June 25, 2025

Deputy Administrator Chris Klomp
Center for Medicare
Centers for Medicare & Medicaid Services (CMS)

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair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

Dear Deputy Administrator Klomp:

Thank you for the opportunity to comment on CMS's draft guidance on the Medicare Drug Price Negotiation Program. This comment focuses on Section 30.2 and the identification of Part B high spend drugs. Specifically, this group of experts in policy, operational, and legal issues affecting the Medicare Drug Price Negotiation Program believes the identification of Part B high spend drugs under section 1192(d)(1)(B) of the Social Security Act can and should account for spending on Part B drugs administered to Medicare Advantage enrollees. Inclusion of such spending is necessary for the law to function as intended, is the best reading of the statute, and is operationally feasible.

Failure to Include Medicare Advantage Usage Distorts the Proper Functioning of the Law

Section 1192 of the Social Security Act, as amended by Section 11001 of the Inflation Reduction Act (IRA), governs the process by which CMS selects drugs for which prices may be negotiated under the Medicare Drug Price Negotiation Program. For initial price applicability year (IPAY) 2028 and later years, the statute directs Medicare to (1) identify qualifying single source drugs; (2) determine the 50 qualifying single source drugs with the highest "total expenditures under Part D" and the 50 with the highest "total expenditures under Part B"; (3) rank the combined list of drugs from highest to lowest total Medicare spending; and (4) select the up to 15 (or 20 in IPAY 2029 and beyond) highest spending drugs as drugs for which prices may be negotiated (with various exclusions and removals at each step of the process).

The IPAY 2028 negotiation is the first time that drugs paid for under Part B may be selected for negotiation, and, accordingly, the most recent draft guidance is the first time CMS has addressed policy and procedures applicable to Part B drugs. Specifically, CMS must describe for the first time how it will calculate "total expenditures under Part B" for these drugs. In Section 30.2, the agency proposes to use "Part B claims data" for the 12 months ending October 31, 2025 for purposes of this calculation.

However, "Part B claims data" are not a complete metric of "total expenditures under Part B," because Part B claims include expenditures *only* for claims paid for fee-for-service Medicare beneficiaries. This metric excludes expenditures associated with beneficiaries who receive their Medicare Part B benefits through enrollment in a Medicare Advantage (MA) plan. (CMS receives detailed information about the Medicare Part B drugs that MA enrollees receive from MA plans in the form of encounter data, but they do not receive claims with payment information in the way they do for fee-for-service beneficiaries.) Importantly, when a Part B

drug is selected for negotiation and the manufacturer agrees to a maximum fair price, that negotiated price unambiguously applies to utilization of the drug by MA beneficiaries.[1]

This exclusion of MA expenditures from the computation of total expenditures for Part B drugs would significantly distort the operation of the statute. The most recent estimates indicate that about 54% of all Medicare beneficiaries are enrolled in an MA plan.[2] Because overall use of prescription drugs by MA enrollees and those in fee-for-service Medicare are similar, it is likely that more than half of beneficiaries receive their Part B drugs through an MA plan – and this share is projected to grow over time. Accordingly, by looking only to fee-for-service claims data, CMS would exclude roughly half of total spending on Medicare Part B drugs thereby underestimating the true total spending on Part B drugs by roughly half. Importantly, this underestimate would not apply equally to all drugs and would be larger for some products and lower for others, given differential patterns of use.[3] Thus, when spending on Part B drugs is compared to spending on Part D drugs for purposes of selecting the overall top 15 (or 20) drugs by total Medicare expenditures, Medicare would be far less likely to select Part B drugs for negotiation.

A variety of negative consequences would follow. Most prominently, it would reduce the overall impact of the Medicare Drug Price Negotiation Program. Medicare would select Part D drugs with total expenditures that are *lower* than "true" Medicare spending on Part B drugs. Thus, negotiated price discounts would be applied to lower levels of prescription drug spending, thereby reducing the potential savings to beneficiaries and taxpayers from the negotiation program. This distortion would also create incentives for manufacturers and investors to prefer upstream investments in drug development projects that are more likely to lead to a Part B drug rather than a Part D drug coming to market. Similarly, to the extent an active moiety can be administered as either a Part B or a Part D drug, manufacturers would have incentives to shift usage into the Part B drug (like a physician-administered infusion or injectable), even though providers may recommend and patients may prefer a Part D self-administered formulation. Indeed, physician-administered formulations are likely to be more burdensome for patients and generally have more significant access barriers, potentially leading to lower medication adherence. Part B formulations may also be more expensive for the program. That is, the exclusion of Part B drugs administered to MA enrollees from the computation of total expenditures will have ramifications far beyond the Medicare Drug Price Negotiation Program. Furthermore, this distortion would create new incentives for manufacturers of Part B drugs to promote enrollment of their patient population into MA plans to reduce the likelihood of being selected for negotiation, for example, through targeted outreach or through pricing behavior.

All of these effects would be inconsistent with the goals of the law and would create unproductive and costly distortions in health care markets. These impacts are unnecessary because CMS has the legal authority and operational capacity to use a complete measure of total expenditures under Medicare Part B inclusive of spending for MA enrollees, as described below.

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[1] See Social Security Act Sec. 1191(c)(2)(b), discussed further below; see also Social Security Act Sec. 1852(a)(1)(B).

[2] Meredith Freed et al., "Medicare Advantage in 2024: Enrollment Update and Key Trends," KFF (Aug. 8, 2024) https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2024-enrollment-update-and-key-trends/.

[3] See Kelly E. Anderson et al., Prescribing of Low- Versus High-Cost Part B Drugs in Medicare Advantage and Traditional Medicare, 57 Health Servs. Res. 537 (2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC9108062.

Section 1192(d)(1)(B) Is Best Read To Include Medicare Advantage Expenditures

Section 1192 instructs CMS as to how to measure total spending on prescription drugs and use that information to select drugs for negotiation. Beginning for 2028, the operative language directs CMS to identify "the 50 qualifying single source drugs with the highest total expenditures under part B of title XVIII, as determined by the Secretary ...,"[4] identify a parallel 50 drugs under Part D,[5] rank the resulting group of up to 100 drugs "according to the total expenditures for such drugs under parts B and D of title XVIII, as determined by the Secretary,"[6] and select the top 15 (or 20 for 2029 and subsequent years) drugs.[7]

The key question is how CMS should understand the term "total expenditures under Part B" -- and whether that term includes expenditures on Part B drugs administered to MA enrollees. As a starting place, the IRA defines "total expenditures" as follows:

> (5) Total expenditures.--The term 'total expenditures' includes, in the case of expenditures with respect to part D of title XVIII, the total gross covered prescription drug costs (as defined in section 1860D-15(b)(3)). The term 'total expenditures' excludes, in the case of expenditures with respect to part B of such title, expenditures for a drug or biological product that are bundled or packaged into the payment for another service.[8]

Notably, this definition is clear on what is *not* included as a relevant Part B expenditure (expenditures where payment for the drug is bundled with payment for another Part B service) but does not provide specific examples of what *is* included. The use of the word "total" would imply comprehensive inclusion of expenditures on Part B drugs, and absent indications to the contrary, that is the natural starting point for the agency's approach.

Some may argue that because the rules for MA plans are codified in Part C of the Medicare statute, not within Part B, expenditures within MA cannot be considered expenditures "under Part B."[9] However, such an interpretation would be based on a misunderstanding of the structure of Part C and the relationship between the provisions of Part B and Part C.

When it enacted the IRA, Congress made clear in the statute's text that Part B benefits received through MA plans are benefits received "under" Part B. In describing the individuals to whom a negotiated price applies, the statute reaches any "individual who is enrolled *under* part B of title XVIII, *including* an individual who is enrolled in an MA plan under part C of such title, if payment may be made under part B for such selected drug."[10] The IRA itself thus defines Part B drug benefits received through MA as Part B benefits covered by the statute. That text alone

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[4] Social Security Act Sec. 1192(d)(1)(B).
[5] Social Security Act Sec. 1192(d)(1)(A).
[6] Social Security Act Sec. 1192(b)(1)(A).
[7] Social Security Act Sec. 1192(a).
[8] Social Security Act Sec. 1191(c)(5).
[9] Drug manufacturers have advanced similar arguments under a different provision of the Inflation Reduction Act, related to inflation rebates. See, e.g., Christen Linke Young, "The Inflation Rebate for Medicare Part B-Covered Drugs Should Apply to Medicare Advantage," Brookings Institution (May 14, 2025), https://www.brookings.edu/articles/the-inflation-rebate-for-medicare-part-b-covered-drugs-should-apply-to-medicare-advantage/.
[10] Social Security Act Sec. 1191(c)(2)(B), emphasis added.

makes clear that expenditures for Part B benefits made through MA plans are among the "total expenditures under Part B" that must be included in determining the highest spend drugs.

Indeed, there is no logical basis for attributing to Congress the odd policy of applying the results of the negotiation to payment for MA drugs, but not including MA spend in the selection of those drugs. The agency is directed to select qualifying drugs based on total spending in order to maximize the reach of the program, whereas this exclusion systematically distorts that goal as noted above. For Congress to have created these market-distorting effects without comment is particularly implausible.

Nor would such an outcome be consistent with language used throughout the Medicare statute. In drafting these IRA provisions, Congress followed the basic approach of the Medicare statute, which consistently describes benefits provided through MA plans as benefits "under" Part A or B. For example, the foundational statutory text that defines the "basic benefits" for MA explains that plans "shall provide to members enrolled under this part [Part C]... benefits *under* the original [M]edicare fee-for-service program option."[11] That is, the statute fundamentally defines the services provided to MA enrollees as benefits "under" Part A and Part B.

Further, throughout sections 1191 and 1192, Congress created a variety of exclusions and limitations – e.g. excluding certain "small biotech" companies, certain orphan drugs, and biologics with an expectation of imminent biosimilar entry from being selected for negotiation. The language defining "total expenditures" similarly features a clear exclusion for drugs where payment is packaged with another service, as described above.[12] If Congress wanted to exclude expenditures for MA enrollees, they could have done so, and the fact that they did not specify an exclusion for expenditures amounting to more than half of the total expenditures by the Medicare program for Part B drugs indicates those expenditures should be included.

Finally, it is useful to underscore how Medicare funds flow to MA. MA plans are paid capitated payment amounts, and the share of the capitated payment that is attributable to benefits "under part B" (including payment for Part B drugs) is drawn from the Federal Supplementary Medical Insurance Trust Fund, i.e., the source of funding for fee-for-service Part B payments.[13] Therefore, payment to MA plans for Part B drugs is mechanically an expenditure "under" the same account as fee-for-service Part B claims.

Thus, there is no basis in the statute for excluding expenditures on Part B drugs for MA enrollees, and such spending should be included in the calculation of "total expenditures under part B."

Inclusion of Medicare Advantage Usage Is Operationally Feasible

CMS has proposed to look to "Part B claims data" -- which will reveal the dollar value of Medicare paid claims for Part B drugs received by fee-for-service Medicare beneficiaries over

[11] Social Security Act Sec. 1852(a)(1), emphasis added.
[12] Section 1191(d)(5) excludes from the definition of "total expenditures" those expenditures under part B for a drug or biological product that are bundles or packaged into the payment for another service. Although Medicare makes capitated payments to MA plans, these capitated payments are not packaged payments "for another service," and so MA expenditures do not categorically fall within the exclusion described in Section 1191(d)(5).
[13] Social Security Act Sec. 1853(f).

the specified time period. CMS does not possess claims data for MA enrollees and therefore does not have precisely the same source of information. However, the agency has workable options to exercise the authority that Congress has delegated to it to "determin[e]" total expenditures[14] to define a methodology to compute expenditures attributable to MA enrollees.

Specifically, CMS receives detailed encounter data from MA plans, which provide information on the specific services received by MA enrollees. The encounter data do not include the dollar value of the payment from an MA plan to the health care provider that administered the service, but they do include robust information about the services received. For Part B drugs, this will include the amount of the drug administered and other information about the specific dosage and form and strength. CMS can rely on the encounter data to provide a complete and accurate picture of the units of a drug that have been administered at the NDC-11 level (and can generally determine when payment for the drug has been bundled with other services). The agency can use a straightforward approach to assign a dollar value to these encounters by applying the fee-for-service methodology for payment described at Section 1847A of the Social Security Act, i.e., payment at 106% of Average Sales Price (ASP).

This calculation represents a reasonably accurate measure of the likely payment from MA plans to providers for Part B drugs. Moreover, it is an *exact* measure of how funds flow from the Part B Federal Supplementary Medical Insurance Trust Fund to MA plans: the share of the capitated payment attributable to this trust fund is based on the actuarial value of Part B services, which is in turn reflective of the ASP-based methodology.[15] Therefore, it can appropriately be considered a measure of "expenditures under Part B" for MA plans, and this calculation can appropriately be added to fee-for-service claims data to compute total expenditures.

Of course, claims data and encounter data are provided to CMS on different timelines, with encounter data lagging behind claims data by a significant margin. Therefore, the agency may require more time to lapse between the period of measurement and the computation of total expenditures to have accurate information for Part B drugs provided to MA enrollees. Fortunately, the statute unambiguously provides flexibility to CMS to make such a timing adjustment. Specifically, throughout section 1192 of the IRA, Congress directs CMS to look to the "most recent period of 12 months... for which data are available." The statute notes parenthetically that this 12-month period must "end[] not *later* than October 31 of the year prior"[16] – but does not specify how early the 12-month period could end. Therefore, CMS can determine how much additional time is necessary for reliable encounter data to be available and begin and end the 12-month period accordingly. Alternatively, CMS can require submission of encounter data for Part B drugs on a more rapid timeline – a change which may also be important to best effectuate negotiated prices for providers – and select the 12-month period accordingly.

Conclusion

For Part B drugs, "total expenditures under Part B" should reflect Medicare spending on drugs provided to both fee-for-service Medicare beneficiaries and MA enrollees. This is important to avoid distortionary incentives and promote proper functioning of the IRA. Moreover, it is the best reading of the statute: when a health care provider is paid for administering a drug covered

[14] Social Security Act Sec. 1192(b)(1)(A), (d)(1)(B).
[15] 42 C.F.R. 422.322(a)(1).
[16] E.g. Social Security Act Sec. 1192(b)(1)(A).

under Part B to an MA enrollee, that is properly understood as an expenditure under Part B and there is no indication Congress intended to exclude such spending. CMS can compute these expenditures by using MA encounter data to determine utilization at the NDC-11 level, and assigning payment based on the fee-for-service ASP methodology. We encourage the agency to make this adjustment and are of course happy to discuss these issues at any time.

Sincerely,[17]

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