Insight

Maximum Fair Price Impacts in Medicare, Medicaid, and the 340B Program

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Executive Summary

- The Centers for Medicare and Medicaid Services continues to negotiate a maximum fair price (MFP) for the top 10 most used drugs in Medicare as required by the Inflation Reduction Act (IRA).
- Medicare Part D plans are less likely to prefer MFP drugs over non-MFP drugs – as the former will not offer additional rebates or discounts to the plan, meaning they cannot generate revenue to offset premiums or generate plan profits – and thus, MFP drugs will become less attractive over time.
- Establishing an MFP in Medicare will have a ripple effect on Medicaid's Best Price formula and the 340B Drug Pricing Program, pushing the latter's procurement to favor non-MFP drugs over MFP drugs; this would likely reduce access to commonly used medications and raise prescription drug costs for seniors, contrary to the intent of the IRA's drug pricing negotiation provisions.

Introduction

The Centers for Medicare and Medicaid Services (CMS) continues to negotiate a maximum fair price (MFP) for the top 10 most used drugs in Medicare as required by the Inflation Reduction Act (IRA). CMS has stated in regulatory guidance that Medicare prescription drug plans (PDPs) and Medicare Advantage (MA) plans will have to include MFP products on all formularies – but not yet as a preferred product .[i] Typically, a preferred drug is selected based on being more cost or medically effective than other drugs by an independent group of physicians, pharmacists, or other medical experts. MFP prices for the first 10 drugs are expected to be effective 2026, with additional products phased in over the coming years.

Medicare Part D plans are less likely to prefer MFP drugs over non-MFP drugs, as the former will not offer additional rebates or discounts to the plan. Thus, MFP drugs will become less attractive over time, as plans cannot generate revenue from MFP drugs to offset premiums or generate plan profits. The reason for this is simple: Suppose a drug manufacturer offers a drug with a list price of $100. The manufacturer could go as low as $50, and so is able to offer up to $50 in rebates to lower the price of that drug to plan sponsors. If, however, CMS negotiates an MFP at a lower list price of $50, the manufacturer will be less able to offer rebates on the MFP drug. On the other hand, a non-MFP drug with a list price of $100 could offer a rebate of $50 and receive preferred status on a drug formulary from a plan sponsor. Alternatively, beneficiaries may see higher out-of-pocket costs, as plan sponsors prefer non-MFP drugs with rebates to MFP drugs.

Establishing an MFP in Medicare will have a ripple effect on Medicaid's Best Price formula and the 340B Drug Pricing Program (340B Program), pushing the latter's procurement to favor non-MFP drugs over MFP drugs. Although these negotiations intend to lower drug list prices, the long-term outcome is likely reduced access to commonly used medications as well as increased prescription drug costs for seniors.

This insight explores potential impacts the first 10 MFPs could have in Medicare, Medicaid, and the 340B Program. Each of these programs has distinct regulatory pricing requirements, but the introduction of MFPs may cause meaningful disruption.

Understanding Drug Formulary Design

Drug formularies can be created based on a variety of designs including open, value-based, tiered, closed (limited brand coverage) and closed (generic only). Each of these formulary offerings is designed by qualified medical officers but can rely on certain utilization management tools such as step therapy or prior authorization to direct patients to the most appropriate and cost-effective medicine. Plan sponsors use prescription drug rebates to keep overall costs down for beneficiaries with the Government Accountability Office (GAO) finding these rebates subsidize approximately 75 percent of the cost of premiums for Medicare beneficiaries.

Pharmacy benefit managers (PBMs) construct formularies that are either off-the-shelf or bespoke for clients including plans, employers, unions, and governments. Drugs with higher rebates can typically increase market share by receiving a preferred status on a drug formulary over other drugs. For non-MFP drugs, manufacturers are likely to offer significant rebates to obtain preferred status from PBMs, even if their drug will have greater out-of-pocket costs for beneficiaries, as compared to MFP drugs.

Traditionally, PBMs use their negotiation power to obtain sizeable rebates from drug manufacturers seeking preferred placement on a drug formulary. Now, CMS' MFP mandate intends to lower the list price of drug, thus eliminating the potential for a PBM to secure additional rebates or discounts on MFP drugs. It is likely that PBMs will receive sizable rebates from non-MFP drugs and place non-MFP products on preferred formulary tiers. MFP drugs can neither generate funds for plan revenue nor reduce premiums for seniors, making them drugs *non grata*.

In summary, CMS is price fixing MFP drugs and distorting the traditional market incentives used by manufacturers to obtain preferred formulary placement. As noted earlier, the only potential losers in this scenario are seniors, as they are likely to have greater out-of-pocket costs and less access to MFP drugs.

MFP Outlook: Medicare Formulary Challenges

Background: The IRA put in motion three big changes in Medicare: price negotiation, inflationary rebates in Parts D and B, and plan redesign. In 2022, the Congressional Budget Office (CBO) projected $100 billion in Medicare savings between 2026–2031 from direct negotiations in Medicare Part D. CBO estimated that inflationary penalties would reduce the deficit by $8 billion in 2031. The IRA also redesigned the Part D benefit with PDPs, including MA prescription drug plans now required to absorb substantial costs to cover beneficiaries' catastrophic drug expenses and the low-income-subsidy population. Yet CBO could not predict if MFP drugs would become discouraged by Medicare Part D plans – and therefore less likely to be dispensed to seniors – which will prefer patients use higher list price and rebated drugs. Ultimately, the MFP may increase drug costs as Medicare Part D plans select drugs that have higher list prices to obtain greater rebates for the plan, thus increasing costs for seniors while decreasing access to MFP drugs.

MFP Potential Impact: For products that have large rebate offerings, it could be assumed that PDPs will prefer that members fill non-MFP drugs over MFP drugs. Although CMS issued guidance to require PDPs to cover drugs with MFPs, it remains to be seen whether MFPs will be preferred products.[ii] If not, PDPs are likely to move products with higher rebates into the preferred formulary tier, bypassing MFP products. Moreover,

Medicare Part D plans can generate profit on the rebates received from drug manufacturers. For example, a 2023 GAO report found that in three of the seven groups they examined "…plan sponsors received more in rebates than they paid for the higher-gross-cost, highly rebated drugs, resulting in a net profit with respect to these specific drugs based only on the rebates received." Therefore, it is very unlikely plan sponsors will look to prefer MFP drugs, as they cannot generate revenue from those drugs.

For a deeper dive into the IRA's drug pricing provisions, see the American Action Forum's (AAF) series page.

MFP Outlook: Medicaid and Best Price Calculation

Background: Medicaid requires manufacturers to offer the best price, which is understood to be the lowest price the manufacturer would offer their best customer. While federal law does not require state Medicaid programs to cover outpatient prescription drugs – provided by a pharmacy or in a doctor's office – all states have chosen to provide such coverage. Medicaid is expected to release a final rule updating best price methodology to require manufacturers to "stack" rebates and discounts offered throughout the drug supply chain (whether to the wholesaler, PBM, or provider) on a single drug to calculate the lowest realized price.

MFP Potential Impact: For a drug with an MFP, it could be assumed that best price will also be set at MFP. Yet, there is potential for an MFP drug to have to offer a lower price to Medicaid than MFP if the manufacturer offers any rebates or discounts to commercial payers across the prescription drug supply chain. If the number of products with MFPs increases in the future, some manufacturers may remove their products as they have done following the elimination of the 100 percent average manufacturer price (AMP) cap on Medicaid drug rebates on January 1, 2024.[iii]

As of March 2024, KFF reported that one drug manufacturer has discounted the sale of branded inhalers due to the removal of the AMP cap. Moreover, even when generic products such as insulin are available to Medicaid beneficiaries via the state's Prescription Drug List, KFF found that "while this may be shifting [the preference for highly rebated products by Medicaid], insulin utilization in Medicaid has been largely concentrated among brand-name drugs likely due to high rebate amounts." Most likely, the removal of the AMP cap alongside the expected "stack" rebates final rule will drive manufacturers to set higher launch prices to mitigate longer-term financial risks.

For a deeper dive into the Medicaid Drug Rebate Program, see AAF's PRIMER: The Medicaid Drug Rebate Program and Medicaid's Best Price: A Bad Calculation.

MFP Outlook: 340B Drug Pricing Program

Background: The 340B Program was created in 1992 to "stretch scarce federal resources" by allowing covered entities, such as hospitals, to purchase physician-administered and out-patient drugs at a discount (typically 25 percent) from those manufacturers participating in the Medicaid program. The drugs would then be reimbursed by insured patients' health plans at a higher price. In turn, the covered entities should, in theory, use the gains from the sale of the drugs to provide uncompensated care to underinsured or uninsured patients.

MFP Potential Impact: The MFP will likely reduce Medicare's reimbursement on eligible products to hospitals that participate in the 340B Program. Avalere, a health care consulting firm, has argued that negotiated products are likely to be reimbursed by Medicare at MFP plus 6 percent as compared to the current Average Sales Price plus 6 percent. Furthermore, CMS stated in guidance that a manufacturer "that provides an MFP on a selected

drug is not also required to provide a 340B discount on that same drug." For some hospitals, this could have an impact on revenue generated from these drugs as Medicare is the second largest payer in the program. There is evidence that covered entities participating in the 340B drug pricing program may prefer products with large rebates, potentially making products with MFPs less desirable. Hospitals generate profit based on the size of the delta between the discounted sale of the drug to them from the manufacturer and the greater reimbursement from the payer.

For deeper dives into the 340B Program, see AAF's PRIMER: The 340B Drug Pricing Program and PRIMER: The 340B Drug Pricing Program – Challenges and Solutions.

Conclusion

CMS setting an MFP may create new perverse incentives in three ways. For Medicare, plans are likely to select formularies where the MFP is not preferred. For Medicaid, MFP will become Medicaid best price which will likely put pressure on manufacturers to reduce patient access if a drug is removed from the market. For the 340B Program, purchasers are likely to avoid MFP products, as they cannot generate additional revenue from Medicare on MFP-reimbursed products. Drug pricing is complex, and the Biden Administration's approach to expand the number of MFP products undermines the ability of a drug formulary to be both clinically appropriate and cost-effective. Time will tell if Medicare's most used drugs will become the least desirable, ultimately increasing prescription drug costs while decreasing access to commonly used medications for patients.

[i] KFF summarized that "In the revised guidance, CMS stated that it intends to use the annual formulary review process to ensure that all Part D plans cover all dosages and formulations of selected drugs. CMS also expects plans to provide a justification if selected drugs are placed on non-preferred formulary tiers or on higher tiers than non-selected drugs in the same class, if more restrictive utilization management is applied to selected drugs relative to non-selected drugs in the same class, or if utilization management restrictions that are not based on medical appropriateness are applied to selected drugs."

[ii] According to CMS in June 2023 "In accordance with section 1860D-4(b)(3)(I) of the Act, Medicare Part D plans shall include each covered Part D drug that is a selected drug under section 1192 of the Act on Part D formularies during contract year 2026 and all subsequent years for which the MFP of the selected drug is in effect during the price applicability period."

[iii] For example, GSK removed an asthma inhaler, Flovent, at the same time the drug cap was removed. GSK was reported as replacing Flovent with an authorized generic drug to ensure that the price history of the new drug will not fall afoul of the AMP cap.