Focus on Access:

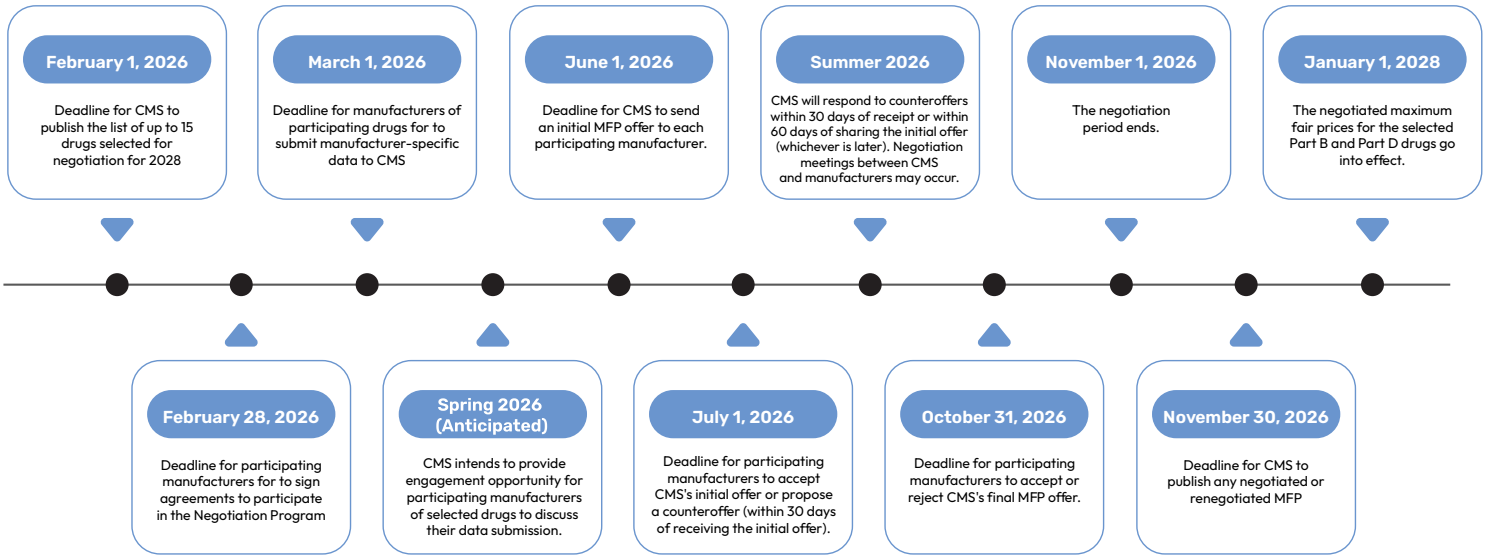
Navigating Medicare Part B Negotiation and Its Unintended Consequences

A cornerstone of the Inflation Reduction Act (IRA) of 2022 is the Medicare Drug Price Negotiation Program, which empowers the Centers for Medicare & Medicaid Services (CMS) to directly negotiate prices for a select number of high-expenditure Part D and, beginning in 2028, Part B drugs. The IRA aims to generate savings for beneficiaries through the Part D out-of-pocket cost share cap and savings for the government through drug negotiations and inflationary rebates in Medicare Part B and D. As CMS moves forward, there are a host of unanswered questions and a growing list of potential unintended consequences. The consequences impact both Medicare Part B and Part D – with unique impacts to the Part B program. Part B drugs, which are typically administered by health care professionals in outpatient settings (e.g., in a physician's office, hospital outpatient department, or infusion center), are crucial for treating conditions like cancer, autoimmune diseases, and numerous chronic illnesses.

The Negotiation Process – An Overview

The negotiation process, while still evolving in its specific details, follows a general framework outlined by the IRA and subsequent CMS guidance. To start, CMS will identify negotiation-eligible drugs based on criteria that include time on the market at the time of implementation (9 years small molecules, 13 years for biologics) and total expenditures.

2028 Medicare Negotiation Timeline



Once a drug is selected, CMS will engage in direct negotiation with the drug manufacturer to determine a "Maximum Fair Price" (MFP), or the maximum amount the government will pay for a medication within the Medicare program. The IRA mandates that CMS consider various factors during this negotiation, including clinical benefit and therapeutic alternatives, unmet medical need, prices of other drugs, research and development costs, production and distribution costs, prior federal financial support and sales volume and revenue.

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Manufacturers who opt out of negotiations are prohibited from participating in federal insurance programs for all their marketed products, effectively requiring them to participate and accept the final price.

The Maximum Fair Price (MFP) will be the new basis for Part B Medicare reimbursement and directly impact clinicians. Providers will be reimbursed at the MFP plus a 6% add-on payment to cover overhead costs, replacing the current Average Sales Price (ASP) plus 6% methodology. This is a critical change with significant implications for provider revenue and drug acquisition costs.

Average Sales Price (ASP)

- **Provider-administered drugs are often reimbursed at ASP, plus a negotiated percentage markup.**
- **ASP is often chosen as a reimbursement metric because it is publicly available.**
- **ASP published quarterly by the federal government and reflects the volume-weighted average manufacturer sales price net of all rebates, discounts, and other price concessions.**
- **It excludes discounts and rebates provided to programs such as the Department of Veterans Affairs,Medicaid or the 340B.**
- **The IRA Part B Medicare negotiated prices – the Maximum Fair Price - are not specifically excluded from ASP so it is assumed that they will be included in ASP and drive ASP down.**

Open Questions about Medicare Negotiation in Part B

Despite it being nearly three years since the IRA passed, numerous critical questions and mechanics of the Medicare Part B drug negotiation program are not yet fully determined.

Questions when it comes to the process for determining MFP:

- **Transparency of Negotiation:** While CMS has committed to publishing a narrative explanation of the negotiation process, the extent of transparency during the actual negotiation meetings and the rationale behind specific price determinations are still largely opaque. The materials published in support of the 2026 negotiations were vague and standardized between the 10 drugs. Patients, providers and the public had limited opportunities to weigh in.

- **Impact of New Indications:** Some previously selected drugs will be subject to a renegotiation process that is still being refined. For example, it is uncertain how new indication approvals will be factored into the MFP for a drug that is already negotiated, especially if it addresses a significant unmet need or offers superior clinical benefit.

Questions when it comes to operational challenges:

- **Data Flow and System Integration:** Implementing the MFP will require robust data exchange and system integration between CMS, manufacturers, providers, and pharmacies. There is no current process for manufacturers to submit payment to pharmacies and then, with Part B, for manufacturers to pay providers for the difference between their acquisition cost and the MFP price. This entire "behind-the-scenes" data and financial transfer will need to be created and is a huge and uncertain administrative burden across the entire system.

- **Provider Reimbursement and Billing:** The transition from ASP to MFP-based reimbursement for Part B drugs necessitates changes in billing systems and processes for physicians and hospitals. For many Part B medicines, providers purchase drugs directly and then wait for reimbursement; implementing the MFP process could delay payment and hinder clinicians' ability to prescribe and administer the negotiated medicines. This concern is already being realized on the Medicare Part D side with independent pharmacies saying they may not carry negotiated products as the delays could cost them tens of thousands of dollars per year.[1] It is possible we could see a similar pattern with provider-administered drugs.

Unintended Consequences of the Negotiated Drug Process

While the negotiation program aims for positive outcomes, there are a range of unintended consequences that could change the health care landscape including provider reimbursement, site of care and patient access.

Clinician Reimbursement – The most immediate concern for many providers is the potential drop in the Average Sales Price (ASP) for negotiated Part B drugs. Currently, providers are reimbursed at ASP plus 6%. If the negotiated Maximum Fair Price (MFP) is significantly lower than the current ASP, and the 6% add-on is applied to this lower MFP, providers will see a direct reduction in their reimbursement.

For example, let's say that a drug has an ASP of $500. Currently, Medicare reimburses provider-administered drugs at ASP + 6%. Medicare covers 80% of this and patients cover 20%. In this example, Medicare pays $424 (80% of $530). The provider must collect the remaining $106 from the patient.

The provider may be able to purchase the product for less than ASP, but let's say they purchased it at the "average" and paid $500. They would have $30 in additional revenue over purchase price. This 6% add-on is intended to cover fixed overhead costs associated with acquiring, storing, and administering drugs (e.g., staff time, refrigeration, administrative burden) and bad patient debt (providers are responsible for collecting cost-sharing.)

But let's say that the MFP of the drug is $300. Currently, the assumption is that the provider would still purchase the drug at its usual acquisition price and be "made whole" after submitting a patient's claim.

In this example, the provider would purchase the drug for $500. Afte the drug is administered, the provider would submit a claim, and Medicare would reimburse the provider $254.50 (80% of MFP + 6%). The provider would collect the remaining 20% from the patient ($63.60.)

Understanding Medicare Reimbursement for Provider-Administered Drugs

Example: Medicare drug, non-negotiated

Drug has an ASP of $500

- Purchases drug for $500
- Administers drug to patient and collects $106 (20% coinsurance)
- Bills Medicare $424 ((ASP + 6%) – 20% coinsurance)
- Provider retains $30 for overhead and profit

Medicare reimbursement is ASP + 6%

Example: Medicare Negotiated Drug

Drug has an ASP of $500

Medicare negotiates an MFP of $300

- Purchases drug for $500
- Administers drug to patient and collects $63.60 (20% coinsurance)
- Bills Medicare $254.50 ((MFP + 6%) – 20% coinsurance)
- Provider gets reimbursed $182 by pharmaceutical manufacturer
- Provider retains $18 for overhead and profit

Medicare reimbursement is MFP + 6%

If the revenue from the add-on decreases while these costs remain constant, providers, especially smaller practices and those in rural areas, could face significant financial strain. A reduction in add-on payments, coupled with potentially stable or rising acquisition costs, will erode provider margins and ability to operate. A study by Avalere found that providers could lose at least $25 billion in add-on payments for the first 10 Part B drugs to be negotiated.[2]

Commercial Payer Implications – Also concerning is how payers may react to these changes. While the IRA negotiation targets Medicare, there is concern about the potential "spillover" impact on commercial markets. The MFP price will factor in the product's ASP, dragging that further down so that providers will potentially make less add-on revenue for patient claims in non-Medicare markets. This is also true for providers who rely on 340B; the difference between their acquisition price and the reimbursement (whether at MFP or ASP plus a percentage) will be lower.

Another possible scenario would be worse for providers. Depending on the timing, providers may not be able to "catch" the right acquisition price as the ASP goes down and may end up paying more for drugs than they are being reimbursed because they sales will not be made whole like the MFP drugs will be.

Clinician Payment Timing – Historically over half of providers have been paid based on the "buy and bill' model of ASP plus a percentage but, with ASP being a now moving target with the addition of MFP sales, providers will look to be reimbursed based on alternate pricing mechanisms like Wholesale Acquisition Cost (WAC.) This is an administrative burden for providers and could lead to changes in prescribing practices.[3]

CMS has been working through potential timing issues with Part D pharmacy payments for the 10 negotiated drugs which take effect in just few months, but there are still questions about how quickly providers will be paid – particularly if there are disputes and appeals about claims. Providers could be "underwater" for extended periods and may face payment settlement delays and significant cash flow issues. This could impact whether providers can justify being in the business of paying upfront for provider-administered drugs; they may look to embrace white bagging where specialty pharmacies send the drugs to the office specifically for a patient.

Impacts on Patient Access

Medication Changes – As providers face uncertainty on reimbursement level and timing, they might be incentivized to prescribe alternative drugs not subject to negotiation if the reimbursement for negotiated drugs becomes too low to cover their overhead.

Drugs Anticipated for Part B Negotiation

Part B drugs likely to be negotiated in 2028/2029[4]:

Keytruda **Opdivo** **Tecentriq**

Limits on Sites of Care – If providers, especially those in smaller practices, choose not to offer provider-administered products, we could see a shift in terms of patient site of care. Patients could be pushed from physician offices to hospital outpatient departments, which often have higher facility fees, ultimately increasing overall healthcare costs for some services. It could also have an impact on patient access as patients may need to travel further distances to reach care.

In addition, the financial pressures on smaller practices could accelerate the trend of consolidation, as independent practices may be forced to merge with larger health systems or close. This too could reduce patient choice and access to care in their community.

Patient Access to New Therapies – Beyond providers, there is concern that patient access to innovative drugs could be hampered by Medicare drug negotiation. Pharmaceutical companies have said that lower negotiated prices reduce their return on investment, thereby dampening incentives for research and development. This could lead to a decrease in the pipeline of new, innovative treatments. This is especially concerning for rare diseases and the development of orphan drugs.

Conclusion

The objective of reducing prescription drug spend is widely supported, but the path to operationalizing Part B negotiations is fraught with complexities. The mechanics of determining the MFP, the challenge of implementing new reimbursement models, and the potential for unintended consequences – particularly the impact on ASP and provider viability – demand careful observation and adaptation. Maybe most importantly, the impacts on beneficiaries will become clearer but limited access, increased direct costs, changes in site of care and access to new therapies are all legitimate concerns.

Moving forward, the success of the Medicare Part B drug negotiation program will hinge on a delicate balancing act. CMS must strive for:

- **Transparency and Predictability:** Clear guidance on the negotiation methodology and factors will help all stakeholders anticipate impacts and adjust.
- **Flexibility and Responsiveness:** It will be crucial for CMS to be able to adapt policies based on observed outcomes and address unforeseen challenges.
- **Balanced Incentives:** Maintaining innovation and affordability need to remain central in thinking through implementation. This might involve exploring alternative incentive structures for research and development or mechanisms to mitigate the most severe negative impacts on providers.
- **Continued Stakeholder Engagement:** Ongoing dialogue with all stakeholders – manufacturers, providers, patients, and payers – will be essential for identifying problems and collaboratively developing solutions.

Sources

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