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Issue Brief

How to Deliver Lower Prices for Seniors: A Market-Based Reform for Expensive Drugs with Limited Competition

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Introduction

As the 2024 campaign unfolds, the debate over drug prices will likely follow a predictable trajectory. The Biden administration will champion new Medicare price controls established by the Inflation Reduction Act (IRA) of 2022,[1] with a key announcement on the prices on the first tranche of eligible drugs expected in September. The Republican nominee, former president Donald J. Trump, will tout a different approach: tying Medicare prices to the lowest price obtained by foreign nations with comparably developed economies, which he has labeled "most favored nation" (MFN) pricing. To the extent that there is a third narrative, it will come from the pharmaceutical industry, which will argue that both these policies will diminish innovation, thus reducing the availability of future treatments.[2] Medicare beneficiaries, taxpayers—all voters—would benefit from a broader conversation that highlights new approaches to drug prices.

A new approach is particularly important for drugs with little or no therapeutic competition that are covered under Medicare Part B—which are some of the most expensive on the market today and whose prices would not be affected by IRA price controls or by MFN.

This issue brief proposes a market-based reform that would lower prices on these drugs. It would incentivize, but not require, Medicare Advantage (MA) plans to negotiate prices with drug manufacturers for novel therapeutics. If a sufficient number of MA plans reach a contract with the manufacturer, the drug would be covered for all Medicare beneficiaries. The price that results from these negotiations would then be used to set reimbursement rates for the drug, both for MA plans and for providers in traditional fee-for-service Medicare.

This reform will help guarantee that the price of a drug reflects the value that it provides for American patients, rather than the judgments of government administrators in Washington and Europe.

Why Medicare Pays Too Much for an Important Subset of Drugs

Currently, the Medicare reimbursement rate for physician-administered drugs through Part B equals the average of discounts obtained by payers in the commercial market—referred to as "average sales price" (ASP)—plus 6%.[3] This formula works well for most drugs covered under Part B. As long as there are generic alternatives or brand competition driven by a large number of non-Medicare users of a drug, Medicare simply benefits from the often large discounts achieved by commercial payers.

This approach does not work well for drugs that have limited competition and that generate most of their revenue from Medicare. This is a significant problem because many of Part B's most expensive drugs are oncology, ophthalmology, and rheumatology medicines that are mainly needed by those over 65. For these therapeutics, over half the anticipated revenues can come from Medicare, as opposed to the commercial market.[4] For this subset of drugs, pharmaceutical manufacturers have a strong incentive not to offer discounts in the commercial market, which would directly reduce how much they receive in Medicare reimbursement; Medicare is effectively a "powerless price taker."[5] This subset of drugs is exceptionally costly for the government and is growing in number.

Spending for Part B drugs has grown faster than almost any other part of the Medicare program. From 2008 to 2021, per-beneficiary spending on physician-administered drugs in Part B grew 9.2%, more than three times as fast as per-beneficiary spending on retail pharmaceuticals under Part D (2.6%).[6] Of the top 50 drugs according to total spending in Part B, over half were first in class, as defined by the Food and Drug Administration (FDA).[7] Of those novel therapies, 40% still had no competitors at the time of the study, while the remaining 60% had gone, on average, 7.3 years without competition within the drug class.

It should be expected that novel and innovative therapies with patent protection make up a large portion of spending, but the current payment methodology of Part B exacerbates this dynamic. A recent analysis showed that the top 10 highest-cost drugs by total spending accounted for 46% of Part B spending but only 18% of Part D spending.[8] About 75% of Part B drug spending goes to the top 50 drugs by total spending, which represent only 8% of covered drugs in the program.[9]

Price-Control Regimes, Do Not Solve This Problem

IRA price controls do not begin to apply to therapies covered under Part B until 2028. Furthermore, biologics (large-molecule therapeutics) are ineligible for price controls for the first 13 years that the drug is on the market, and small-molecule drugs are ineligible for the first nine years. The vast majority of novel, high-cost new drugs reimbursed through Medicare Part B are biologics.[10]

The use of MFN drug pricing, which was unveiled in the last months of the Trump administration, might be difficult to apply to these types of drugs. Under MFN, the reimbursement rate for the top 50 Part B single-source drugs, according to spending, was set to match the lowest price for a given drug in a handful of developed nations.[11] However, in order for there to be an international reference price, other countries must cover and pay for the drug. Given that novel therapies

consistently come to market first in the U.S.—and do not become available in our most developed peer nations for a year, on average—an MFN price may not even be available for some time.[12] In addition, because MFN would make manufacturers more reluctant to make a drug available in foreign markets if doing so would reduce how much they receive in reimbursement from their largest source of revenue, it is likely that the delay between availability in the U.S. and availability in these peer nations would only grow if MFN were adopted.

Harnessing Competition Among Current Market Participants

Like previous Part B drug-pricing reforms—such as the Competitive Acquisition Program (CAP)[13] created by the Medicare Modernization Act of 2003,[14] or the Drug Value Program proposed by Medicare Payment Advisory Commission (MedPAC)[15]—the reform proposed in this issue brief would empower intermediaries to negotiate lower prices with drug manufacturers. Unlike past proposals, however, it would provide intermediaries with leverage to negotiate prices even for drugs with little or no competition, and it would utilize the current structure of Medicare to minimize disruption.

Most Medicare beneficiaries are covered by private MA plans, which provide the Part B benefit, including physician-administered drugs.[16] In theory, these plans could negotiate prices lower than the statutory rate of ASP + 6% for fee-for-service. But they do not have much leverage to do so because they are required to cover any drug, regardless of cost or efficacy, compared with alternatives. This proposal would change that dynamic by initially providing plans with an incentive—but not a mandate—to cover novel therapies at a price that reflects the value of those drugs. Fee-for-service Medicare would take advantage of the larger discounts obtained by MA plans. Unlike in previous thoughtful but failed,[17] abandoned,[18] or untried[19] Part B drug reforms, the general parameters of physician reimbursement would be left intact.

Process—Annual Negotiation

Under this proposal, MA plans would not initially be required to cover novel therapies under Part B. Instead, each year, MA plans would have the opportunity to negotiate a contract with the manufacturer to cover a given drug at a mutually agreed-upon price. If a threshold of plans (e.g., 50% by enrollment)[20] achieve such a contract, the drug will be covered by Medicare. All MA plans will be required to cover it, but they will also be reimbursed separately, outside the capitated payment for this subset of drugs.

The highest-priced contract above the volume threshold will determine the "clearing price" for the drug, which, in turn, will be used to set the price of the drug as well as reimbursements to MA plans. Manufacturers will be required to sell the drug for, at most, the clearing price minus 1%, or they will not be allowed to participate in Medicare.

MA plans that reached a contract will receive a reimbursement equal to the clearing price minus 1%, which will often be more than the amount that they have negotiated to pay for the drug. MA plans that did not reach a contract will receive a reimbursement equal to the clearing price.

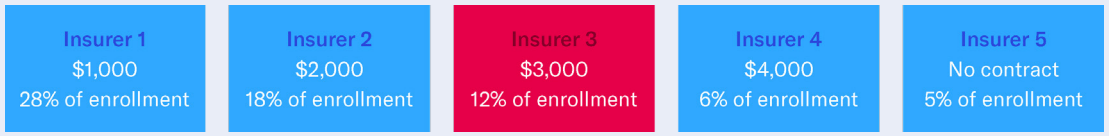
The clearing price would also be used to set the reimbursement rates paid to providers who see traditional fee-for-service Medicare beneficiaries (those who are not enrolled in an MA plan). Instead of being reimbursed at ASP + 6%, providers would be reimbursed at the clearing price plus an add-on payment.

If the coverage threshold (e.g., 50%) is not met, the drug would not be covered by Medicare for the next year. The process would repeat for the next plan year.

Figure 1

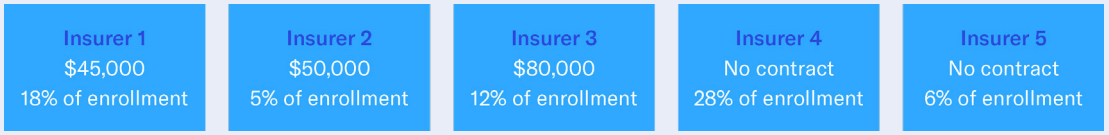
Two examples of how the process might play out.

Example 1:



Outcome: The drug must be covered and the manufacturer must sell at clearing price of $2,970. Reimbursement to Medicare Advantage plans 1 through 4 set at $2,970. Reimbursement for plan 5 set at $3,000. Fee-for-service reimbursement set at $3,000 plus an administration fee.

Example 2:



Outcome: Medicare Advantage plans with only 35% of enrollment reached a deal to cover this drug. Therefore, the drug would not be covered by Medicare and the contracting process would start again the next year.

Discussion of Incentives

Plan sponsors want to cover as many drugs as possible in order to make the plan attractive to potential enrollees. Under this proposal, they will be incentivized to negotiate and cover those drugs at the best price possible because they stand to gain any margin between the clearing price minus 1% and their negotiated rate. But at the same time, plans would not have an incentive to cover a drug if they think that the price that they are being asked to pay by the manufacturer is too high—because if a plan agrees to pay a price higher than the ultimate clearing price, it will lose money on that drug.

Manufacturers would be incentivized to negotiate and offer discounts because their therapy would not be covered unless the coverage threshold is met.

Discussion of Current "Reasonable and Necessary" Coverage Standard

Currently, Medicare Part B covers physician-administered drugs that are "reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body member."[21] However, "reasonable and necessary" is not defined in statute or regulation,[22] and determinations about whether a drug meets this standard are typically outsourced to Medicare Administrative Contractors (MACs) that make "local coverage determinations" at a regional level.[23] Less often, the Coverage and Analysis Group within the Centers for Medicare and Medicaid Services (CMS) may make "national coverage determinations" that apply across the country.

In making reasonable-and-necessary determinations, CMS and MACs are not to supposed to take into account a drug's value. But this policy has been the subject of ongoing debate for decades,[24] including in June 2021, when Aduhelm became the first FDA-approved therapy to treat Alzheimer's disease in decades. Given Aduhelm's announced price of $56,000 per patient per year,[25] and that roughly 80% of its recipients would have been on Medicare, CMS responded to the FDA approval by increasing Part B premiums by 14.5% in one year.[26]

However, despite the premium increase, CMS did not immediately grant full coverage to Aduhelm, opting instead to conduct an unprecedented months-long review.[27] Facing weak commercial sales and fearing that it could no longer count on Medicare coverage, the manufacturer of the drug cut its commercial-market price in half in December 2021.[28] One month later, CMS issued a National Coverage Determination that explained that, because Aduhelm had been approved only under FDA's "Accelerated Approval" pathway,[29] it would be covered only for patients enrolled in a clinical trial.[30] In 2024, the manufacturer stopped marketing the drug.[31]

This issue brief does not weigh in on the merits of CMS's decision to cover Aduhelm, but the episode helps clarify two features of the status quo that this proposal would help address. First, CMS is willing to wield the power of reasonable-and-necessary coverage determinations to restrict access to certain novel therapies that are FDA-approved but that CMS believes are of unclear value. Instead of consolidating that authority within an opaque bureaucracy, this proposal would make it a collective decision by several market participants subject to checks and balances, including patient demand and assessment of value.

Second, the current Part B reimbursement rules seem to have led the manufacturer of Aduhelm to restrict the discounts that it was willing to offer in the commercial market. When it believed that the drug would be fully covered, it kept prices high in order to maximize how much it would receive in reimbursement; but as it became more apparent that CMS would sharply limit coverage, the manufacturer slashed the price. This proposal would ensure that CMS, Medicare beneficiaries, and all taxpayers are no longer "powerless price takers" who must take whatever price the manufacturer believes that the system can bear.

Price-Control Regimes, Even When Applicable, Are Inferior to Market-Based Mechanisms

Well-designed market-based pricing mechanisms are inherently superior to government price controls, such as those established by IRA, primarily because the former integrate the value judgments of multiple market participants, while the latter rely on the limited knowledge of a small group of politicians or bureaucrats.

Consider IRA, which tasks officials at HHS to determine the Medicare reimbursement rate for a drug, based on factors such as the cost of manufacturing and research and development, revenue and sales volume, and the comparative effectiveness of alternatives, among others. The law requires that all these factors are taken into account, but there is no guidance on the weight that each should be given, leaving government officials with near-total discretion to the make value judgments while implementing the law. These judgments have huge implications for how care will be delivered (e.g., which drug gets favored over an alternative) and where investment will flow and thus the direction of future innovation. But the process by which these decisions are made is opaque. Anyone who disagrees with the announced price is left with little recourse but to petition Congress.

The IRA price controls have thus far led to questionable results. Even advocates of price controls noted that many drugs included in the first round of negotiation are already heavily discounted in Part D, through private negotiation,[32] and that, for one drug on the list, there already was a biosimilar that competitors anticipated would enter the market shortly.[33]

Contrast this result with the various feedback loops in this proposal. The market participants are, first and foremost, enrollees who choose from various plans on the basis of the drugs covered, the network of providers, the associated cost-sharing, and the premium rate. Providers can decide which plans they are willing to contract with at what rate, and they have leverage via the recommendations that they give their patients about which plan to sign up for when asked. Drug companies weigh the level of discount to offer a plan based on its utilization management and associated patient cost-sharing. Plans must balance costs and accommodate the desires of potential enrollees, providers, and drug manufacturers as contracts are negotiated, or they risk losing enrollees to other plans.

Additionally, unlike government price controls—which can be altered only through rigid bureaucratic processes subject to inertia and regulatory capture by the most interested parties—market-based pricing mechanisms allow multiple actors to constantly anticipate and adapt to evolving circumstances and changing preferences in order to gain an edge on competitors.

Conclusion

The federal government is often the largest purchaser of drugs that have little or no competition, which has sharply increased costs for patients and all taxpayers alike. In response, those who are confident in the power of the government to solve the problem coercively have been more than willing to fill the void by putting forward proposals that rely, for example, on rate setting. But those

who believe in the primacy of the preferences of individual people—revealed through voluntary purchasing decisions that they make with (at least some of) their own resources—have largely failed to offer anything better.

This proposal does just that by proposing an approach that does not rely on the biases of a handful of government officials making decisions that do not affect them but instead utilizes the revealed preferences of millions of individuals voluntarily making decisions to their own benefit.

Endnotes

1 Public Law 117-169.

2 Pharmaceutical Research and Manufacturers of America, "Price Setting."

3 For many years since 2013, the 2% mandatory sequester created by the Budget Control Act (Public Law 112-25) effectively has reduced the amount to ASP + 4.3%.

4 See Government Accountability Office (GAO), "Medicare Part B: Medicare Represented at Least Half of the Market for 22 of the 84 Most Expensive Drugs in 2015" (December 2017), which found that for 30% of the 84 most expensive Part B drugs, Medicare represented at least half the market: "[W]hen Medicare accounts for a large share of the market for a drug, a manufacturer may have less incentive to price the drug competitively."

5 This description was used by former CMS administrator Seema Verma on Nov. 20, 2020; see https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-delivering-lower-prescription-drug-prices-americans.

6 Nguyen X. Nguyen et al., "Medicare Part B Drugs: Trends in Spending and Utilization, 2008–2021," U.S. Dept. of Health and Human Services (HHS), Office of the Assistant Secretary for Planning and Evaluation (ASPE), June 9, 2023.

7 I calculate the share of Part B spending from first-in-class drugs and the average length without competition by comparing two lists: one compiled by FDA researchers of first-in-class drugs, 1986–2018 (see supplemental data from Michael L. Lanthier, Kirk W. Kerr, and Kathleen L. Miller, "An Analysis of Follow-On Development in New Drug Classes, January 1986–June 2018," *Clinical Pharmacology & Therapeutics* 106, no. 5 (November 2019): 1125–32); and the other compiled of top-spending Part B drugs from Centers for Medicare and Medicaid Services (CMS), "Medicare Part B Spending by Drug," updated 2022.

8 HHS ASPE, "Report to Congress: Prescription Drug Pricing," May 20, 2020.

9 CMS, "Medicare Part B Spending by Drug."

10 See Nguyen et al., "Medicare Part B Drugs": "89 percent of growth in Medicare Part B drug spending from 2008 to 2021 was due to spending on biologics."

11 The MFN proposal included prices of the 20 nations within the OECD within 60% of U.S. GDP per capita. See 85 Fed. Reg. 76,180 (Nov. 27, 2020).

12 See HHS ASPE, "Comparing New Prescription Drug Availability and Launch Timing in the United States and Other OECD Countries," February 2024, which provides a review of new drugs from 2018 to 2022 and finds that about 85% were available in the U.S., or in the U.S. and at least one other country; 50% were available at first only in the U.S. There was an average lag of about one year before the launch in other major OECD markets (Australia, Canada, France, Italy, Japan, and the UK).

13 The Competitive Acquisition Program attempted to utilize intermediaries that would compete to contract with physicians for the provision of Part B drugs. However: "The CAP vendor was required to offer all biologics and single-source drugs and was not permitted to create a

formulary, giving the vendor little leverage to obtain favorable prices from manufacturers"; see Medicare Payment Advisory Commission (MedPAC), "Report to the Congress: Medicare and the Health Care Delivery System," June 2016, chap. 5.

14 Public Law 108-173.

15 The Drug Value Program is a proposal structurally similar to CAP but would allow the use of formularies for therapies that have competition within a drug class. However, instead of utilizing a market-oriented mechanism for driving lower prices for drugs with no competition, MedPAC proposed the use of government-mandated binding arbitration. See MedPAC, "Report to the Congress: Medicare and the Health Care Delivery System," June 2017, chap. 2.

16 Bob Herman, "Medicare Advantage Enrollment Races Past 33 Million," *StatNews*, Feb. 16, 2024.

17 CAP was disbanded in 2009; see CMS, "Competitive Acquisition for Part B Drugs & Biologicals."

18 The Obama administration proposed, but did not finalize, major reforms to Medicare Part B drug reimbursement; see 81 Fed. Reg. 13,230–61 (Mar. 11, 2016).

19 The MedPAC Drug Value Program was proposed in 2017 but has not gained traction; see MedPAC, "Report to the Congress," June 2017, chap. 2.

20 Based on current market share, a 50% threshold would guarantee that at least three of the major nationwide insurers have agreed to a contract; Nancy Ochieng et al., "Medicare Advantage in 2023: Enrollment Update and Key Trends," Kaiser Family Foundation (KFF), Aug. 9, 2023, fig. 9.

21 CMS, "Medicare Coverage Determination Process."

22 On Jan. 14, 2021, the Trump administration finalized a midnight rule that would have defined "reasonable and necessary" for the first time. However, its implementation was immediately delayed by the Biden administration and repealed approximately one year later; 86 Fed. Reg. 62,944 (Nov. 15, 2021).

23 CMS, "Local Coverage Determinations."

24 My Manhattan Institute colleague Chris Pope demonstrates the past and future implications of the lack of cost-conscious coverage determinations in his report "Keeping Medicare Affordable: The Cost of Adding Services," Manhattan Institute, May 30, 2023.

25 Zachary B. Wolf, "The Hard Math on the New $56,000 Alzheimer's Drug," CNN, July 20, 2021.

26 86 Fed. Reg. 64,205 (Nov. 17, 2021).

27 Pam Belluck, "Decision Looms That Could Determine Fate of Alzheimer's Drug," *New York Times*, Dec. 31, 2021.

28 Biogen, "Biogen Announces Reduced Price for ADUHELM® to Improve Access for Patients with Early Alzheimer's Disease," press release, Dec. 20, 2021.

29 The Accelerated Approval pathway allows FDA to approve drugs based upon achieving surrogate endpoints as opposed to clinical outcomes; see FDA, "Accelerated Approval Program."

30 CMS, proposed decision memo, "Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease," Jan. 11, 2022.

31 "Biogen Drops Alzheimer's Drug Aduhelm, Ending a 17-Year Chapter," Reuters, Jan. 31, 2024.

32 See Caitlin Owens, "Medicare Drug Price Negotiations Could Have Limited Impact at First," *Axios*, Aug. 30, 2023: "'In a lot of cases, we don't expect the negotiated price to go lower than even the net price today. I think this list is chock-full of highly rebated drugs,' said Stacie Dusetzina, a drug pricing expert at Vanderbilt University Medical Center."

33 One of the initial 10 drugs chosen for IRA price controls is Johnson & Johnson's Stelara, which is set to have biosimilar competition before the price controls kick in; Nyah Phengsitthy, "Stelara Biosimilar Tests Market Impact of Drug Price Program," *Bloomberg Law*, Nov. 22, 2023.