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Via Electronic Submission

PUBLIC DOCUMENT
CMS-4210-N

Mr. Chris Klomp
Deputy Administrator, and Director, Center for Medicare
Centers for Medicare & Medicaid Services
5900 Security Boulevard
Baltimore, MD 21244-1859

Re: Draft Guidance on the Medicare Drug Price Negotiation Program

Dear Mr. Klomp:

OVERVIEW

The Part B Access for Seniors and Physicians Coalition ("ASP Coalition"), representing more than 300 patient and provider organizations across the country, offers the following comments in response to Centers for Medicare and Medicaid Services (CMS) Draft Guidance entitled, "Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair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," dated May 12, 2025. The ASP Coalition appreciates the opportunity to provide our perspective and recommendations, which focus on Maximum Fair Price (MFP) effectuation for Part B selected drugs beginning in Initial Price Applicability Year (IPAY) 2028, and the agency's related solicitation for feedback on whether a standard default refund amount (SDRA) should be utilized and how it should be calculated.

Specifically, the Coalition strongly urges CMS to exclude the MFP from calculation of Average Sales Price (ASP) in the Medicare Part B program. In addition, we recommend that, if CMS establishes an SDRA to effectuate the MFP for Medicare Part B selected drugs, the agency should fully account for the acquisition costs of the many providers who purchase drugs at prices above the MFP.

Our recommendations are intended to avoid a worst-case scenario of provider reimbursement cuts that would inevitably harm access to essential health services for beneficiaries with chronic and disabling conditions. Since Medicare Part B drugs will be included for the first time in the Medicare Drug Price Negotiation Program for IPAY 2028, it is essential that the agency's implementation approach address Part B provider concerns at the outset. This is necessary to avoid a downward spiral of reimbursement cuts that could decimate beneficiary access to Part B covered drugs, which has been under extreme pressure for many years.

PART B ACCESS
for Seniors and Physicians Coalition

Background – Impact of the Inflation Reduction Act on Medicare Part B Providers and Beneficiaries

Medicare Part B covers drug therapies for over 62 million beneficiaries, including those with cancer and other serious and complex chronic conditions such as rheumatologic, autoimmune and inflammatory conditions; and those with blinding eye diseases, Crohn's disease and ulcerative colitis, rare chronic diseases, and serious mental illnesses. Given the often life-threatening complexity of their health conditions, these beneficiaries require accessible medical care; yet, their providers face increasingly challenging reimbursement realities.

We remain deeply concerned that implementation of provisions included in the Inflation Reduction Act (IRA) will further worsen reimbursement cuts to Medicare Part B provider payments, resulting in even more provider practices closing, and consolidating into the more expensive hospital setting. The Coalition has been sounding the alarm since its inception that Medicare Part B reductions threaten the ability of physicians to continue to provide high-quality medical care to seniors and other Medicare beneficiaries. Most recently, a Milliman analysis released by the Coalition in May 2025 concluded that "under the IRA as written, provider reimbursement for Part B drugs will change from being tied to Average Sales Price (ASP) to being tied to what the act refers to as 'Maximum Fair Prices' (MFPs) for selected drugs. This change is estimated to decrease provider reimbursement (or increase provider costs) by $56.3B over 10 years.[1]"

Summary of Recommendations & Rationale

Implementation decisions by CMS will have a direct and material impact on the scope and severity of reimbursement changes affecting providers who serve Medicare beneficiaries in the Medicare Part B program. To that end, the Coalition has developed the following recommendations to help mitigate the most harmful cuts to providers.

Recommendation #1: Exclude the Maximum Fair Price (MFP) from Calculation of the Average Sales Price (ASP)

The ASP Coalition urges CMS to exclude the MFP from calculation of the ASP. This policy would help address multiple challenges associated with the IRA's Medicare drug price negotiation program, in which provider reimbursement will be based on the MFP rather than the ASP plus an add-on fee to cover acquiring, storing and administering the medicine. First, since Medicare will base provider reimbursement for Part B selected drugs using the MFP rather than ASP, Medicare reimbursement for provider-administered medicines subject to negotiation will be drastically reduced. In addition, the IRA has the potential to reduce reimbursement by commercial insurers, which has traditionally been based on the ASP across a wide range of

[1] (Michelle (Klein) Robb, 2025)

plans and payers. Failure to exclude the MFP from ASP would lower commercial reimbursement for physician-administered drugs. This is particularly true since MFP will likely be lower than ASP. A recent analysis by Avalere Health concluded that "physicians could lose at least $25 billion in add-on payments for 10 Part B drugs expected to be negotiated by CMS, with oncology products accounting for at least $12 billion.[2]" Removing ASP from the MFP will help reduce the scope of payment cuts that will inevitably affect health care providers as a result of the IRA. Mitigating these cuts is particularly important for providers that are small, independent, or who serve rural or other communities with low resources and high rates of chronic disease – these providers are essential to keeping Americans healthy and reducing the costs associated with unchecked chronic illnesses, while being least able to absorb further cuts.

Recommendation #2: If CMS Elects to Establish an SDRA to Effectuate the MFP for Medicare Part B Selected Drugs, the SDRA Should be Carefully Constructed to Fully Account for the Acquisition Costs of Providers Purchasing Drugs Above the MFP.

In Sec. 40.4 of the draft guidance, entitled "Providing Access to the MFP in 2026, 2027, and 2028," CMS requested input regarding "how the effectuation of MFP refund payments for drugs payable under Part B might differ from what is outlined for drugs covered under Part D;" and recommendations on whether to include "a standard default refund amount among the claim-level data elements and how such refund amount could be calculated," among other related issues. We note that CMS stated it "intends to provide detailed policy on providing access to the MFP for selected drugs payable under Part B in the future." CMS clarified that it is not "including detailed policy on providing access to the MFP for selected drugs payable under Part B;" however, the agency also indicated that, "to the extent appropriate and feasible, CMS intends to align the policies and operations for providing access to the MFP for selected drugs payable under Part B with those for selected drugs covered under Part D."

CMS guidance for the Medicare Part D program permits manufacturers to provide a retrospective refund to providers who purchase drugs at a price above the MFP, and the draft guidance specifies that the agency "believes using WAC to calculate an SDRA generally best approximates the acquisition costs of dispensing entities and offers a reliable refund amount for both manufacturers and dispensing entities that agree to use such a standardized pricing metric." Further, CMS suggested that using WAC "addresses concerns raised by interested parties that use of acquisition cost would create significant administrative burdens," adding that "WAC is a widely available pricing metric, published and regularly updated in common pharmaceutical pricing database compendia that would be accessible and transparent to interested parties in the MFP effectuation process," among other cited benefits.

The Coalition is concerned that, for Medicare Part B covered drugs, no pricing metric exists that approximates acquisition costs for the majority of providers. Moreover, superimposing

[2] (Milena Sullivan, 2024)

the Medicare Part D model for calculating an SDRA would significantly harm Part B providers. Most importantly, substituting the ASP for WAC in calculating an SDRA for selected Medicare Part B drugs would fail to account for the costs of all of the providers who purchase drugs at a price above the ASP. These providers would face a double challenge: reimbursement cuts associated with the shift from ASP-based reimbursement to MFP-based reimbursement, compounded by manufacturer refunds that fail to account for their true acquisition costs. Accordingly, the Coalition urges CMS to develop an SDRA approach carefully, and ensure that refunds required to be paid under the IRA fully compensate providers who purchase drugs at higher costs.

Conclusion

The ASP Coalition thanks CMS for your commitment to engage with stakeholders, improve transparency in the Medicare Drug Price Negotiation Program, and place beneficiaries at the heart of decision-making while fostering innovation. We urge CMS to implement our recommendations as you move forward with detailed guidance on inclusion of Medicare Part B drugs in IPAY 2028. We also request that CMS provide draft guidance and a further opportunity for stakeholders and interested parties to provide comments before finalizing any guidance related to inclusion of Medicare Part B covered drugs in the drug price negotiation program. We appreciate your consideration and look forward to engaging with the agency.