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Mintz **IRA Update**

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Mintz's **Managed Care, PBMs & Pharmacies** Practice is pleased to present the 'Fifth Edition: Q3 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 developments related to the IRA, the *Mintz IRA Update* provides informed and insightful analyses on the issues that directly affect your business. In this edition of the *Mintz IRA Update* covers developments through August 2025.

IRA Medicare Drug Price Negotiation Program Updates for Q3 2025

By Rachel Alexander, Stephnie John, Samantha Hawkins, Hassan Shaikh

On May 12, 2025, the Centers for Medicare & Medicaid Services (CMS) issued draft guidance for the third cycle of the IRA's Medicare Drug Price Negotiation Program (Negotiation Program). This draft guidance (Draft Guidance) addresses the Negotiation Program's expansion into Medicare Part B and introduces a framework for renegotiating previously negotiated drug prices. However, recent legislative activity may affect the timing of this third cycle of negotiations. The inclusion of Part B drugs in the Negotiation Program allows CMS to target high-cost medications not previously captured under the Negotiation Program. Renegotiations allow CMS and manufacturers a second chance to take into consideration changes in the pharmaceutical market.

Timeline for Third Cycle of the Negotiation Program

Under the IRA, CMS is authorized to negotiate "maximum fair prices" (MFPs) for select high-cost, single-source drugs that lack generic or biosimilar competition. The first cycle of negotiations concluded in 2024 and covered 10 Part D medications, with negotiated MFPs for those drugs slated to go into effect on January 1, 2026. A second cycle of negotiations targeting 15 additional Part D drugs is underway, with the final negotiated MFPs scheduled to go into effect on January 1, 2027. CMS's publication of the Draft Guidance kicks off the third cycle of negotiations, issuing proposed collection requests focused on gathering information necessary to identify (1) which drugs qualify for the small biotech exception, (2) which biological products qualify for an initial delay in consideration for selection for the Negotiation Program in 2028, and (3) which drugs will be selected for the third cycle of negotiation and renegotiation of MFPs from prior cycles. In addition, the Draft Guidance seeks comment from stakeholders on how to increase transparency in the Negotiation Program. The comment period closed on June 26, 2025. Key dates in the timeline for the third cycle of the Negotiation Program are as follows:

- ***May 12, 2025***: Draft Guidance issued. Public comment period began.
- ***June 26, 2025***: Public comment period closed.
- ***Summer – Fall 2025***: Additional data collection requests, and issuance of final guidance.
- ***February 1, 2026***: CMS will publish (1) a list of up to 15 Part B and/or Part D drugs selected for the third cycle of MFP negotiations, (2) a list of up to 50 Part B and/or Part D drugs that were eligible for negotiation in the third cycle (which will include the list of selected drugs for 2028), and (3) a list of any previously selected

drugs from the first or second cycles of negotiations that are slated for renegotiation in the third cycle.

- ***March 1, 2026***: Deadline for (1) manufacturers of drugs selected for participation in the 2028 Negotiation Program to submit data for consideration in the negotiation or renegotiation of MFPs, and (2) public stakeholder input.
- ***June 1, 2026***: Deadline for CMS to issue initial MFP offers to manufacturers of selected drugs.
- ***November 1, 2026***: Negotiation period ends.
- ***November 30, 2026***: CMS to publish finalized negotiated and renegotiated MFPs for the third cycle selected drugs.
- ***January 1, 2028***: New and renegotiated MFPs take effect.

Key Developments in the Draft Guidance

1. *Broadening Scope to Include Part B Drugs*. Beginning in 2028, certain drugs payable under Medicare Part B (typically medications administered in a hospital or a physician's office) will be subject to MFP negotiations. The Draft Guidance invited input on approaches to calculating the MFP for those selected drugs that are not paid based on average sales price or wholesale acquisition methods.

2. *Introducing Renegotiation*. As directed by the IRA, CMS outlines criteria for the renegotiation of MFPs for drugs selected during the first cycle and second cycle of negotiations, all of which currently have MFP effective dates in 2026 or 2027. Renegotiation-eligible drugs that have had a change in monopoly status to become either a long-monopoly drug (a drug that has been FDA-approved for at least 16 years) or extended-monopoly drug (a drug that has been FDA-approved for at least 12 years and less than 16 years) will automatically be selected for renegotiation. CMS will then review the remaining selected drugs from the first two cycles of negotiation and identify those for which a new indication has been added. This includes both new indications that have received FDA approval, as well as new indications that are not FDA-approved but have been added in nationally recognized, evidence-based guidelines and listed in CMS-recognized Part D compendia. Finally, CMS will review the remaining selected drugs from the first two cycles of negotiation for a material change in any Social Security Act Section 1194(e) factor and consider the likelihood that, after renegotiation, the renegotiated MFP would represent a 15% or greater change relative to the current MFP. If the renegotiated MFP would meet that 15% threshold, the drug will be eligible for renegotiation. The Draft Guidance invited comment on whether applying the standard MFP negotiation process to renegotiation would be practicable.

3. *Enhancing Transparency and Efficiency*. The Draft Guidance seeks to promote greater transparency in the process for identifying selected drugs by publishing a list of up to 50 of the top negotiation eligible Part B and/or Part D drugs (including the list of up to 15 drugs already selected for MFP in 2028). The list will be ranked by combined total expenditures under Part B and Part D. The list will not include those negotiation eligible drugs that qualify for the Biosimilar Delay. The Draft Guidance solicited comments on ways to increase transparency in the process for selecting MFP drugs for renegotiation.

4. *Public Engagement*. In the Draft Guidance, CMS states it plans to host up to 15 patient-focused roundtable events and town hall meetings in Spring 2026 to gather input on drugs selected for negotiation or renegotiation. The roundtables will be open to patients, patient advocacy organizations, and caregivers. CMS further encourages practicing clinicians and researchers, as well as other interested parties, to register to participate.

5. *Medicare Transaction Facilitator*. The Draft Guidance proposes parameters and requirements for data exchange between participating manufacturers and dispensing entities (via a Medicare Transaction Facilitator) to facilitate access to MFPs of selected drugs for

entities that dispense a selected Part D drug to a verified MFP-eligible beneficiary.

6. *Enforcing Manufacturer Obligations*. The Draft Guidance outlines the requirements for manufacturers to comply with the Negotiation Program and proposes civil monetary penalties for, among other things, a manufacturer's (1) failure to ensure access to a price less than or equal to the MFP for MFP-eligible beneficiaries and pharmacies and other dispensing entities; (2) failure to pay the rebate amount for a biological product for which inclusion on the selected drug list was delayed but which has since undergone negotiation; (3) provision of false information related to the Small Biotech Exemption and the Biosimilar Delay; or (4) failure to pay a Biosimilar Delay rebate.

"One Big Beautiful" Exemption

On July 4, 2025, President Trump signed into law the One Big Beautiful Bill Act (OBBBA) that combines tax, spending, and health care measures and forms the core of the president's agenda for his second term. The OBBBA contains a provision that, while brief, has significant implications for the Negotiation Program. Section 71203(a) of the OBBBA expands and clarifies the exclusion for orphan drugs under the Negotiation Program by amending the exemption at 42 U.S.C. 1320f 1(e)(3)(A) to include drugs that are designated for one *or more* rare diseases or conditions, and clarify that the negotiation period for drugs or biological products that have lost their orphan drug exclusion status will begin the day after such drug is approved as a non-orphan drug or such biological product is licensed as a non-biological product. As a result of this provision, drugs that are approved for several orphan diseases but not for more common conditions are now exempted entirely from the Negotiation Program, and Medicare price negotiations for products that were first approved as orphan disease drugs but later were approved for wider use, including several blockbuster drugs, could now face postponed negotiation timelines. This section of the OBBBA could potentially delay anticipated savings for seniors and taxpayers and, according to a Congressional Budget Office's report, cost Medicare nearly $5 billion in lost MFP-related savings over the next decade.

The Draft Guidance sets forth CMS's preferred approach to the future of the Negotiation Program, but prior to issuing the final guidance for the third cycle in Fall 2025, CMS will need to account for any legislative changes enacted, including those in the OBBBA, while preserving the Negotiation Program's goals of containing costs, streamlining negotiations, and increasing transparency in the process.

Still Undefeated: Government Notches Three More Victories in Negotiation Program Lawsuits

By Theresa Carnegie, Mitchell Clough, Xavier Hardy, Hassan Shaikh

What's Been Happening

As we wrote in May, the Third Circuit handed down the first appellate decision on the merits of manufacturers' claims. In affirming the trial court and rejecting claims by AstraZeneca that the Negotiation Program violated its procedural due process rights, the court relied heavily on the fact that participation in Medicare is purely voluntary.

The government has continued to chalk up victories both on the merits and procedurally since May. This month, the Second Circuit joined the Third Circuit in concluding that manufacturers cannot claim any injury to their constitutional rights because participation in Medicare is voluntary. The ruling affirmed an earlier decision from a Connecticut federal judge dismissing Boehringer Ingelheim's claims. Boehringer Ingelheim had brought claims alleging a violation of the Takings Clause and compelled speech in violation of the First Amendment, and that the Negotiation Program

placed unconstitutional conditions on its participation in Medicare.

Additionally, a federal district judge in Texas rejected the merits of claims brought by the Pharmaceutical Research and Manufacturers of America (PhRMA) and two other trade associations. The case had previously been dismissed on procedural grounds but was reversed by the Fifth Circuit and sent back for a ruling on the merits. On remand, the district court granted the government another complete victory, aligning itself with the decisions from the Third Circuit and other district courts that have already rejected each of the manufacturers' claims. Once again, the voluntariness of participation in Medicare was the touchstone of the court's decision.

The Sixth Circuit also affirmed an Ohio federal district judge's dismissal on procedural grounds of a claim brought by several chambers of commerce, purportedly on behalf of AbbVie. The chambers relied on their associational standing to sue on behalf of their members, but the district court found that the only chambers with the ability to sue in the chosen district lacked standing. The Sixth Circuit agreed, calling AbbVie a "stalking horse" behind the chambers and criticizing the decision to sue through the regional chambers of commerce as an attempt to "manipulate the system and manufacture standing to obtain a favorable venue." The Sixth Circuit's decision spells the likely end of the manufacturers' attempt to obtain a favorable decision from the Sixth Circuit on the merits.

Finally, following Medicare's release of negotiation-eligible drugs for 2025, Teva Pharmaceuticals, whose drugs AUSTEDO and AUSTEDO XR were listed for negotiation, sued in DC federal court. Teva's suit is based on three theories, each of which has some similarities to those pressed by other manufacturers, including: (1) an Administrative Procedures Act violation relating to CMS's definition of "qualifying single source drug," (2) another APA violation relating to the "bona fide marketing" standard, and (3) a violation of Teva's procedural due process rights. This is the second case brought in DC federal court; the first, brought by Merck, has been awaiting a decision on the parties' cross-motions for summary judgment since November 2023.

What We're Watching For

Although the government remains undefeated, manufacturers still have several cases offering a chance of victory. PhRMA's loss in a Texas court tees up an appeal to the conservative-leaning Fifth Circuit, where one judge expressed some skepticism about the legality of the Negotiation Program overall during arguments on an appeal from a procedural dismissal of the case. Though a three-judge panel of the Third Circuit rejected AstraZeneca's claims, the same panel is still working on its decision in four other manufacturers' cases raising various claims and theories. Finally — and unsurprisingly — AstraZeneca has indicated it may ask the Supreme Court to review the Third Circuit's decision rejecting its claims, with its petition due in September. If the justices decide to take up the case, they will likely issue a decision by June 2026.

Redesigning Part D for CY 2026

By Tara Dwyer, Samantha Hawkins

The Inflation Reduction Act of 2022 (IRA) adopted many changes to the Medicare Part D program and plan benefit design. Instead of reforming the Part D program all at once, the IRA set forth a path for the Medicare Part D program to evolve through the years. One of the tools that the Centers for Medicare & Medicaid (CMS) uses to implement IRA-needed changes and provide guidance to Part D plan sponsors about upcoming changes is the "Redesign Instructions." The Final CY 2026 Part D Redesign Program Instructions (2026 Redesign Instructions) largely mirror the Final CY 2025 Part D Resign Program Instructions, which we covered in our third edition.

In this issue, we provide an update on the key changes made to Medicare Part D as explained in the 2026 Redesign Instructions since our last issue.

The 2026 Redesign Instructions finalized the following changes that we discussed at length in our last issue:

- Increase in Beneficiary OOP Cost Maximum to $2,100.
- *Establishment of the Selected Drug Subsidy Program*. The Selected Drug Subsidy Program lowers Part D sponsor liability on the negotiated price of selected drugs. The 2026 Redesign Instructions provide guidance on several topics related to the subsidy, including the policy for drugs not subject to the defined standard deductible, selected drug subsidy prospective payments, and reinsurance methodology.
- *Creditable Coverage Determination*. Creditable Coverage Determination methodology is used to assess whether a non–Part D prescription drug plan provides coverage that is at least as good as Medicare Part D. If an individual does not enroll in Part D when they become Medicare eligible, they face a penalty when they elect to enroll unless they maintained "Creditable Coverage" prior to Part D enrollment. Under the 2026 Redesign Instructions, CMS provides two main options for determining whether a plan offers Creditable Coverage: (1) the actuarial equivalence method that requires actuarial analysis comparing the employer plan to the standard Part D benefit; and (2) the simplified determination method available for non–Retiree Drug Subsidy (non-RDS) plans, which requires a group health plan (GHP) to be designed to pay at least 60% of a participant's prescription drug expenses. Given the changes to the Part D benefit under the IRA, CMS felt the simplified determination methodology no longer reflected actuarial equivalence with defined standard Part D coverage. Therefore, CMS revised the simplified determination methodology to require GHP coverage to be designed to pay at least 72% of participants' prescription drug expenses. For CY 2026 only, non-RDS group health plans (GHPs) are allowed to use either the existing (60%) or revised (72%) simplified determination methodology — but for CY 2027 and beyond, they will be expected to use the revised approach. The 2026 Redesign Instructions noted general support from commenters on the revised simplified determination methodology proposed by CMS.

The 2026 Redesign Instructions also provided new changes and guidance:

- *Redesigned Part D Benefit*. The 2026 Redesign Instructions added new requirements to the

Initial Coverage and Catastrophic phases of the Part D benefit. Now, during the initial coverage phase, CMS will pay a 10% subsidy for selected drugs during a price applicability period; in the catastrophic phase, CMS will provide 40% reinsurance for selected drugs during a price applicability period.

- *PDP Meaningful Difference*. In response to sponsors' concerns, CMS revised the meaningful difference standard for standalone Part D Prescription Drug Plans (PDPs), lowering the threshold from the 15% that was included in the Draft Instructions to 10% for CY 2026. This change means that Part D plan sponsors must demonstrate that each Enhanced Alternative plan's Part D OOP Cost value generated from the OOP Cost model is at least 10% lower than the Part D OOP Cost value for the basic plan offered by the same parent organization in the same region.
- *Successor Regulation Exception Permitting Formulary Substitutions of Selected Drugs*. The 2026 Redesign Instructions adopts Section 423.120(e)(2)(i) and the associated notice requirements at Section 423.120(f)(2), (3), and (4) as the "successor regulation" to Section 423.120(b)(5)(iv) for purposes of allowing immediate substitution or negative formative changes for selected drugs when an applicable generic or interchangeable biological product becomes available.

Under Pressure: The Trump Administration's Drug Pricing Executive Orders

By Theresa Carnegie, Xavier Hardy, Hassan Shaikh, Abdie Santiago

On January 29, 2025, the Center for Medicare & Medicaid Services (CMS) released a statement highlighting that "[l]owering the cost of prescription drugs for Americans is a top priority of President Trump and his Administration." The statement further explained that the Trump administration and CMS were "committed to incorporating lessons learned to date from the program and to considering opportunities to bring greater transparency in the Negotiation Program." Since CMS's initial statement, the Trump administration has moved forward a number of initiatives to tackle the high costs of prescription drugs in the US. In this post, we summarize the unilateral initiatives taken by the administration over the past few months to curb drug costs, and we discuss Congress's potential role in helping effect such changes.

The First Executive Order

Three months after the CMS statement, on April 15, 2025, President Trump issued his first Executive Order aimed at curbing high drug prices in the United States. The Executive Order (Reform Order) instructs federal agencies to implement a variety of drug pricing reforms, several of which specifically address reforming the IRA. We previously discussed the broader scope of the Reform Order, which proposes drug pricing solutions from several different angles, including removing the so-called "pill penalty" from the Medicare Drug Price Negotiation Program (Negotiation Program), increasing pharmacy benefit manager (PBM) competition and transparency, and studying Medicare and Medicaid drug pricing, international importation options, and drug manufacturer competition.

The Reform Order also directed the Secretary of Health and Human Services (HHS) to propose and seek comment on guidance for the Negotiation Program. The stated purpose of the guidance is to "improve the transparency of the Negotiation Program, prioritize the selection of prescription drugs with high costs to the Medicare program, and minimize any negative impacts of the maximum fair price (MFP) on pharmaceutical innovation within the United States." Prior predictions that a second Trump administration would seek to repeal the Inflation Reduction Act (IRA) and replace the Negotiation Program now seem off the table. Instead, the inclusion of a directive for HHS to seek further public comment on the Negotiation Program suggests that this second Trump administration will, at least initially, seek opportunities to improve the existing Negotiation Program through more surgical measures.

The Second Executive Order

One month later, on May 12, 2025, President Trump issued a second Executive Order related to drug pricing. This Executive Order (MFN Order) seeks to reduce the price of drugs by requiring manufacturers to offer the United States most-favored-nation pricing — in other words, the lowest price offered to any "comparably developed" foreign country that pays for the same drugs. We discussed the MFN Order shortly after its release, noting similarities between the MFN Order and an Executive Order (First Term Executive Order) released during President Trump's first term that required CMS to issue rulemaking to test a payment model under which Medicare would pay no more than a most-favored-nation price for drugs covered by Medicare Part B and Part D. The First Term Executive Order was challenged in court and later rescinded by the Biden administration.

The MFN Order authorizes the Secretary of HHS, among other members of the current administration, to take immediate steps to ensure the United States receives most-favored-nation pricing for prescription drugs and to enforce the MFN Order should manufacturers fail to make significant progress toward meeting the most-favored-nation pricing requirements. In addition, the MFN Order requires the Secretary of HHS to facilitate a process whereby manufacturers can sell drugs directly to patients at most-favored-nation pricing.

The Manufacturer Letters

On July 31, 2025, the White House released a Fact Sheet indicating that President Trump had "sent letters to leading pharmaceutical manufacturers outlining the steps they must take to bring down the prices of prescription drugs in the United States to match the lowest price offered in other developed nations (known as the most-favored-nation, or MFN, price)." According to the Fact Sheet, addressed in our recent blog post, the steps include:

- Calling on manufacturers to provide MFN prices to every single Medicaid patient.
- Requiring manufacturers to stipulate that they will not offer other developed nations better prices for new drugs than prices offered in the United States.
- Providing manufacturers with an avenue to cut out intermediaries and sell medicines directly to patients, provided they do so at a price no higher than the best price available in developed nations.
- Using trade policy to support manufacturers in raising prices internationally, provided that increased revenues abroad are reinvested directly into lowering prices for American patients and taxpayers.

Should the 17 manufacturers identified by the White House refuse to comply with the proposed steps by September 29, 2025, the Fact Sheet warned manufacturers that the federal government would "deploy every tool in [its] arsenal to protect American families from continued abusive drug pricing practices." The Fact Sheet further explains that "decisive action" is needed to address concerns expressed by the Trump administration that American consumers are subsidizing the costs of pharmaceuticals for foreign nations.

The Fact Sheet raises several new issues that we are actively monitoring, including:

1. How will the White House determine if a manufacturer has "refused to step up"? Must the manufacturer comply with all requested steps, or will incremental progress be accepted by the administration?
2. Is it possible for manufacturers to commit not to offer better prices abroad, given existing drug pricing schemes in foreign jurisdictions?
3. How will the MFN pricing work in conjunction with President Trump's proposed plan to implement tariffs up to 250% on imported pharmaceutical products?
4. What authority, if any, does the Trump administration have to implement the most-favored-nation requirements without Congressional action?
5. How will manufacturers respond to the Trump administration's directives? We note that at least one manufacturer, Eli Lilly, has indicated it is increasing the list price of its GLP-1 drug in Europe to reduce the price disparity with its US list price.

Opportunity for Congressional Action

The remaining piece of the puzzle is determining if and how Congress will seek to support the president's drug pricing goals, particularly with respect to MFN pricing. One such proposal, put forth by Senate Health, Education, Labor & Pensions (HELP) Committee Chair Bill Cassidy (R-LA) would have reportedly imposed a clawback penalty on manufacturers that were found selling certain Medicare drugs below a GDP-adjusted price floor. Despite Senator Cassidy's efforts, such bill has reportedly stalled, as there is not much appetite in the Senate for an MFN pricing approach. It remains to be seen what, if any, support President Trump's drug pricing executive orders will receive from Capitol Hill.

340B Roundup

By Lauren Moldawer, Xavier Hardy, Abdie Santiago, Jordyn Flaherty

I. States and Manufacturers Continue to Battle over 340B Contract Pharmacies

Over the last two and a half years, the management of the 340B program has increasingly come under legislative and regulatory scrutiny as hospitals and manufacturers dispute the role of contract pharmacies. As we've previously written, the 340B Drug Pricing Program allows 340B entities to purchase outpatient drugs at discounted prices from manufacturers. 340B hospitals often contract with outside retail pharmacies (or "contract pharmacies") to dispense 340B drugs to "patients." Manufacturers have argued that contract pharmacies increase the likelihood that manufacturers would pay duplicate discounts, which occurs when a manufacturer offers both a discounted 340B price and a Medicaid drug rebate for the same drug.

Federal law prohibits duplicate discounts; however, manufacturers have historically struggled to identify them, an issue that has only grown since the Affordable Care Act extended Medicaid drug rebates to Medicaid managed care. As a result, in 2020 and 2021, several manufacturers instituted policies to restrict the ability of contract pharmacies to obtain drugs at 340B prices, arguing that these restrictions were necessary to avoid paying duplicate discounts. These actions resulted in the Health Resources and Services Administration (HRSA) issuing several violation letters against

manufacturers claiming that these contract pharmacy restrictions violate the 340B statute. Several manufacturers subsequently challenged HRSA's authority to issue the violation letters in federal court, notching victories in the Third and DC Circuits. A lawsuit filed by Eli Lilly is awaiting a ruling in the Seventh Circuit.

Prompted by the federal court rulings, states have increasingly stepped in to ensure that 340B entities can continue to utilize contract pharmacies by enacting "pharmacy access" laws, which prohibit drug manufacturers from restricting 340B entities from using contract pharmacies. The first two states to enact such laws were Arkansas in 2021 and Louisiana in 2023, followed by Maryland, Kansas, Minnesota, Mississippi, Missouri, and West Virginia in 2024. In the first half of 2025, Colorado, Idaho, Nebraska, New Mexico, North Dakota, South Dakota, Tennessee, Utah, and Oregon, among others, have also enacted pharmacy access laws. While manufacturers have responded with a flurry of lawsuits and well-funded lobbying campaigns, their success in halting implementation and enforcement has been mixed. For example:

- In 2021, Arkansas's 340B pharmacy access laws were challenged by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the district court ruled in favor of the state. In March 2024, the Eighth Circuit upheld Arkansas's law and subsequently denied PhRMA's request for a rehearing. In December, the Supreme Court refused to hear PhRMA's appeal.
- In June 2024, a federal district court rejected challenges from AstraZeneca and AbbVie against Mississippi's law. This lawsuit has since been appealed to the Fifth Circuit.
- In December 2024, a federal court issued a preliminary injunction in favor of PhRMA and the manufacturer Novartis, prohibiting West Virginia from enforcing its pharmacy access law.
- In December 2024, AbbVie and AstraZeneca also dropped lawsuits challenging Kansas's law after the state attorney general announced that it did not "prohibit or forbid" manufacturer restrictions on contract pharmacies.
- The Michigan legislature adjourned in 2024 before passing a pharmacy access bill that was considered to have strong momentum.
- Manufacturers have filed a flurry of lawsuits in response to pharmacy access bills enacted in 2025.
    - In June 2025, AstraZeneca filed a federal lawsuit against Nebraska Attorney General Michael Hilgers, seeking to block the state's newly enacted contract pharmacy access law.
    - In July 2025, PhRMA and AbbVie sued Hawaii over its 340B contract pharmacy access law, with PhRMA additionally filing suits in Vermont and Colorado.

Furthermore, AbbVie and Novartis have challenged several pharmacy access laws, including in Oklahoma, Rhode Island, and Oregon. After AbbVie challenged a Missouri law, a federal judge dismissed the lawsuit, claiming that it lacked standing.

Despite the extensive litigation noted above, the legal battle over these state laws appears to be just beginning. Pharmacy access bills have been introduced in Hawaii, Rhode Island, Connecticut, New York, and Illinois, among other states, and it is likely that states will continue to join this growing list in 2025. States enacting legislation will likely continue to face manufacturer challenges, which will ultimately allow the courts to decide the legality of 340B contract pharmacies going forward.

II. HRSA Launches 340B Rebate Model Pilot Program Amid Ongoing Legal and Regulatory Shifts

On July 31, 2025, the Health Resources and Services Administration (HRSA) released long-awaited guidance establishing a 340B Rebate Model Pilot Program (Pilot Program). The announcement marks a pivotal moment in the evolution of the 340B Drug Pricing Program, capping off months of litigation, regulatory proposals, and shifting agency priorities.

The Pilot Program offers a structured pathway for manufacturers to provide post-sale rebates to covered entities in lieu of the traditional upfront 340B discounts. In introducing the Pilot Program, HRSA announced that "[the] Pilot Program addresses concerns we have received from both covered entities and manufacturers, while creating a measured approach to the process of approving manufacturer rebate models under the 340B Program."

Program Overview

The Pilot Program is voluntary and limited to drugs selected for negotiation under the Medicare Drug Price Negotiation Program (Negotiation Program). Manufacturers with Negotiation Program agreements for the 2026 Applicability Year must submit plans to HRSA by September 15, 2025. If approved, those plans will take effect on January 1, 2026. HRSA has emphasized that manufacturers may not implement rebate models without prior agency approval, a position recently upheld by multiple federal courts, as described below.

The rebate model represents a significant departure from the traditional 340B replenishment model. Under the Pilot Program, participating manufacturers will offer post-purchase rebates to covered entities rather than upfront discounts. Covered entities will pay the wholesale acquisition cost (WAC) for selected drugs and later receive a rebate equal to the difference between the WAC and the 340B ceiling price. Covered entities may submit claims data up to 45 calendar days from the date of dispense. Rebates must be paid within 10 calendar days of data submission. HRSA's guidance outlines detailed criteria for participation, including data security requirements, reporting timelines, and assurances that no administrative costs will be passed on to covered entities. Lastly, in the announcement, HRSA explains that rebates cannot be denied based on concerns about diversion or Medicaid duplicate discounts unless properly documented. HRSA adds that disputes must be handled through HRSA's existing audit and ADR mechanisms.

Litigation Landscape

The Pilot Program arrives on the heels of a series of legal decisions affirming HRSA's authority to require preapproval of rebate models. In June 2025, a federal district court in Washington, DC ruled against Johnson & Johnson (J&J), rejecting the company's claim that HRSA lacked statutory authority to block its proposed rebate model. The court found that the 340B statute clearly delegates discretion to the Secretary of Health and Human Services to determine whether and how rebate models may be implemented. The court also upheld HRSA's position that J&J's model could not be implemented without prior approval and that HRSA's reasoning was neither arbitrary nor capricious.

This decision aligns with earlier rulings in related cases brought by Eli Lilly, Bristol Myers Squibb, Sanofi, and Novartis. In each case, federal courts upheld HRSA's authority to require prior approval of rebate models under the 340B statute. Together, these decisions reinforce the federal government's ability to oversee and enforce rebate and discount mechanisms within the 340B program.

Regulatory Developments and Claims-Based Tracking

The rebate model also intersects with broader efforts to prevent duplicate discounts under the Inflation Reduction Act (IRA). The IRA requires manufacturers to charge 340B covered entities the lesser of the 340B price or the Maximum Fair Price. This has prompted the Centers for Medicare & Medicaid Services (CMS) to propose in the CY 2026 Physician Fee Schedule, for the first time, claims-based methods to identify 340B drugs in Medicare Part D.

CMS's proposal includes two key mechanisms: voluntary reporting of five data elements per claim, and cross-referencing prescriber and pharmacy NPIs with known 340B relationships. The use of claim-level modifiers to identify 340B utilization is a notable development, as it lays the groundwork for more precise tracking and enforcement under both the 340B and Negotiation Program frameworks.

Stakeholder Reactions and Future Outlook

Initial reactions from covered entities have been cautious. The American Hospital Association (AHA) expressed concern that HRSA's guidance "authorizes a significant departure from how the 340B program has successfully operated for decades and sets a dangerous precedent for possible harmful expansions in the future." The AHA characterized the pilot as a response to a "non-existent program integrity problem" and warned that any delays or cost-shifting could pose serious financial risks to hospitals and the communities they serve. At the same time, the AHA acknowledged HRSA's efforts to impose strict guardrails and emphasized the importance of ensuring that manufacturers bear all implementation costs and provide rebates expeditiously.

As the 340B program continues to evolve, the rebate model introduced in the Pilot Program may serve as a bellwether for future reforms. With no clear legislative path forward in Congress and the Trump administration proposing to shift 340B oversight from HRSA to CMS, the Pilot Program offers a glimpse into how federal agencies may reshape the program through administrative action.

III. CMS Proposes Steeper OPPS Clawbacks, Launches Drug Cost Survey with Public Comment

In July 2025, CMS issued its 2026 Hospital Outpatient Prospective Payment System (OPPS) proposed rule, which includes two significant 340B policies. First, it includes cuts in the OPPS rates paid to hospitals to accelerate the reduction to the OPPS conversion factor for non-drug services to account for the "overpayment" made to hospitals from 2018 – 2022 as a result of the first Trump administration's reduction in payment for outpatient 340B drugs during that time. The proposed rule also notified hospitals that CMS plans to conduct a hospital drug acquisition cost survey. The two proposals stem from the same complicated fight between the government and 340B hospitals over reimbursement.

OPPS Payment Cuts

Most drugs under the OPPS are bundled or packaged into the Ambulatory Payment Classifications (APCs) that are established for a procedure. Broadly, APCs are payment rates CMS establishes for outpatient procedures that are meant to capture the cost it would take to provide those services. However, new and/or high-cost drugs are not bunded into the standard APC payment rates that providers receive. These non-bundled drugs, referred to as "separately payable drugs," have accounted for more than a quarter of all spending under the OPPS in recent years.

Prior to 2018, the Medicare OPPS reimbursed hospitals at 106% of average sales price (ASP) for separately payable drugs. CMS calculates and publishes an ASP — which is the average amount that drug manufacturers receive for a drug product after accounting for all discounts and rebates — pricing file quarterly based on sales and discount data submitted by manufacturers.

In 2018, under the first Trump administration, CMS reduced the OPPS rate paid to 340B hospitals for separately payable drugs by nearly 30% (from *106% of ASP down to ASP minus 22.5%*), reasoning that these hospitals (which can acquire drugs at a discounted rate) were receiving a windfall from Medicare. Non-340B hospitals continued to receive the 106% of ASP rate for separately payable drugs. However, the Medicare statute imposes a budget neutrality requirement, meaning any change in payment policies must not increase or decrease Medicare spending by more than a set threshold. As such, the 2018 payment reduction to 340B hospitals for separately payable drugs was offset by an increase in OPPS reimbursement rates for non-drug items and services for all hospitals.

The American Hospital Association (AHA) challenged the 340B payment cuts shortly after they were finalized in 2017. In 2022, the Supreme Court in American Hospital *Association et al. v. Becerra et al.* ruled that the payment reduction was unlawful and remanded the case. On remand, the district court, rather than formally vacating the OPPS ruling,

instructed HHS to remediate the underpayments made to 340B hospitals between 2018 – 2022.

Following the Supreme Court's ruling, the agency issued a one-time $9 billion payment to approximately 1,600 affected providers and restored 340B reimbursement to 106% of ASP beginning in 2023. As noted, CMS had increased payments for non-drug items and services by $7.8 billion during that same period. To ensure budget neutrality, CMS announced that it would impose a 0.5% annual reduction to the OPPS conversion factor for non-drug services starting in 2025 and ending in 2041 to, in effect, claw back the overpayments made from 2018 – 2022.

As part of the CY 2026 OPPS proposed rule, CMS is seeking to accelerate this clawback / annual payment reduction from 16 to 6 years by increasing the annual conversion factor reduction from 0.5% to 2%. Hospitals paid under the OPPS, including many 340B hospitals, have raised concerns about the financial strain of this acceleration and frontloading of the payments.

Drug Acquisition Cost Survey

Simultaneously, CMS announced that it was conducting a survey on drug acquisition costs and soliciting public comment. The Supreme Court's ruling in the *Becerra* case that the 340B payment cuts were invalid was based in part on the fact that the agency did not conduct a proper survey to justify imposing disparate reimbursement on 340B versus non-340B hospitals. Therefore, the survey appears to be laying the groundwork for reimposing reduced OPPS payment to 340B hospitals in the future, although the fact that CMS is soliciting comments on whether participation in the survey should be mandatory for *all* OPPS hospitals indicates the Trump administration is considering broader payment cuts in Medicare. The survey is expected to run from late 2025 through early 2026 and will inform the 2027 OPPS rulemaking cycle.

Hospitals and stakeholders should closely monitor the evolving regulatory landscape, particularly the implications of the proposed clawback acceleration and the potential for future rate setting based on newly collected acquisition cost data.

IV. Senate HELP Committee's Long-Awaited 340B Report Highlights Ongoing Problems but Provides Few Solutions

On April 24, 2025, the Senate Health, Education, Labor & Pensions (HELP) Committee, led by Sen. Bill Cassidy (R-La.), released a report on its investigation into the 340B program. The investigation, which began in 2023, sought information from a group of eight 340B program participants — comprising two covered entities, contract pharmacies, third-party administrations (TPAs), and drug manufacturers — in order "to gain a comprehensive understanding of where the dollars generated by … the program flow and how such revenue benefits patients."

Despite only targeting eight participants, the HELP Committee gathered substantial information on 340B program operations through participant responses to narrative questions and other disclosed information, including PBM agreements, network pharmacy participation agreements, and 340B drug spending data. Much of this material is included in the Report's Appendix. Although the Report did not propose any specific legislative language, it includes a number of recommendations for Congress, including:

- Requiring covered entities to provide detailed annual reporting on how 340B revenue is used to ensure direct savings for patients, providing a more transparent link between program savings and patient benefit.
- Addressing potential logistical challenges caused by increased administrative complexity, leading to burdens that may impede patient benefit from the program.
- Investigating the types of financial benefits contract pharmacies and TPAs receive for administering the 340B program to ensure that increasing fees do not disadvantage covered entities and patients.
- Requiring transparency and data reporting for entities supporting participants in the 340B program (i.e., contract pharmacies and TPAs).

- Providing clear guidelines to ensure that manufacturer discounts actually benefit 340B-eligible patients, including examining legislative changes to the definition of "eligible patient" and contract pharmacies' use of the inventory replenishment model.

Given the lack of proposed federal 340B program legislation, and no mention of the program in President Trump's FY 2026 Budget Proposal, it is unclear what shape potential federal 340B program reform will take. As a result, all eyes appear to be shifting back to HHS and HRSA as we await further implementation of the 340B rebate model.

PhRMA's 2025 Policy Agenda and the Industry's Crossroads with the IRA and Drug Pricing Reform

By Theresa Carnegie, Hassan Shaikh

As US pharmaceutical manufacturers continue to lead biopharmaceutical research and development, they find themselves increasingly at odds with the nation's shifting regulatory landscape — a reality underscored in a 2025 policy agenda published by the industry's largest trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA).

The policy agenda, which sets forth PhRMA's comprehensive framework for preserving American leadership in innovation while addressing growing concerns around affordability and access, proposes four core policy initiatives to "strengthen American leadership" in innovation while ultimately ensuring a "healthier America." In this post, we provide an overview of PhRMA's proposed policy priorities and examine how they intersect with ongoing drug pricing reforms — particularly those introduced under the Inflation Reduction Act (IRA) and the Trump administration's related executive orders.

PhRMA's Policy Framework

PhRMA's 2025 agenda is built around four core policy priorities:

1. Adopting a pro-innovation regulatory and trade agenda,
2. Protecting the US from the harms of price setting,
3. Stopping abuse of the 340B program, and
4. Reigning in PBMs and health insurers to put patients over profits.

Together, these pillars reflect a strategic effort to (1) defend the sector from what PhRMA views as regulatory overreach, market distortions, and misaligned incentives that threaten innovation and patient access to affordable medications, while (2) directing attention to other players and regulations in the supply chain for more effective drug price controls.

Price Setting and the IRA: Innovation Under Pressure

The "Pill Penalty"

PhRMA's most pointed critiques target the IRA's Medicare Drug Price Negotiation Program (Negotiation Program) — specifically as it relates to the so-called "pill penalty," which permits small molecule drugs to be subject to price controls nine years after FDA approval, versus 13 years for biologics.

According to PhRMA, the policy is likely to chill manufacturer investment in the development of pill-based treatments that are often more convenient, cost effective, and preferred by patients. PhRMA estimates that the pill penalty could result in 188 fewer small molecule innovations over the next two decades, with downstream impacts on cancer care, mental health, and chronic

disease management. PhRMA further warns that the curb of investments to small molecule drugs will increase costs and impact patient adherence to medication protocols.

As we discussed in a previous post, in April the Trump administration directed the Department of Health and Human Services to work with Congress to modify the Negotiation Program to align the treatment of small molecule prescription drugs with that of biological products — potentially notching a significant victory for PhRMA's proposed policy agenda.

Bureaucratic Overreach

PhRMA broadly criticizes federal and state price setting initiatives — namely the Negotiation Program and the creation of state-level price setting boards (e.g., PDABs) — as material threats to innovation and patient access.

The policy agenda continues to argue that participation in the Negotiation Program is coerced through disproportionate penalties (e.g., through the imposition of an excise tax that could equal up to 1,900% of a drug's daily revenues) and asserts that the Program is materially responsible for an increase in prescription drug coverage restrictions that put millions of beneficiaries' access to Part D drugs at risk. It also posits that the Negotiation Program poses a significant threat to the sustainability of independent and regional chain pharmacies, especially in rural areas, due to delayed reimbursements and reduced margins on price-set drugs. According to the policy agenda, "due to typical differences between prices at which pharmacies acquire price-set drugs and the amount Part D plans will reimburse under the IRA, each pharmacy stands to lose $11,000 in weekly cash flow and could forfeit an average of $43,000 in annual revenue due to payment delays," resulting in reduced availability of medications, staffing issues, and pharmacy closures.

PhRMA also asserts that state prescription drug affordability boards (PDABs) are a material threat to patient access to medications — arguing that state price-setting initiatives will result in health plans developing more stringent utilization management protocols that will further hinder patient access to previously available medications. We previously discussed this long-standing belief in a prior edition of the *Mintz IRA Update*, but its inclusion in the policy agenda underscores the industry's continued interest in minimizing shifting regulatory regimes at not only the federal level but also the state level.

PhRMA's Other Policy Priorities

340B Reform

The policy agenda calls for comprehensive reform of the 340B drug discount program, citing widespread abuse and lack of oversight. PhRMA argues that under the current framework, eligible hospitals and clinics purchase outpatient drugs at steep discounts and then mark up prices significantly when billing insurers and patients, resulting in increased costs at the pharmacy counter without the delivery of meaningful benefits to the underserved communities for whom the 340B program is intended. We discuss the current state of 340B reform in our 340B Roundup.

PBMs and the Supply Chain

PhRMA's third core policy initiative targets other players in the pharmacy supply chain, arguing that such other entities (primarily PBMs and health plans) account for the largest share in brand drug spending and should be more closely regulated to materially move the needle on drug costs in the US. PhRMA's proposed policy reforms include requiring PBMs and health plans to share negotiated savings with patients at the point of sale, delinking PBM compensation from drug prices, prohibiting copay accumulator and maximizer programs, and increasing oversight of PBM and health plan utilization management practices.

Defending the Innovation Ecosystem

Finally, PhRMA emphasizes the need to adopt a modernized regulatory and trade agenda to foster a predictable and reliable environment for pharmaceutical innovation. Its three proposed initiatives for accomplishing the goal include adopting AI and real-world evidence to streamline

and expedite FDA review, preserving post-approval R&D incentives (e.g., patent term restoration and new drug product exclusivity programs), and negotiating trade agreements that expand market access and require foreign compliance with global IP commitments to prevent "free-riding on American innovation."

Conclusion

PhRMA's 2025 policy agenda offers a detailed roadmap of what PhRMA and its members perceive as the most significant threats to the pharmaceutical industry. The policy agenda also may reflect where we will see legal disputes and policy debates over the next year among various pharmaceutical supply chain stakeholders. The agenda underscores the complex network of interests and the delicate balance of affordability, access, and innovation that legislators and regulators must keep in mind as they seek to address drug pricing in the United States.

Disrupting the Pharmaceutical Supply Chain: The Era of the DTC Model

By Theresa Carnegie, Stephnie John

While the pharmaceutical industry has reacted negatively to President Trump's May 12 "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" Executive Order (Executive Order), manufacturers appear to be leveraging one of Trump's directives in the Executive Order, accelerating the industry's shift toward a new model of drug delivery: direct-to-consumer (DTC) programs.

As a quick recap, the Executive Order requires the Secretary of the Department of Health and Human Services (HHS Secretary) to create direct-to-consumer purchasing programs that allow pharmaceutical manufacturers to sell their products to American patients at most-favored-nation pricing, i.e., the lowest price the manufacturer offers to any "comparably developed" foreign nation purchasing a particular drug. Prior to President Trump's Executive Order, manufacturers had already identified the DTC drug delivery model as a potential mechanism for making their most expensive medications accessible to patients. For years, manufacturers, insurers, and pharmacy benefit managers (PBMs) have attributed high drug costs to one another. Now, manufacturers are exploring ways to bypass traditional intermediaries — i.e., insurers and PBMs — by using telehealth platforms and other DTC providers that facilitate direct delivery of medication to patients. More than 60% of the top 10 highest-grossing pharmaceutical manufacturers have implemented or are preparing to implement DTC programs.

- ***Eli Lilly & Novo Nordisk***: Eli Lilly and Novo Nordisk have partnered with telehealth platforms Ro, Hims & Hers, and Life MD to provide their respective obesity and diabetes treatments at a discounted price directly to consumers without insurance coverage for the drugs. The telehealth platforms directly integrate with the manufacturers' self-pay pharmacies and allow patients to secure direct delivery of the drugs at the discounted cash price with a prescription from a provider affiliated with the telehealth platforms. Each of the telehealth platforms also offers the GLP-1 drug bundled with additional services, such as ongoing clinical support, nutrition guidance, virtual consultations, and weight management programs.

  Eli Lilly also launched its own DTC website, LillyDirect. Through its partnerships with other DTC providers, including telemedicine platforms and digital pharmacies, patients can

access Lilly's diabetes, migraine, and obesity medications. LillyDirect also ensures that its patient assistance and discount card programs are automatically applied to patients who qualify.

- ***Pfizer & Bristol Myers Squibb***: In response to the Executive Order, Pfizer and Bristol Myers Squibb have launched a DTC online program, Eliquis 360 Support, that allows uninsured or underinsured patients to buy their blood thinner Eliquis online at a discount — $346 per month, a 43% reduction from its current list price of $606 per month. Even with this discount, the DTC price is still over nine times the average monthly out-of-pocket cost for commercially insured patients and remains well above Medicare's negotiated maximum fair price (MFP) of $231, set to take effect next year. Notably, the Eliquis 360 Support program targets a small group of current and potential users of the drug, as more than 90% of the patients who are currently prescribed the medication access it through Medicare or commercial insurance.

  Similar to LillyDirect, Pfizer also has its own DTC virtual platform, PfizerForAll. Through PfizerForAll, patients can directly access vaccines and medications, order diagnostic tests and treatments, and make doctor appointments using their existing insurance coverage and pharmacy benefits. If patients are prescribed Pfizer medications, the platform connects eligible consumers with Pfizer's patient assistance programs that help cover drug costs.

- ***Roche***: Roche told investors it has begun discussions with the HHS Secretary under the Executive Order to explore a DTC model, but cannot share details in light of its ongoing conversations with the government. However, Roche's CEO noted to investors that the DTC model could be a great option for its obesity products.

Scrutiny of Telehealth Platforms in DTC Drug Delivery Model

Integrating telehealth platforms into the DTC drug delivery model facilitates direct communication between the manufacturer and the patient — effectively eliminating the role of the PBM — and increases access to care, particularly for the uninsured and underinsured. By partnering with telehealth providers, manufacturers can supply their medications directly to patients while offering added services, such as tailored patient education, refill reminders, and disease management support. Despite these benefits, lawmakers have raised concerns that such partnerships will drive patients toward use of expensive and unnecessary medications, increasing spending for federal health care programs. Democratic Senators Dick Durbin (IL), Elizabeth Warren (MA), and Peter Welch (VT) and Independent Senator Bernie Sanders (VT) led a nine-month investigation into various arrangements between manufacturers and DTC telehealth companies. The manufacturers and their telehealth partners have emphasized that clinician decisions about which drugs to prescribe are not influenced by these arrangements, i.e., the manufacturers are not paying incentives or bonuses per prescription or contracting for a predetermined volume of prescriptions. However, following their investigation, the senators published a report identifying specific concerns about how these partnerships may indirectly lead toward patient / provider steering, including the following:

- Partnering with clinicians or practices that may already have a preference to prescribe certain drugs
- Equipping manufacturers with additional tools to aim their marketing efforts at prescribing physicians
- Patients preselect which medication they seek prior to starting a consultation with a physician

While the senators' report did not identify any overt fraud and abuse risks, it suggested its findings signal DTC providers and manufacturers may be at risk of implicating the federal Anti-Kickback Statute (AKS).

The report referenced a 2022 HHS Office of Inspector General (OIG) Special Fraud Alert highlighting the risks of arrangements with telehealth platforms, and noted that OIG has previously identified "limited interactions with the purported patient, limited opportunity to review the patient's medical records, and/or a directive to prescribe a preselected item, regardless of clinical appropriateness" as fraudulent aspects of an arrangement between a provider and a telehealth platform. While the lawmakers did not announce any particular legislative agenda targeting the DTC drug delivery model, it is evident that partnerships between manufacturers and telehealth platforms will be subject to heightened scrutiny for fraud and abuse risks as manufacturers strive to effectuate President Trump's Executive Order.

Scrutiny of Advertising in DTC Drug Delivery Model

Another area of heightened concern in the DTC drug delivery model, this one with bipartisan support, is consumer advertising. In early June, Independent Senators Bernie Sanders (VT) and Angus King (ME) introduced the End Prescription Drug Ads Now Act, which would ban manufacturers from advertising their prescription drugs and biologics through television, radio, print, digital platforms, and social media. The End Prescription Drug Ads Now Act follows previous bipartisan efforts to restrict pharmaceutical advertising, including a bill sponsored by Senators Durbin (D-IL) and Chuck Grassley (R-IA) that would require price disclosures on advertisements for prescription drugs, and another bill sponsored by Senators Durbin and Roger Marshall (R-KS) that would have imposed civil penalties on health care providers and social media influencers for making false or misleading statements regarding prescription drugs and biologics. Congress has yet to act on the End Prescription Drug Ads Now Act and it will undoubtedly face a number of legal challenges, as US courts have held that advertising is protected under the First Amendment's right to free speech. Nonetheless, it is likely to receive support from the Trump administration, given that HHS Secretary Kennedy has previously announced his plan to issue an executive order to stop drug ads from appearing on television. In light of HHS Secretary Kennedy's and bipartisan Congressional support of efforts to rein in pharmaceutical advertising, we expect to see some reform materialize in DTC advertising of drugs and biologics.

Proceeding (Carefully) Forward

While President Trump's Executive Order has pushed manufacturers to accelerate their adoption of the DTC drug delivery model, the industry remains cautious for the reasons noted above. Further, widespread adoption of the DTC drug delivery model will pose logistical challenges and disrupt traditional drug distribution channels through wholesalers and distributors — manufacturers may be required to invest in distribution infrastructure in order to send medications directly to patients. However, we are already seeing industry stakeholders step up to fill the gap. For example, BlinkRx has unveiled a new initiative to help manufacturers set up direct distribution channels. BlinkRx's Operation Access Now program advertises the ability to launch DTC sales of manufacturer drug products within 21 days. The Trump administration has also met with Walmart, Amazon, and other retailers to explore ways to facilitate distribution and delivery of drugs directly from manufacturers to patients. In addition to the new operational demands, manufacturers will be forced to confront the tension created by the DTC model in existing relationships with insurers and PBMs. Despite the operational and relational challenges, the DTC drug delivery model appears poised to drive a change in drug distribution and patient access.

Medicare Part B Physician Fee Schedule Guidance and Its Potential Implications for Medicare Part D

By Theresa Carnegie, Tara Dwyer, Rachel Yount, Hassan Shaikh

As we discussed in a recently published post, the CY 2026 Physician Fee Schedule Proposed Rule (PFS Proposed Rule) introduces significant changes to how drug manufacturers must treat Bona Fide Service Fees (BFSFs) when calculating Average Sales Price (ASP) for Medicare Part B drugs. And although the rule is directed at manufacturers, it has important implications for plans, pharmacy benefit managers (PBMs), group purchasing organizations (GPOs), and other entities that receive BFSFs. We provide a high-level analysis of the PFS Proposed Rule below, given its material implications for Part B and — at Centers for Medicare and Medicaid Services' (CMS) discretion — potential to similarly affect Part D.

Fair Market Value: A New Standard for BFSFs

The PFS Proposed Rule seeks to eliminate historical ambiguities regarding what is considered "fair market value" for BFSFs under current regulations and more clearly delineate what fees may (and may not) be considered BFSFs. Additionally, the PFS Proposed Rule seeks to shift previous CMS policy by repealing the well-established presumption that if a manufacturer has determined that a fee paid meets the other elements of the definition of a BFSF, then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of any entity.

Assessing FMV and Delineating Price Concessions from BFSFs

CMS includes three new requirements to assist in FMV assessments of BFSFs: (1) prescribing standards and methodologies for determining FMV based on whether fees are tied to drug prices or sales volume (e.g., percentage of Wholesale Acquisition Cost); (2) requiring manufacturers to reassess and update FMV determinations as frequently as the underlying service agreement's renewal periods; and (3) requiring FMV assessments to be conducted by independent third-party valuators with no financial interest in the outcome of the determination.

The PFS Proposed Rule also establishes a presumption that fees paid by a manufacturer to an entity based on drug price or volume — such as percentage-based fees — will be presumed to be price concessions unless validated as FMV using the cost-plus approach.

Repealing the "Not Passed On" Presumption

Under the PFS Proposed Rule, CMS would require manufacturers to obtain certifications or warranties from BFSF recipients that confirm that the fees received are not passed on — either in whole or in part — to clients, customers, or affiliates. Manufacturers will have to submit these certifications or warranties as part of quarterly data submissions. In addition, manufacturers will have to submit documentation substantiating that the BFSFs are consistent with FMV and demonstrating the methodology used to reach that determination. This represents a shift from prior CMS policy, which currently allows manufacturers to presume BFSFs are not passed on without evidence to the contrary, and places new compliance expectations on BFSF recipients.

Implications for Part D and Direct and Indirect Reporting (DIR)

Although the PFS Proposed Rule applies only to Medicare Part B drugs, CMS could choose to extend similar requirements to Part D and DIR reporting due to the overlap between the programs in terms of the definition and requirements related to BFSFs. For these requirements to impact Part D, CMS would

first need to finalize the PFS Proposed Rule, and CMS would need to propose and ultimately finalize a change to the Part D rules.

As noted above, the PFS Proposed Rule introduces substantial changes to how BFSFs must be evaluated, especially when fees are tied to drug prices, such as those paid to GPOs or for data services. If CMS adopts the PFS Proposed Rule and chooses in the future to adopt similar requirements for Part D DIR reporting, manufacturers and plans would need to use a cost-plus methodology to establish whether GPO and data fees are consistent with FMV, since such fees are generally based on the price of drugs. Additionally, manufacturers would be required to report quarterly on the assumptions and FMV determinations used in their pricing calculations.

The Uncertain State of Affairs for GLP-1s

By Theresa Carnegie, Hassan Shaikh, Samantha Hawkins

GLP-1 receptor agonists (GLP-1s) such as semaglutide, and dual agonists like tirzepatide, are transforming obesity treatment and reshaping the US health care landscape. Originally developed to manage type 2 diabetes, these drugs are now being widely prescribed to treat obesity and to manage cardiovascular issues. But while demand has soared, federal and state health policies, supply constraints, and access issues are raising questions about patient access and how the health care system will manage the financial burden of these treatments.

Supply Challenges and the Role of Compounded Medications

Fueled by social media advertisements and celebrity endorsements, GLP-1s have rapidly shifted from primarily being used by diabetics to being sought by anyone looking to lose weight. Despite the increase in demand, many are unable to afford these medications. GLP-1s typically retail for anywhere between $900 and $1,300 per month and insurance coverage is inconsistent, especially for patients seeking treatment for obesity rather than diabetes. For Medicaid patients, the picture is even more complex: a patchwork of state-level policies governs access, and only a few states (like Connecticut and Michigan) have opted to cover GLP-1s for weight loss in their Medicaid programs.

Even for those with the financial means to obtain these medications, the surge in demand for GLP-1s has led to widespread shortages. To address this, in March 2022, the Food and Drug Administration (FDA) added GLP 1s, specifically Wegovy and Ozempic, to its drug shortage list. This move permitted compounding pharmacies to produce compounded semaglutide formulations, expanding the public's, especially uninsured patients', access to cheaper alternatives to the brand versions. However, on February 21, 2025, the FDA announced that the shortages had been resolved and set a deadline of May 22, 2025 for compounding pharmacies to cease production of compounded semaglutide. While this may have been a win for the pharmaceutical manufacturers, it has left many patients struggling to access the product due to financial concerns.

Direct-to-Consumer Offerings Disrupt Traditional Models

As an alternative to the traditional approach of filling a prescription at a pharmacy, some pharmaceutical companies and health care providers have adopted direct-to-consumer (DTC) models to meet patient demand. Platforms like LillyDirect and Sesame's Success by Sesame, for instance, offer telehealth consultations and home

delivery of GLP-1s. Meanwhile, retailers such as Costco have partnered with Sesame to provide weight-loss programs, including access to GLP-1s, at a fraction of the manufacturers' costs. As we discuss in this edition, the DTC model is part of a broader shift toward patient-centric care.

Simultaneously, telehealth startups, wellness clinics, med spas, and other non-traditional providers have begun offering GLP-1 injections, albeit sometimes through less-regulated routes, often involving compounded versions of the drugs. While this creates new revenue streams and increases patients' access, it also invites scrutiny from medical boards and regulators concerned about credentialing, patient safety, and the increasingly blurred lines between medical care and wellness.

Medicare Hesitates on Coverage Expansion

Despite the rising demand for GLP-1s and the fact that more than 40% of the US adult population is obese, the Centers for Medicare & Medicaid Services (CMS) recently declined to finalize a Biden-era proposal that would have expanded Medicare and Medicaid coverage of anti-obesity medications. The decision, issued without explanation in CMS's final rule in April 2025, leaves millions of Medicare patients without coverage for GLP-1s unless prescribed for conditions like diabetes or cardiovascular risk. Drug makers and patient advocates were quick to express disappointment. Eli Lilly, maker of Zepbound, said that it would "continue to work with the Trump Administration and congressional leaders" to pursue broader access; Novo Nordisk echoed the sentiment, calling on CMS to define obesity as a treatable chronic disease under Medicare.

Experts note that Medicare decisions often influence commercial insurance policies. If CMS were to recognize obesity as a treatable condition eligible for drug coverage, private insurers would likely follow. Without that endorsement, however, access will remain limited to those who can pay out-of-pocket or whose plans voluntarily offer coverage.

Market Outlook

In the short term, the market outlook remains strong for manufacturers of GLP-1s. The market is poised for continued growth, with pharmaceutical companies investing in new formulations, including oral formulations of the drugs and combination therapies. As analysts point out, manufacturers do not need Medicare coverage to hit short-term revenue targets. But in the longer term, the ability to serve a broader patient base — and fend off biosimilars — may depend on policy shifts, new clinical indications, delivery innovations (like oral formulations and fixed-dose combinations), and potential spillover of a steep Medicare discount following CMS's selection of Novo Nordisk's GLP-1 product for the second cycle of negotiations, with the MFP slated to go into effect in 2027.

Conclusion: A Defining Moment for GLP-1s and US Health Care

GLP-1 medications have shifted the paradigm for chronic disease management, but questions around affordability, access, and long-term coverage remain unresolved. The growth and outlook of GLP-1s as treatment for obesity will depend not only on manufacturer innovation, but on public health policy, affordability, and manufacturers' infrastructure to scale to meet the moment.

WHAT WE ARE READING

- **Drugmakers form new group to lobby on impact of Medicare drug price negotiations (STAT)**
- **1 big thing: Pharma firms walk a tightrope with Trump (Axios Vitals)**

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