiated MFP by permitting manufacturers to make the MFP available to dispensing entities by retrospectively reimbursing the dispensing entity for the difference between the entity's acquisition cost and the MFP. The AHA claimed the proposed retrospective refund process would be "complex, burdensome, and would be operationally unworkable with respect to the critical 340B Drug Pricing Program" and expressed concern that the proposal would cause providers to have to chase down rebates and 340B discounts from manufacturers instead of requiring manufacturers to make the negotiated MFP available upfront, which is consistent with how the 340B program currently operates.

Drug Manufacturers Change Perspective on the IRA's Impact

Despite their frustration with the Draft Guidance, manufacturers have begun to concede that the Negotiation Program may not have as drastic of an impact as initially anticipated. In a 2023 **interview**, Pfizer's CEO initially described the Negotiation Program as "negotiation with a gun to your head." Recently, however, Pfizer's CFO **acknowledged** that "the impact of the IRA over time would be modest" given that many of its products that are "at risk [of being subject to the Negotiation Program] in the near term" are nearing the end of their marketing exclusivity period. Once the

exclusivity periods end, generic competitors are likely to enter the market and drive down the prices for those same drugs; therefore, Pfizer already anticipates lower profit margins from these drugs. Similarly, AstraZeneca, one of nearly a dozen manufacturers to file a lawsuit against the government for IRA price negotiations, has since revealed that CMS's first offer for its diabetes medication, Farxiga, was "relatively encouraging." The public is not privy to the exact prices discussed during the negotiations, but some patient groups suspect the recent statements by manufacturers may be an attempt by corporate executives to stem market concerns about the financial impacts of the Negotiation Program and protect the manufacturers' share value. However, Leigh Purvis, prescription drug policy principal at AARP's Public Policy Institute, believes CMS may be offering reasonable prices for the Selected Drugs, and manufacturers recognize the importance of conceding early to maintain their reputation with the public. If CMS ultimately decides upon reasonable MFPs for the Selected Drugs, manufacturers who continue to claim they will be significantly financially harmed by the Negotiation Program may lose their credibility and influence on public opinion.

Whatever the reason for the manufacturers' change of tone with regard to the Negotiation Program, drug affordability advocates assert that research supports reduced premiums and out-of-pocket costs for MFP-eligible individuals and the federal government can still expect to see significant savings over the next few years.

IRA Litigation Update: Courts Begin to Address Legal Challenges to the Medicare Drug Price Negotiation Program

By Xavier Hardy, Mitchell Clough

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 over the last year. Manufacturers and trade associations began filing lawsuits against the government even before the first 10 negotiation-eligible drugs were published in late August 2023. All but one of the manufacturers of those drugs has since filed suit seeking to enjoin the Negotiation Program, and nine lawsuits are currently pending across the country challenging the constitutionality and legality of the Negotiation Program **on several grounds**. As we **previously reported**, a federal district court in the Fifth Circuit tossed a lawsuit on procedural grounds, and another in the Sixth Circuit reached a preliminary determination that the plaintiffs had not shown a likelihood of success on the merits of their claim.

Since our last update, three more courts, two in the Third Circuit and another in the Second Circuit, have weighed in on the issues presented and have concluded that the Program passes constitutional muster. In total, each of the courts that has issued a decision so far has either dismissed the plaintiffs' challenges on procedural grounds or upheld the legality of the Program on the merits. Below, we summarize those new cases and what we can expect going forward.

Federal Judge in Delaware Dismisses AstraZeneca's Challenge

On March 1, 2024, a judge in the District of Delaware, located in the Third Circuit, **dismissed** AstraZeneca's suit challenging the constitutionality of the Negotiation Program and the legality of two Centers for Medicare & Medicaid Services (CMS) interpretive rules under the IRA. AstraZeneca alleged that the Negotiation Program violated its Fifth Amendment due process rights and thus was

unconstitutional. The first inquiry for due process challenges is whether the plaintiff has been deprived of a protected interest in property or liberty. As the court discussed, a protected property interest requires "more than an abstract need or desire" and "more than a unilateral expectation"; the plaintiff must have a legitimate claim of entitlement to" the property. The court found that AstraZeneca's purported property interest — which the court described as "the ability to sell its drugs to Medicare at prices above the ceiling prices and negotiated maximum fair prices established by the IRA" — was not protected by the Fifth Amendment, reasoning that the manufacturer does not have a right to force the government to buy its products at a particular price. AstraZeneca had also argued that participation in the Program was not voluntary because the consequence of not participating — which includes not being able to sell drugs to Medicare and Medicaid patients — essentially amounted to a "gun to the head." The court reasoned that while the "opportunity to sell drugs to 50% of the potential market for prescription drugs" may be a strong economic incentive, there was nothing improper about the federal government wielding its market share to obtain better prices. As for the claims based on the Administrative Procedure Act, the court concluded that AstraZeneca lacked Article III standing to bring the claims because CMS's allegedly erroneous interpretations of the IRA would not force AstraZeneca to suffer any concrete harm for years. The court, therefore, did not address the merits of those claims, dismissing them on procedural grounds.

New Jersey Federal Court Rejects Challenges Brought by Bristol Myers Squibb and J&J

In another string of cases arising out of the Third Circuit, nearly two months later, on April 29, 2024, the New Jersey federal judge overseeing four of the legal challenges to the IRA brought by multiple manufacturers **rejected** the constitutional challenges lodged by Bristol Myers Squibb Company (BMS) and Janssen Pharmaceuticals, Inc., a division of Johnson & Johnson (J&J). BMS and J&J both alleged that the Program violated three constitutional principles: (1) the Takings Clause of the Fifth Amendment by forcing manufacturers to transfer their drugs to Medicare participants at a government-dictated and below-market price; (2) the First Amendment right to free speech by compelling them to enter into "faux agreements" to "negotiate" a "maximum fair price"; and (3) placement of an unconstitutional condition on BMS's and J&J's exercise of those First and Fifth Amendment constitutional rights. In line with the *AstraZeneca* court, the New Jersey court concluded that because participation in Medicare is purely voluntary, the manufacturers could not complain of any constitutional infringements. The New Jersey court further concluded that the Program did not violate the Fifth Amendment or the First Amendment at all, and so the Program did not place an unconstitutional condition on the manufacturers' constitutional rights.

Connecticut Court Agrees that Manufacturer Claims Are Meritless

On July 3, the district court in Connecticut (located in the Second Circuit) overseeing the case brought by Boehringer Ingelheim became the latest to join the chorus of district courts, concluding that the Negotiation Program passes constitutional muster. Boehringer Ingelheim brought claims that overlapped with many other manufacturers (including the First Amendment, Takings Clause, and Unconstitutional Conditions claims considered and rejected by other courts). In line with all the courts to date, the Connecticut court concluded that these constitutional claims failed, resting largely on the conclusion that participation in the Medicare program is purely voluntary — though the court, in dictum, rejected the government's argument that there is no constitutional violation because a manufacturer can simply divest its interest in the Selected Drug. The case also offered a first look at additional claims brought by other manufacturers but not yet addressed by the courts, including claims (which we **summarized** in a prior

edition) that (1) the Negotiation Program's excise tax levied on non-compliant manufacturers was an excessive fine in violation of the Eighth Amendment, and (2) CMS violated the Administrative Procedures Act when it promulgated the manufacturer agreement without following notice-and-comment procedures. The court rejected the latter claim, concluding that Congress exempted much of the Negotiation Program's regulatory framework from the typical notice-and-comment procedures. Further, the court refused to consider Boehringer Ingelheim's Eighth Amendment excessive-fines claim, concluding that doing so would violate the Anti-Injunction Act, which generally prohibits preemptive suits by taxpayers to prohibit the collection of taxes and instead requires that they sue for a refund after paying. In sum, the Connecticut court handed the government yet another complete victory.

What's in the Pipeline

Three other cases, brought by Merck & Co. in DC (DC Circuit) and Novartis and Novo Nordisk in New Jersey (also in the Third Circuit), are awaiting decisions from the district courts. Each case brings claims that overlap with those that have been rejected by the *AstraZeneca*, *BMS/J&J*, and *Boehringer Ingelheim* courts but also inject additional claims that have not been heard on the merits by any court yet, including (1) constitutional challenges that the Program violates the nondelegation doctrine and levies excessive fines in violation of the Eight Amendment, and (2) challenges under the Administrative Procedures Act to certain CMS agency actions under the IRA.

While the parties in those three cases await district court rulings, the appellate process has already begun to take shape for some of the cases where decisions have been issued. AstraZeneca, BMS, and J&J have each filed appeals to the Third Circuit, and the *Boehringer Ingelheim* case is likely to percolate up to the New York–based Second Circuit. As we **previously reported**, the Texas-based lawsuit brought by Pharmaceutical Research and Manufacturers of America (PhRMA) was dismissed on procedural grounds. PhRMA and its co-plaintiffs have since appealed that ruling, and the Fifth Circuit recently heard oral arguments on whether to reinstate the case and require the district court to proceed to hearing the case on its merits. (At least one Fifth Circuit judge **appeared skeptical** of the government's argument that participation in Medicare is purely voluntary.) If the Fifth Circuit reinstates PhRMA's case, then the Fifth Circuit district court will join the district courts in the Second, Third, Sixth, and DC Circuits in having the opportunity to rule on the merits of the challenges to the Negotiation Program.

Uncertainty over the legality of the Program seems as though it will persist into 2025. Decisions from the district courts will continue to come in on a rolling basis, and we expect to see the appellate courts begin to weigh in on the merits. So far, the government has yet to lose a case, although manufacturers will have many opportunities to notch a first victory. Whether or not a circuit split emerges, there is still a reasonable chance that at least some of the cases will eventually wind up at the Supreme Court. Given the current timeline, the Supreme Court could hear the cases and issue a decision as early as the next term, which runs from October 2024 through June 2025.

The Consequences and Costs of Redesigning the Part D Program

By Tara Dwyer, Lauren Moldawer, David Gilboa, Samantha Hawkins, Stephnie John, Matthew Tikhonovsky

The passage of the Inflation Reduction Act of 2022 (IRA) marked a significant milestone in Congress's ongoing efforts to address escalating health care costs. While the IRA aims to rein in government spending on Medicare and to lower point-of-sale prescription drug costs for Medicare beneficiaries, its implementation, and adoption of the redesigned Medicare Part D program has sparked a cascade of consequences for Medicare Part D plan sponsors ("PDPs"), beneficiaries, and manufacturers.

Overview of 2025 Part D Redesign

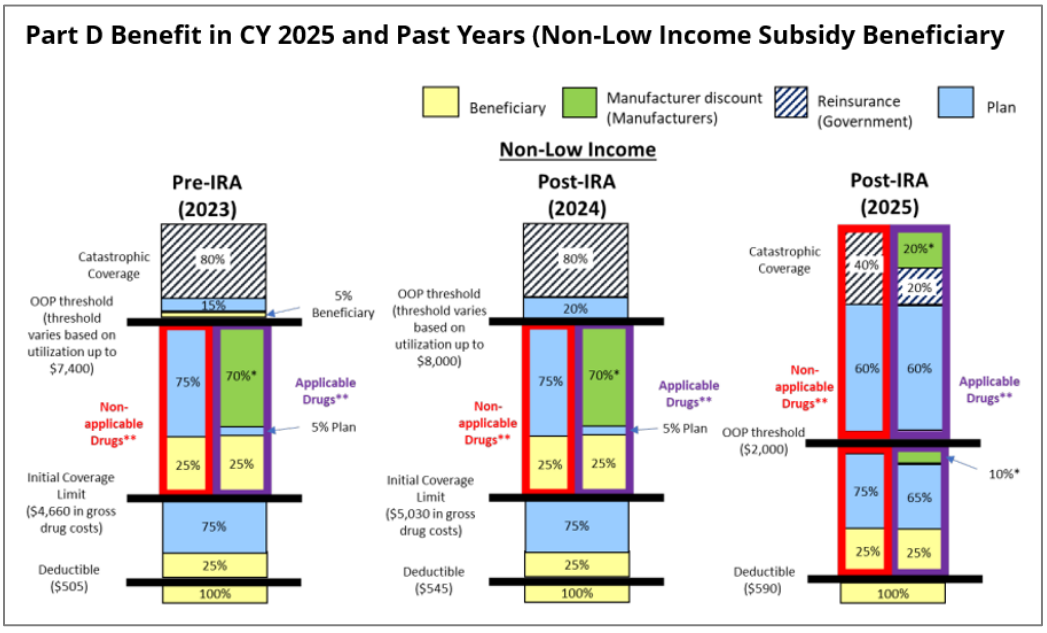
At a high level, the IRA is making the following changes to the standard Part D benefit design and other program elements that will go into effect on January 1, 2025:

- *Elimination of the Coverage Gap.* The coverage gap will be eliminated in 2025. As a result, the Part D benefit design will consist of three, instead of four, benefit phases: annual deductible, initial coverage, and catastrophic coverage.
- *Changes to Share of Medicare Part D Drug Costs Paid by Beneficiaries, Plans, Drug Manufacturers, and CMS*. In 2025, the liability for drug costs paid by a beneficiary, and the costs and risks carried by PDPs, manufacturers, and CMS during each coverage phase will change significantly. Below are the contemplated cost-sharing amounts by benefit phase.
    - **Annual deductible phase:** The beneficiary is responsible for 100% of the cost of drugs during the annual deductible phase.
    - **Initial coverage phase:** The beneficiary will continue to be responsible for 25% of the cost of both Non-Applicable and Applicable Drugs (described below) during the initial coverage phase, which is consistent with prior years. PDPs will be responsible for 65% of the cost of Applicable Drugs, and the remaining 10% of the cost of Applicable Drugs will be covered by the manufacturer's discount. For Non-Applicable Drugs, the PDP must cover 75% of costs, and the manufacturer does not share responsibility for any costs.
    - **Catastrophic phase:** During the catastrophic phase, PDPs will be responsible for 60% of the cost of both Non-Applicable and Applicable Drugs, an increase from 20% in past years. The government (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.
- *Capping Out-Of-Pocket Costs.* The beneficiary's annual out-of-pocket threshold will be capped at $2,000.
- *Calculation of TROOP.* The IRA updated what costs are counted towards True Out-Of-Pocket Costs (TrOOP), which are used to determine when a beneficiary moves through each coverage phase and reaches the annual out-of-pocket threshold. Beginning in 2025, the IRA makes changes to the definition of "incurred costs," which is used to calculate TrOOP. Under the

amended definition for 2025, the definition of "incurred costs" includes costs incurred for supplemental Part D coverage provided by enhanced alternative (EA) Part D plans and other health insurance (OHI). This includes supplemental coverage provided by EGWPs (a long-standing policy), plan reductions in cost sharing for enrolled beneficiaries, such as reductions by Medicare-Medicaid Plans and D-SNPs, and CMMI model benefits that reimburse costs for covered Part D drugs (unless stated otherwise in a Request for Applications).

- *The Medicare Discount Program.* Under the Medicare Discount Program (which conceptually replaces the Coverage Gap Discount Program), Part D drugs dispensed to beneficiaries will be subject to manufacturer discounts during both the initial and catastrophic coverage phases of the Part D benefit. Manufacturers are required to offer a 10% discount on Applicable Drugs in the initial coverage phase and a 20% discount on Applicable Drugs in the catastrophic coverage phase. However, a manufacturer is not required to offer a discount under the Medicare Discount Program on a drug that has been selected for the Medicare Drug Price Negotiation program, referred to as "Selected Drugs." For purposes of the Medicare Discount Program, Selected Drugs are defined to be "Non-Applicable Drugs."
- *Reinsurance*. The change in reinsurance for Applicable versus Non-Applicable Drugs has downstream impacts on the reinsurance methodology. Specifically, these changes impact the calculations for annual payments made to PDPs after the reconciliation process that takes into account the PDP-reported direct and indirect remuneration ("DIR"). In CY 2025, CMS will calculate the reinsurance subsidy separately for Applicable and Non-Applicable Drugs and allocate the share of DIR for Applicable and Non-Applicable Drugs based on their respective share of gross drug costs that fall in the catastrophic phase.

In its **Fact Sheet on Final CY 2025 Part D Redesign Program Instructions**, CMS provided the below visual comparing the 2025 cost sharing to prior years:



As displayed in CMS's comparison, the changes to the Part D benefit design shift liabilities and financial risk towards PDPs. The shifting liability specifically moves risk that was historically carried by beneficiaries, CMS, and drug manufacturers to PDPs. In 2025, PDPs will take on financial risk:

- From beneficiaries, by introducing the $2,000 out-of-pocket threshold for all beneficiaries;
- From manufacturers, who used to fund 70% of drug costs that were incurred during the Coverage Gap for Applicable Drugs (typically brand drugs); and
- From CMS in the catastrophic phase, where CMS historically covered 80% of the cost of the drug but will now only cover 40% of costs for Non-Applicable Drugs (typically generic drugs and Selected Drugs) and 20% of costs for Applicable Drugs.

While these changes may bring relief to many Medicare beneficiaries in terms of capped out-of-pocket costs, it is yet to be determined if these changes will result in increased beneficiaries' premiums or more restrictive formularies. These changes are also anticipated to have material impacts on PDPs, beneficiaries, and manufacturers.

Impacts on PDPs

On Monday, June 3, 2024, PDPs submitted their bids for contract year 2025. These bids needed to take into account the new benefit design resulting from the IRA. The impact to PDPs was the focus of many comments that CMS responded to as part of its **Final Calendar Year Part D Redesign Program Instructions** that it released on April 1, 2024 to provide guidance on the implementation of the IRA changes to the Part D program. While the overall changes for PDPs are significant, the true impact of the shifts will be most directly felt by PDPs that enroll a higher-than-average number of beneficiaries who have historically reached the catastrophic coverage phase and are projected to exceed the $2,000 out-of-pocket maximum.

Pressure on Premiums

When CMS released its **Draft CY 2025 Part D Redesign Program Instructions**, commenters expressed concerns that PDPs would increase premiums due to the number of changes and urged CMS to narrow the risk corridors under Part D for 2025 and beyond. CMS declined this suggestion, noting that it does not have the authority to do so, and stated that the premium stabilization provisions of the IRA would accomplish the same result. The premium stabilization program, which began in 2024 and continues through 2029, limits increases in the Part D base beneficiary premium (BBP) to 6% growth each year.

If PDPs did not have to contend with the IRA limit on premium increases or market competition, PDPs would likely want to increase premiums by a notable amount. PDPs are required to take on more financial risk and, therefore, sell a more comprehensive plan product. Such a change would typically justify a higher premium. PDPs may also want to increase premiums because they might see a sizable loss of rebates, which PDPs cite as a tool to reduce premiums, as manufacturers reduce or eliminate rebates offered on Selected Drugs. PDPs may also see reduced rebates if manufacturers of Applicable Drugs refuse to pay historical rebate amounts as a result of their obligations under the Medicare Discount Program. Further, as discussed more fully below, because PDPs will see a reduced incentive to favor higher-cost drugs as a means to move beneficiaries through coverage phases, PDPs may forego additional rebates.

However, because premium increases are limited by the IRA and high premiums can quickly make a PDP uncompetitive, PDPs may try to dull the impact of the new financial risk by adjusting formularies.

Pressure on Formularies

Some believe that the old benefit structure incentivized PDPs to adopt benefit designs and

formularies favoring higher-cost point-of-sale drugs (with higher rebates) because the benefit design could cause beneficiaries to accrue higher-cost shares quickly and reach the Coverage Gap and catastrophic coverage faster. The redesigned Part D benefit provides little reason for PDPs to push beneficiaries beyond the initial coverage phase and potentially incentivizes PDPs to alter their formularies (by putting certain drugs on non-preferred formulary tiers or removing a drug outright) and to employ utilization management tools, like prior authorization or step therapy, to moderate demand growth for certain drugs.

In fact, the drugs that could be most affected by this new incentive structure are those drugs that have yielded the highest total Medicare Part D spending in the past (i.e., Selected Drugs). These Selected Drugs have historically been heavily rebated by manufacturers, contributing to revenue that PDPs use to reduce plan premiums and have been placed in favorable formulary tiers. As a result of the Negotiation Program, PDPs can expect a decrease in manufacturer rebates, which could lead to lower direct & indirect remuneration, higher plan premiums, and lower profits for PDPs. Going forward, the Selected Drugs may be at a disadvantage in PDP formulary designs depending on whether a PDP elects to focus more on rebates and premiums versus lower-cost shares.

While the law requires PDPs to cover the Selected Drugs, there is no requirement that PDPs put those products on a preferred formulary tier, nor are there limits on utilization management tools that PDPs can impose. CMS has acknowledged and expressed its concern that PDPs may be incentivized in certain circumstances to disadvantage Selected Drugs by placing these drugs on less favorable tiers compared to non-Selected Drugs and has promised to continue reviewing clinical formularies to ensure that all PDPs meet applicable formulary requirements.

Impacts on Beneficiaries

The redesigned Part D program will likely have both positive and negative impacts on beneficiaries.

- *Negative – Premiums*: PDPs will likely face financial pressure to increase premiums to account for the new level of coverage, which will impact all beneficiaries.
- *Positive/Negative – Formularies*:
    - PDPs do not have a strong financial incentive to move beneficiaries through benefit phases, and therefore PDPs may favor lower-cost drugs on formularies more than they have historically. This could result in lower point-of-sale cost shares for many beneficiaries.
    - Because PDPs are taking on more financial risks, they may apply more utilization management tools than in the past, which can be frustrating to beneficiaries and their providers.
    - How PDPs will treat Selected Drugs, which are used by many beneficiaries, remains to be seen. However, beneficiaries may see reduced cost shares as a result of cost shares being calculated off of the Selected Drug's CMS-negotiated price.
- *Positive – Capping Out-of-Pocket Costs at $2,000*: This change will materially assist beneficiaries who have historically had high drug costs, who are predicted to be a low percentage of the Medicare population.
- *Positive – Changes in True Out-of-Pocket Costs*: This change will result in some beneficiaries reaching the out-of-pocket maximum faster than they would have otherwise.

Impacts on Manufacturers

The impact of all of the Part D benefit design changes and potential effects on Selected Drugs will likely produce a wide variety of outcomes for manufacturers. The outcomes will vary because manufacturers and the types of drugs that many manufacturers produce are diverse.

For some brand drug manufacturers, the change from the Coverage Gap Discount Program (70% funded by manufacturers) to the Medicare Discount Program may be a welcome one (10% funded by manufacturers in the initial phase, 20% funded by manufacturers in the catastrophic phase). However, the actual impact of this new program will be different for each manufacturer. A manufacturer with high-cost specialty drugs may have preferred to continue to operate in the Coverage Gap Discount Program because its liability was capped once a beneficiary reached catastrophic coverage.

The introduction of the out-of-pocket maximum to the Part D benefit design could also produce an increase in demand for maintenance drugs that some beneficiaries were not taking as directed in order to reduce costs or were not filling at all.

Further, the overall composition of Part D formularies and potential changes driven by redesigning the Part D benefit could have significant impacts on manufacturers. As discussed above, under *Impacts to PDPs*, PDPs may elect to prefer drugs with lower list prices as a result of no longer having a strong incentive to move beneficiaries through benefit phases. Manufacturers with such drugs could stand to benefit from increased demand for their products. On the other hand, some PDPs could elect to focus on seeking higher-value rebates on drugs that are alternatives to Selected Drugs so that the PDPs can still collect and benefit from rebates. Such a strategy would advantage such alternative drugs through potential utilization growth, but likely demand rebates at levels that a manufacturer may not have previously offered. Similarly, Selected Drugs could see increased utilization because they will be included on all Part D formularies. However, Selected Drugs that face some level of competition from potential alternative treatments may be confronted with less favorable placement.

In the next few months, as PDP premiums and formularies for 2025 are released, we expect that the impacts of redesigning the Part D program felt by PDPs, beneficiaries, and manufacturers will become much clearer.

Opposition to the Use of March-In Rights to Lower Drug Prices

By Stephnie John

In our **previous *Mintz IRA Update***, we covered the Biden administration's proposal exploring the use of "march-in rights" granted under the Bayh-Doyle Act (the "Act") to seize pharmaceutical patents if the administration believes that a pharmaceutical product is not available to the public at a reasonable price. As a quick recap, the Act grants the government authority to exercise "march-in rights," allowing federal agencies to require patent licenses be given to third parties if a product was developed with the assistance of federal funding and one of four statutory criteria under the Act is satisfied. On December 8, 2023, the Biden administration released the **Draft Interagency**

Guidance Framework for Considering the Exercise of March-In Rights (the "Draft Guidance"), providing a framework with specific factors and hypothetical examples to assist agencies in their determination of whether to exercise "march-in rights." The administration's suggestions include having agencies conduct an evaluation of whether the "march-in" would alleviate health or safety concerns, meet public use and access requirements, and for the first time in the Act's history, agencies may consider reasonableness of pricing in considering whether a "march-in" is warranted.

A number of Republican lawmakers oppose the proposal to utilize "march-in rights" to curb rising prescription drug costs, citing concerns over whether the use of "march-in rights" could stifle pharmaceutical innovation and undermine intellectual property rights. On March 4, 2024, U.S. Senator Bill Cassidy, M.D. (R-LA), ranking member of the Senate Health, Education, Labor, and Pensions (HELP) Committee **requested** that the Government Accountability Office (GAO) issue a determination as to whether the Draft Guidance meets the definition of a "rule" under the Congressional Review Act (CRA), rendering the Draft Guidance subject to challenge under the CRA. The CRA adopts the APA's definition of a "rule," which states that a rule is "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedures, or practice requirements of an agency…". 5 U.S.C. § 551(4). However, the CRA excludes three categories of rules from coverage under the CRA: (1) rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. § 804(3). On May 28, 2024, the GAO **issued its decision**, concluding that the Draft Guidance is not a rule. The Draft Guidance does not impose any requirements on agencies or alter the rights or obligations of regulated parties. Additionally, the NIST received over 52,000 comments in response to the Draft Guidance, which it is analyzing and incorporating into its final guidance document. Because there are additional steps NIST must take before the Draft Guidance is finalized, the GAO concludes that the Draft Guidance is not "certain and final, and therefore does not implement, interpret, or prescribe law and policy."

Criticism of the proposal to use "march-in rights" to lower prescription drug prices is not limited to the Republican party. Senator Chris Coons (D-Del.) and nine other Democrats **signed onto a letter** to President Biden signaling their concern over the exercise of "march-in rights" with respect to pharmaceutical products. The authors point out that fewer than 2% of products approved by the Food and Drug Administration (FDA) are eligible to be subject to full "march-in rights," and thus exercising "march-in rights" would have a negligible impact on tackling drug costs. Additionally, the authors argue that the benefits would be outweighed by the threat to public-private partnerships and private-sector investment in federally funded research for all types of technologies and products, not just pharmaceuticals.

We will continue to monitor developments surrounding the Biden administration's attempts to "march-in" on pharmaceutical patents and drug prices, including Congressional response to the GAO's ruling and will provide updates in future editions.

The Growing Use of State Prescription Drug Affordability Boards

By Madison Castle

In recent years, several states have implemented independent state boards — called Prescription Drug Affordability Boards ("PDABs") — to address high drug prices in their health care systems. Amid federal implementation of the IRA, PDABs are being utilized by state legislatures as an additional lever to curtail high drug prices.

Scope of PDAB Authority

As of July 1, 2024, eleven states have enacted PDABs: Colorado, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Ohio, Oregon, and Washington. The authority of a PDAB varies by state; for example, PDABs in Colorado, Minnesota, Washington, and Massachusetts have the authority to identify unaffordable drugs and establish upper payment limits ("UPLs") for those drugs to reduce drug prices for consumers in their respective states. In Massachusetts, however, the PDAB's UPL authority applies only to Medicaid enrollees, while the PDABs in Colorado, Minnesota, and Washington have broader authority to apply their UPLs to a larger population of consumers. Other states task their PDABs with authority to drive down drug prices in their states, including, for example, the New York state PDAB, which is authorized to negotiate supplemental rebate agreements with manufacturers on behalf of the state's Medicaid program.

Manufacturer's Response

Manufacturers have raised concerns over the use of PDABs, including, for example, a concern that **setting limits on drug prices** may cause patient access issues in the long term. Manufacturers have also indicated concern that prescription drugs for rare diseases ("orphan drugs") may suffer from less manufacturer investment if prices are capped by state boards, given the potentially limited upside in such investments. As a result, some manufacturers are pushing for state legislatures to exempt orphan drugs from the purview of state PDABs' authority.

In some states, manufacturers have filed suit to challenge the actions of state PDABs. We will continue to monitor developments relating to state PDAB actions, and provide updates in future editions.

WHAT WE ARE READING

- **Medicare Plan to Verify Negotiated Drug Prices Spurs Unease**
  Bloomberg Law | May 29, 2024 | **Read here ...**
- **Chinese Biotech Crackdown Would Reset U.S. Drug Development**
  Axios | May 15, 2024 | **Read here ...**
- **Drug Price Program Legal Fight Shifts Focus to Property Rights**
  Bloomberg Law | April 23, 2024 | **Read here ...**
- **Trump Surrogates Hint At How He Could Reshape U.S. Health Care Policy**
  STAT | April 23, 2024 | **Read here ...**

MANAGING EDITORS

RACHEL A. ALEXANDER
Member | Washington, DC
RAlexander@mintz.com
+1.202.434.7474

THERESA C. CARNEGIE
Member | Washington, DC
TCCarnegie@mintz.com
+1.202.661.8710

TARA E. DWYER
Member | Washington, DC
TEDwyer@mintz.com
+1.202.585.3504

LAUREN M. MOLDAWER
Member | Washington, DC
LMMoldawer@mintz.com
+1.202.434.7486

STAFF EDITORS

HASSAN SHAIKH *(Articles Editor)*
Associate | Washington, DC
HShaikh@mintz.com
+1.202.434.7375

BRIDGETTE A. KELLER
Of Counsel | New York
BAKeller@mintz.com
+1.212.692.6735

MADISON M. CASTLE
Associate | Washington, DC
MMCastle@mintz.com
+1.202.434.7309

MITCHELL J. CLOUGH
Associate | Boston
MJClough@mintz.com
+ 1.617.348.1690

DAVID R. GILBOA
Associate | New York
DRGilboa@mintz.com
+1.212.692.6736

XAVIER G. HARDY
Associate | Washington, DC
XGHardy@mintz.com
+1.202.434.7314

SAMANTHA HAWKINS
Associate | Washington, DC
SHawkins@mintz.com
+1.202.434.7358

STEPHNIE A. JOHN
Associate | New York
SAJohn@mintz.com
+1.212.692.6257

ABDIE SANTIAGO
Associate | Washington, DC
ASantiago@mintz.com
+1.202.434.7321

MINTZ

Our team possesses unparalleled experience in the intricate world of the pharmaceutical supply chain. Navigating the maze of federal and state laws and regulations can be daunting for manufacturers, plans, pharmacy benefit managers, pharmacies, and other entities providing goods and services throughout the pharmaceutical supply chain. That's where we come in. With an in-depth understanding of the industry, legal frameworks, and policy trends, we offer insightful and strategic guidance to help clients meet their business objectives.

Visit **mintz.com** to learn more.

Boston | Los Angeles | Miami | New York | San Diego | San Francisco | Toronto | Washington

© 2024 Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.