



Issues and Challenges with the Effectuation of Maximum Fair Prices for Medicare Part B Drugs

AVBCC Part B Drug Effectuation Work Group
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with ADVI Health

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Introduction

Under the authority provided in the Inflation Reduction Act (IRA) of 2022, Medicare can now negotiate prices with drug manufacturers of selected single source prescription drugs that are covered under Medicare Part B and Part D. The goal of the program is to save money for both the Medicare program and beneficiaries. These negotiated prices, known as Maximum Fair Prices (MFPs), must be “made available” to eligible Medicare beneficiaries when they fill their prescriptions under their Part D benefit at pharmacies and other dispensing outlets, or when they are administered or furnished a medication, such as an injectable or infused drug, under Medicare Part B.¹

The Centers for Medicare and Medicaid Services (CMS) is the agency within HHS responsible for the implementation of the program and is working with stakeholders – including manufacturers, patient groups, pharmacies, hospitals, and physicians’ offices – to develop mechanisms to make the MFP prices available on eligible patient claims (i.e., MFP effectuation).

This white paper describes the policy context and operational challenges facing patients, physicians, manufacturers, wholesalers, and other stakeholders with respect to the effectuation of MFPs for Part B drugs. Addressing these challenges is critical, as oncology practices could face substantial administrative burden in participating in Part B effectuation processes, leading to the closure of independent practices, an increase in vertical integration, and lower patient access to critical cancer care. As such, CMS should continue to seek stakeholder feedback before they finalize plans for effectuation of Medicare Part B MFPs.

¹ MFPs for the first 10 drugs covered under Medicare Part D have been announced; and the MFPs for these drugs will be made available to pharmacies starting January 1, 2026. MFPs for an additional 15 drugs covered under Part D will be available January 1, 2027. MFPs for an additional 15 drugs covered under both Part D and Part B will be available starting January 1, 2028, the first applicability year for Part B drugs (IPAY 2028).

AVBCC Part B MFP Effectuation Working Group Background and Principles

AVBCC is a 501 (c)(6) educational and advocacy nonprofit organization dedicated to the exchange of knowledge among all stakeholders in the cancer care ecosystem. The mission is to provide a forum for payers, providers, and the entire oncology team to enter into conversations and evaluate value in terms of impact, quality, and cost on patient care and outcomes. Earlier this year, AVBCC formed a group of concerned stakeholders in the Part B environment representing physicians and physician groups, patients, wholesalers, and manufacturers with the goal of first identifying core principles related to Part B MFP effectuation and subsequently, to recommend solutions to CMS as they are reviewing and finalizing effectuation guidance and rulemaking for IPAY 2028. The following represents the 5 core principles and their considerations.

- 1. The choices CMS makes to effectuate Medicare Part B MFPs should ensure that timely and continuous patient access to the most appropriate treatments are not interrupted.** This is an overarching principle for all others and is consistent with CMS views based on recent guidance.
- 2. Ideally, physicians, hospitals, and other providers (providers) should be removed from the middle of the MFP effectuation process.** CMS, rather than Part B providers, should bear the burden of “floating” the MFP refunds to mitigate financial hardship and disruption to providers that would negatively impact patient care. Providers do not have the infrastructure to manage the administrative burden with MFP effectuation, which includes ensuring the receipt of accurate payments, appealing any discrepancies, and managing practice expenses in the gap between submitting a claim and being made whole through effectuation. These administrative costs and time costs of money further diminish payments for Part B drugs and further jeopardize the current cancer care delivery system. Hand in hand with this ideal approach would be ensuring MFP does not decrease ASP, a historically public pricing benchmark widely used by Commercial insurers and Medicaid programs to establish reimbursement rates for Part B drugs. As part of this approach, CMS should continue to publish ASP for all stakeholders in the Part B ecosystem. This is further outlined below.
- 3. Part B effectuation should be simple, administratively easy and inexpensive for providers, ensuring timely effectuation of the MFP.** CMS should consider that infeasible or complex approaches could significantly impede access to and delivery of quality health care to Medicare beneficiaries by negatively impacting the economics and operations of physician practices, especially oncology practices.
- 4. In establishing the standard drug rebate amount (SDRA), provider reimbursement must be protected through avoidance of an ASP downward spiral.** The basis of the SDRA for Part B drug MFP effectuation should be based on a public, transparent

benchmark that provides predictable and appropriate reimbursement for the providers' acquisition costs of Part B drugs. CMS needs to evaluate the impact of the SDRA chosen on both access to patient care as well as providers' administrative burdens. To be consistent with the methodology for the calculation of a drug's Average Manufacturer's Price (AMP) with respect to the MFP, CMS should instruct manufacturers to exclude (i.e. not deduct) the MFP discounts from the calculation of a selected drug's ASP. This clarification is needed to ensure patient access to these medications in both government-funded and commercial health care programs. The manufacturer reported ASP for selected drugs (excluding MFP) should be published by CMS. The increased costs to the already impacted delivery system of this option should be considered.

5. **Effectuation processes must consider that there are differences between Part B and Part D programs, making MFP effectuation under Part B more complex.** These differences include: the significant number and variety of health care practices and entities that provide Part B drugs; the time frame for the processing of Part B claims in Medicare Advantage (or Part C) plans – considering the differences between Medical Benefit and Pharmacy benefit reimbursements; Part B provider billing and reconciliation systems; provider payment cycle times for Part B drugs; the involvement of multiple Medicare Administrative Contractors (MACs) in the process; purchasing and distribution patterns for Part B drugs; standardized drug refund amounts; the Medicare Part B Discarded Drug Units Program; and, Medicare beneficiary cost sharing policies and procedures under Part B and Medicare Advantage. Creating new and additional administrative burdens for all participants would be costly with proposed approaches, including physician practices, clinics, small rural hospitals, Part C plans and manufacturers.

The working group also acknowledges the impact of the broader reimbursement infrastructure and its intersection with MFP effectuation. When adjusted for inflation, Medicare's Physician Fee Schedule currently pays approximately two-thirds of 2005 payments for the same service and has not increased at the same rate practice expenses have.² Providers are reliant on the margins from Part B drugs, and with the loss of that drug margin, the viability of small or rural community hospitals and independent practices is threatened. Faced with eroding margins, independent practices may be placed in a position to close, merge with a hospital, or be acquired by a private equity firm. As seen historically, hospital purchases of physician practices have increased the cost of care for patients, further impeding access to care.³ Additionally, as financial margins erode, hospitals may

² Medicare physician payment continues to fall further behind practice cost inflation. American Medical Association. (n.d.). <https://www.ama-assn.org/system/files/2025-medicare-updates-inflation-chart.pdf>

³ Cooper, Z., Craig, S., Epanomeritakis, A., Grennan, M., Martinez, J., Scott Morton, F., & Swanson, A. (2025, July). *Hospitals are gobbling up physician practices—and health care prices are rising as a result*. Tobin Center

choose to limit financial losses by closing oncology treatment programs, as is currently occurring with obstetrics services.⁴

Building on the principles outlined above, the following section explores key considerations, challenges, and opportunities within CMS' focus areas as they develop further guidance. It also addresses relevant legislative efforts and recent CMS updates, including the CY 2026 Physician Fee Schedule proposed rule and IPAY 2028 final guidance.

Part D Drug MFP Effectuation

CMS has indicated in its final guidance for IPAY 2028 that while it's still considering how to effectuate MFPs for Medicare Part B, it intends to align, to the extent appropriate and feasible, policies and operations for providing the MFP under Part B with those developed under Part D. Because of this intended alignment, it is important to understand how the agency is implementing the effectuation process for Part D drugs.

For the effectuation of MFPs under Part D, the pharmacy dispensing the selected drug is reimbursed from the Part D plan at no more than the MFP plus the dispensing fee, even though the drug was purchased by the pharmacy at the regular acquisition price from the wholesaler.⁵ To make the pharmacy whole for providing the drug at the MFP, the manufacturer of the selected drug would have to refund the pharmacy for the difference between the pharmacy's purchase price and the MFP.⁶

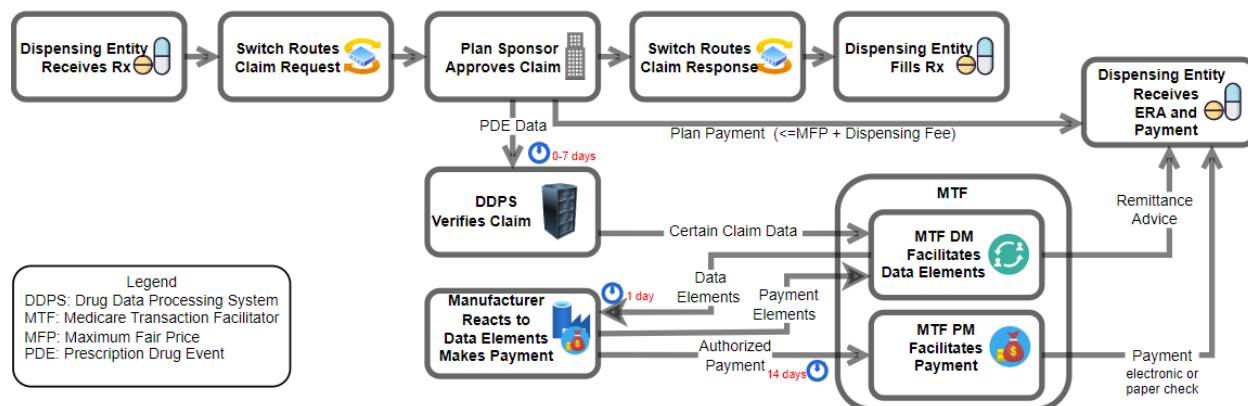
for Economic Policy. <https://tobin.yale.edu/research/hospitals-are-gobbling-physician-practices-and-health-care-prices-are-rising-result>

⁴ Kozhimannil, K. B., Interrante, J. D., Carroll, C., Sheffield, E. C., Fritz, A. H., McGregor, A. J., & Handley, S. C. (2025). Obstetric Care Access declined in rural and urban hospitals across US states, 2010–22. *Health Affairs*, 44(7), 806–811. <https://doi.org/10.1377/hlthaff.2024.01552>

⁵ Beneficiaries pay the pharmacy the cost-sharing amount dictated by the Part D plan.

⁶ In situations where the 340B ceiling price is lower than the MFP and the pharmacy is a 340B contract pharmacy, the MFP will not be applicable.

Overview of the Part D MFP Effectuation Process⁷



Manufacturers and pharmacies do not currently have direct financial connectivity, and there was a need for a process to transmit Part D claims data to manufacturers in a timely manner. To facilitate the transfer of eligible pharmacy claims data from Part D plans to manufacturers and the payments from manufacturers to pharmacies, CMS committed to establishing and contracted for the development of a Medicare Transaction Facilitator, with both a data module component (known as the MTF-DM) and payment module component (known as the MTF-PM). Dispensing entities must enroll in the MTF-DM. Manufacturers of the selected drugs *must* enroll in the MTF-DM to receive claims data from CMS and *can* enroll in the MTF-PM to make refund payments to pharmacies.

Under the effectuation process, when a pharmacy dispenses the selected drug prescription to a Part D eligible individual, the Part D plan pays the pharmacy no more than the MFP for the selected drug plus the dispensing fee. The plan sends the claims data to CMS' Drug Data Processing System (DDPS), which, after performing validation checks, sends data for the Part D selected drug claims to the MTF-DM to facilitate exchange with the manufacturer. The manufacturer receives the data from the MTF-DM, verifies the applicability, and issues the refund amount owed to the pharmacy within 14 days, effectuating the MFP.

The suggested manufacturer refund payment established by CMS (standard default refund amount, or SDRA) for Part D selected drug claims is equal to the Wholesale Acquisition Cost (WAC) for the drug minus the MFP for the drug. The use of WAC allows for verification of the refund amount, because WAC is a public pharmaceutical pricing

⁷ Center for Medicare, & Klomp, C., Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 (2025). Retrieved October 2, 2025, from <https://edit.cms.gov/files/document/ipay-2028-final-guidance.pdf>. Annotations added.

benchmark number. If using the MTF-PM, the manufacturer transmits the authorization to make the refund to the pharmacy to the MTF-DM, which instructs the MTF-PM to make the payment to the pharmacy's bank accounts from the manufacturer's bank accounts.

Part D pharmacies' and dispensers' enrollment in the MTF-DM, as well as the collection of their banking information to facilitate refunds, is critical to the success of MFP effectuation. CMS had no such file of pharmacy information available that could be used for these purposes. Compiling this information is a significant task, with over 90,000 Part D dispensers, including retail pharmacies, hospital outpatient departments, clinics, and physician offices. CMS allows the pharmacies to use information found in their National Council for Prescription Drug Programs (NCPDP) database to populate some of their information in the MTF-DM.

Physician practices are preparing for Part D effectuation to significantly increase administrative burden. Timely fulfillment of oral chemotherapy and support drugs is required for physician-administered drugs to be administered on schedule. Physicians report that today practices must delay scheduling treatment with intravenous drugs until patients have secured the oral component of the treatment. Once practices begin participating in the Part D and Part B effectuation processes, payment delays will further delay patient treatments. Additionally, for Part D drugs, physician offices will likely need to pursue appeals processes to ensure they receive the correct refund, as practices rarely purchase drugs at WAC (the SDRA for Part D).

This overview of the effectuation process for the MFPs for Part D drugs can be instructive in assessing how such effectuation might work for MFPs for Part B drugs. As stated above, CMS has alluded to using a similar approach to the effectuation of the MFPs for Part B drugs. That is, providers of Part B drugs would administer the drugs, charge the beneficiary the cost sharing for the drug based on the MFP plus six percent, and wait for a refund from the manufacturer to be "made whole" from their purchase. However, there are significant differences between the administration and billing for Part B and Part D drugs that the agency must consider in its design of the Part B drug MFP effectuation program, so that providers may remain above water and patients can continue accessing affordable, appropriate treatment.

Policy and Operational Issues with Effectuation of Part B Selected Drugs

The selection of drugs for IPAY 2028, including any selected Part B drugs that would be subject to an MFP will be published by the agency by February 2026, with prices to go into effect in January 2028. While CMS has been focused on Part D MFP effectuation since the enactment of the IRA, given those MFPs will go into effect in January 2026, it must now turn its attention to how the MFPs for Part B drugs will be effectuated. This process must be

defined soon to allow stakeholders enough time to incorporate any resulting changes into their processes. Unlike Part D drugs which mostly are self-administered and dispensed through community retail pharmacies, most Part B drugs are administered (such as injected or infused) by healthcare professionals in hospital outpatient, physician office, and clinic settings. Many Part B drugs are used in cancer and immunological disorders, as well as ophthalmological and rheumatological conditions.⁸ While some Part B drugs are also dispensed through retail or specialty pharmacies – such as oral immunosuppressive drugs and inhaled drugs – these pharmacies are not the primary purchasers of drugs covered under Medicare Part B or the Medical Benefit in Part C.

Differences Between Part B and Part D

Like Part D, under Part B effectuation, CMS must facilitate the collection of Part B and Part C provider drug claims data, to be shared with manufacturers. Unlike the Part D program, where there is a central DDPS system that collects Prescription Drug Event (PDE) data used to facilitate MFP effectuation; hospitals, physicians and other Part B providers submit their claims to several different Medicare Administrative Contractors (known as MACs). For Part B, no central DDPS-like system exists. Currently, there are 12 Medicare Parts A/B and four Durable Medical Equipment (DME) MACs in the program that process Medicare fee-for-service (FFS) claims for nearly 51 percent (34 million beneficiaries) of the total Medicare beneficiary population.⁹ In Fiscal Year 2023 (FY 2023), the MACs served more than 1.2 million health care providers who were enrolled in the Medicare FFS program. Collectively in FY 2023, the MACs processed more than 1.1 billion Medicare FFS claims, comprised of approximately 192 million Part A claims and 950 million Part B claims, and paid out approximately \$431.5 billion in Medicare FFS benefits.¹⁰ Additionally, over 1.5 million providers and 5,000+ hospitals are enrolled in Medicare Part B, across all hospital types and provider specialties – a significantly larger number than the 91,000 dispensers of Part D drugs, including 60,000 community retail pharmacies, hospital outpatient pharmacies, clinics, and some physician offices.

If the agency uses the existing MTF-DM, as it has indicated it would, then CMS must establish a process to enable the MACs to exchange claims data with the MTF-DM. There would also be a need to establish a process for Part C plans to route their claims for Part B selected drugs, whether reimbursed through their Medical Benefit or Pharmacy Benefit to

⁸ ASPE, Nguyen, N. X., Sheingold, S. H., Olsen, T. A., & Delew, N., Medicare Part B Drugs: Trends in Spending and Utilization, 2008-2021 (2023). Retrieved October 2, 2025, from <https://aspe.hhs.gov/reports/medicare-part-b-drugs-spending-utilization>

⁹ Medicare Administrative Contractors. CMS. (2024a, September 10). <https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs>

¹⁰ What's a MAC? CMS. (2024b, September 10). <https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/whats-mac>

the MTF-DM. Such connectivity would have to be built, and the MTF-DM's capacity for receiving and processing claims would have to increase. Failing to effectively develop this connectivity will delay provider payment and limit patient care.

The process of enrolling Part B providers in the MTF-DM and providing refunds to them would be more complex than under Part D, given the sheer numbers. However, given that many of these providers are likely already receiving payments from CMS contractors, all the relevant information that would be needed to enroll Part B providers in the MTF-DM, should that route be chosen, is already available to CMS the Medicare Provider Enrollment, Chain, and Ownership System (PECOS), the system in which all Medicare providers are required to enroll. Through enrollment in PECOS, providers submit their electronic funds transfer (EFT) information, which allows for payment of claims. Use of this pre-existing information alleviates provider administrative burden and aligns Medicare payments at least in FFS, if the MACs are able to transfer this information to the MTF-DM. However, this is only part of the equation and would only apply to FFS.

Regarding billing and reconciliation, Part B providers submit either to their MAC or their beneficiary's Medicare Advantage plan, both of which have different billing and reconciliation systems. Additionally, under Part B, a beneficiary's cost sharing amount differs based on their use of a Medicare Advantage plan, a Medigap plan, or traditional FFS, further complicating the effectuation of selected Part B drugs. Lastly, manufacturers of single-use vial medications may be subject to discarded drug refunds under the Discarded Drug Refund Program, which does not apply for Part D medications. Thus, it will be important to determine how MFP effectuation would interact with the discarded drug program to ensure manufacturers do not pay duplicate discounts.

Provider Reimbursement

Traditionally, the Medicare payment rate to providers for these Part B drugs has been the Average Sales Price of the drug (ASP) plus six percent.¹¹ However, under the IRA, the payment for the drug will now be the MFP for the selected drug, as negotiated between the manufacturers and CMS, plus six percent. This means that provider reimbursement for Part B drugs, which in effect has been helping to compensate providers for a lack of adequate payment for practice expenses, will be reduced because the negotiated MFP amount is expected to be lower than the pre-MFP ASP amount reported for the drug by the manufacturer. Under the current Medicare reimbursement system, physicians are highly dependent on drug margins for the economic viability of their practices. These add-on payments cover drug storage and handling costs and help offset the low Medicare

¹¹ 42 CFR 414.904

reimbursement from rendered physician services. While the add-on payment for these Part B drugs may be lower, the operating costs of practice management under this system will increase, leaving physicians in a perilous financial position which would in the end, dramatically impact patient access to care.

In addition, while ASP amounts for a drug that are calculated by the manufacturer and reported to CMS might change every quarter, the MFP amount for the drug will remain the same during each of the calendar years that the MFP is in effect for the drug, and will only increase by the CPI-U each year after as long as the MFP is in effect.

In the CY 2026 Physician Fee Schedule proposed rule, CMS stated it will only publish the MFP for selected drugs in the ASP Pricing File, noting that when statutory provisions “require that the payment limit be based on a pricing metric other than ASP under specific circumstances... only the actual payment limit is published on the pricing file (and no ASP information is displayed).”¹² This will mean that any payer that uses ASP as the basis for physician-administered drug reimbursement will have to use a different reimbursement metric for physician-administered drugs. Given that the majority of commercial and some Medicaid payers use an ASP-based reimbursement system, the removal of a public ASP from the Quarterly ASP Pricing Files for drugs with an MFP severely disrupts contracting and reimbursement across all payers, with ultimate ramifications to patient access.¹³

Additionally, in the CY 2026 Physician Fee Schedule proposed rule, CMS “clarified” that it will include sales at the MFP in the calculation of ASP.¹⁴ CMS states that “statutory language does not expressly or implicitly exempt units of Medicare Part B or Part D MFP sales from the calculation of the manufacturer's ASP.” This interpretation of statute will result in an “ASP spiral,” where the lower-priced MFP sales pull the ASP down.

A lower ASP can have deleterious effects on provider reimbursement, especially as independent physician practices will be reimbursed for less than their purchasing price of the drug, leading providers to face trade-offs in care choices to maintain financial solvency, which would negatively impact ideal patient care. A recent analysis estimated that, as a result of negotiated MFPs for IPAY 2028, oncology practices will face a 49.5 percent decrease in the top line revenue that is currently used to partially cover the shortfall in payment for

¹² 90 FR 32352. <https://www.federalregister.gov/d/2025-13271/p-1095>

¹³ Sullivan, M., Frazier, L., Gustafson, K., & Leonard, M. (2025, January 27). *Estimating the Spillover Impact of IRA Part B Negotiation*. Avalere. <https://advisory.avalerehealth.com/insights/estimating-the-spillover-impact-of-ira-part-b-negotiation>

¹⁴ 90 FR 32352. <https://www.federalregister.gov/d/2025-13271/p-1094>

other patient services such as infusion.¹⁵ If the commercial payers who currently provide much of the funding for undercompensated services are reimbursing at a lower ASP or at MFP, the loss of cancer care delivery will be accelerated. Providers may be forced to close independent practices or change treatment protocols to other drugs, negatively impacting the patient treatment experience and health outcomes while increasing total cost of care as more physicians bill under the Hospital Outpatient Prospective Payment System.

AVBCC, on behalf of the Part B MFP Drug Effectuation Work Group, provided comments to CMS regarding the ASP calculation and reporting clarifications.¹⁶ AVBCC requested CMS exclude units of selected drugs sold at the MFP in ASP calculations, and continue to publish selected drugs' ASP, exclusive of MFP units, as an additional column in the ASP Pricing File, while allowing 106 percent of MFP to represent the Medicare payment limit.

Medicare Advantage and MFP Effectuation

Part B drugs are also provided to Medicare beneficiaries enrolled in Medicare Advantage (MA) (Part C) plans. CMS will have to determine policies around how Part B drug effectuation will work within Part C plans. That is, how do the Part B drug claims administered to enrollees in Medicare Part C plans get transmitted to the manufacturer so the manufacturer can pay a refund back to the physician that administered or furnished the drug? This would have to account for medical benefit and potentially pharmacy benefit claims through the health plans. The pace at which physicians would be paid by manufacturers for Part B drug refunds from Part C claims depends on how quickly the plans send their encounter data to CMS, and these data are then transmitted to the manufacturer.

Anecdotally, stakeholders have expressed concerns on timing and data lags regarding collection of Medical Benefit claims under Medicare Part C plans, with some delays extending to over a year or more in terms of data provision to CMS by the plans. These complexities will cost physician practices and hospitals time and money, both of which are in limited supply. A delay in data transmission could place independent physician practices underwater financially as they wait for the MFP to be realized through the manufacturer refund.

Additionally, the statute is silent on requiring Part C plans to pay the MFP plus six percent for these drugs. In contrast, the statute instructs the Part D prescription drug plans

¹⁵ Sullivan, M., Tripp, A., Isaiah, E., & Diskey, R. (2022, November 29). *IRA Medicare Part B Negotiation Shifts Financial Risk to Physicians*. Avalere Health Advisory. <https://advisory.avalerehealth.com/insights/ira-medicare-part-b-negotiation-shifts-financial-risk-to-physicians>

¹⁶ AVBCC (2025, September 16). *Regulations.gov*. Retrieved October 7, 2025, from <https://www.regulations.gov/comment/CMS-2025-0304-13266>

to pay pharmacies and other dispensers no more than the MFP for the ingredient cost portion of a selected drug claim. While the MFP will be substituted for the ASP for Medicare Fee for Service Part B payment, the Part C plans generally negotiate their reimbursement with their hospital and physician providers, as CMS is not allowed to interfere in such negotiations.

Selecting an SDRA

As current guidance stands, providers of Medicare Part B drugs are bearing the financial risk for the MFP effectuation process and will have to obtain a refund from the manufacturer to compensate them for the difference between their acquisition cost and the initial reimbursement for the drug. Monitoring the manufacturer's plans to effectuate MFPs in 2026 may shed more light on whether any manufacturers are electing to effectuate the MFP prospectively vs. retroactively through a rebate. It should also be noted that the cost to manufacturers and providers to participate in new payment processes to accommodate the program are unreimbursed expenses.

While WAC is required as the SDRA for Part D drug MFP effectuation, the difference between WAC and the provider's acquisition cost in Part B is likely greater than it is in Part D (as a percentage of the provider's acquisition cost), meaning that the manufacturer refund for the Part B drugs could be substantial if WAC is used.

As mentioned above, given that the ASP for Part B drugs subject to an MFP will not be made public, it is unlikely that manufacturers can use the ASP as the basis of the SDRA; providers and manufacturers would require a way to verify or understand what their expected refund amounts should be. These considerations may require Congressional action and may not reside with CMS alone.

Legislation on Part B Drug Effectuation

Recognizing some of the challenges with MFP effectuation for Part B drugs, legislation was introduced in the 118th and 119th sessions of Congress to modify how Medicare would achieve its savings from Part B drug negotiations. The bill, the Protecting Patient Access to Cancer and Complex Therapies Act of 2025 (H.R. 4299), would require manufacturers to pay rebates to the Federal Supplemental Medicare Insurance Trust Fund within 30 days of receiving a quarterly bill from the Medicare program for Part B drugs subject to an MFP that would be based on the total number of units of the billing and payment code for such selected drug furnished to Medicare beneficiaries during such calendar quarter.¹⁷ The rebate would be based on the difference between ASP plus 6% and MFP plus 6% for the drug.

¹⁷ H.R.4299 - 119th Congress (2025-2026): Protecting Patient Access to Cancer and Complex Therapies Act. (2025, July 7). <https://www.congress.gov/bills/119th-congress/house-bill/4299>

This approach contrasts with the Part D effectuation process established by CMS, in which the MFP refunds are sent by manufacturers to pharmacies and other dispensing entities. Under this approach in the proposed legislation, Part B providers would still be able to “buy and bill” the drugs at their regular price to Medicare, and they would receive payment at ASP plus six percent for the drug. The Medicare program would realize the MFP savings because the manufacturers of the drugs covered under Part B with an MFP would receive rebate bills from CMS no later than six months after the end of each quarter. The rebates would be paid to the HHS Medicare Trust Fund rather than the providers.

However, to maintain the intent of the law to reduce cost sharing for beneficiaries, the legislation would continue beneficiary cost sharing at 20 percent for Part B drugs but would base the 20 percent amount on the MFP for the drug plus six percent rather than the ASP plus six percent. In addition, the bill makes clear that MFP rebates are not deducted by the manufacturer when calculating its ASP, like the statutory instruction given to manufacturers in its calculation of AMP in the original IRA law. This will mean that provider reimbursement under the ASP methodology would not be affected by the inclusion of the MFP discounts in the ASP.

Numerous provider groups have endorsed this legislation, including the Community Oncology Alliance, Infusion Providers Alliance, and LUGPA. These organizations describe the legislation as “achiev[ing]...cost savings without compromising patient access,” “alleviat[ing] yet another reimbursement cut and administrative burden that threatens seniors’ access,” and protecting physicians’ abilities to provide access to complex care treatments.¹⁸

Recent CMS Guidance

Although the Part B drug MFPs will not have to be effectuated until January 2028, given the lag time to draft regulations as well as any government contracting that is needed, CMS needs to determine whether the Part B drug MFP effectuation framework will be overlaid on the Part D MFP framework that has already been adopted. In its September 2025 final guidance for IPAY 2028, the agency stated it “will provide detailed policy on providing access to the MFP for selected drugs payable under Part B in the future.”¹⁹ CMS has the opportunity

¹⁸ *Murphy introduces bipartisan legislation to preserve seniors’ access to critical drugs*. Congressman Greg Murphy. (2025, July 9). <https://murphy.house.gov/media/press-releases/murphy-introduces-bipartisan-legislation-preserve-seniors-access-critical>

¹⁹ Center for Medicare, & Klomp, C., Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 (2025). Retrieved October 2, 2025, from <https://edit.cms.gov/files/document/ipay-2028-final-guidance.pdf>

to gather input from stakeholders so as to create the most suitable effectuation process for provider, manufacturer, health plan, and wholesaler needs.

Conclusion

There are more questions than answers to Part B MFP effectuation. In the limited time remaining before the first Part B drugs are subject to an MFP, CMS must consider the differences between Part B and Part D reimbursement and physician reimbursement challenges. We believe that the financial or operational burden of the Part B drug effectuation process should not be placed on the providers or their patients. In addition, we believe that the agency must view any changes in Part B drug payment, including Part B drug MFP effectuation, in the context of the overall total adequacy of payments made to Part B providers for the Part B drug, the professional fees, and administration fees in a manner to ensure patient access to care can be maintained. To ensure patient access to Part B drugs, CMS should monitor implementation of the Part B drug MFP effectuation process by Medicare Advantage plans (and their contractors), including such aspects as patient cost-sharing, coverage policies and restrictions, and payment policies for these selected Part B drugs.

Through continued stakeholder input and discussion, CMS has the opportunity to implement an effectuation process which prioritizes patient access to affordable and appropriate treatment options. The AVBCC Part B MFP Drug Effectuation Workgroup is committed to providing the most valuable advice to policymakers on Medicare Part B MFP drug effectuation issues and will continue to define aligned recommendations and solutions, updating CMS and this White Paper in the process.