NATIONAL INFUSION CENTER ASSOCIATION

The Nation's Advocacy Voice for In-Office Infusion

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August 13, 2026

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Drug Price Negotiation Program Proposed Rule – Initial Price Applicability Year 2029 (CMS-4215-P)

Dear Administrator Oz:

The National Infusion Center Association (NICA) is a nonprofit organization formed to support non-hospital, community-based infusion centers caring for patients in need of provider-administered medications. To improve access to medical benefit drugs that treat complex, rare, and chronic diseases, we work to ensure that patients can access these drugs in safe, more efficient, and cost-effective alternatives to hospital care settings. NICA supports policies that improve drug affordability for beneficiaries, increase price transparency, reduce disparities in safety across care settings, and foster patient access to the highest-quality, lowest-cost setting.

NICA's members administer medications to patients – including Medicare beneficiaries – with serious conditions such as autoimmune disease, which is lifelong and can result in permanent disability if not managed appropriately upon diagnosis. Fortunately, the treatment of autoimmune disease, including such conditions as rheumatoid arthritis, psoriasis, and lupus, has come a long way in that there are now specialty biologics that enable patients to manage their condition, in many cases with such success that these patients are able to fully engage in activities of daily living and/or remain employed in the same way they were prior to diagnosis.

We appreciate the opportunity to provide comments on the Medicare Drug Price Negotiation Program Proposed Rule – Initial Price Applicability Year 2029 (CMS-4215-P). As providers of Part B medications, NICA is concerned that CMS's broad interpretation of treating *fixed-dose combinations* (FDCs) as the *qualifying single source drugs* (QSSD), would expand the reach of the Medicare Drug Price Negotiation Program beyond the scope and limits established by Congress. We write to raise concerns about how this expansion would compound existing reimbursement and access concerns for community-based infusion providers and the Medicare beneficiaries they serve.

QSSD Definition's Impact on the Scope of the Negotiation Program

Under the proposed rule, CMS would treat every dosage form and strength that shares an active moiety or active ingredient as a single potential QSSD, regardless of whether the products were approved under separate applications, treat different conditions or populations, or reflect materially new clinical applications. In practice, this means that a later-developed formulation — including one that changes only the route by which a drug is administered — would be included in the negotiation status of an earlier, unrelated product. This approach would bring additional products within the negotiation program based on agency interpretation rather than further direction from Congress.

NICA is concerned with the broader policy precedent this approach would establish. . By aggregating distinct applications into one QSSD, the Agency will apply the negotiation eligibility standards to far more products than the maximum targets specified by Congress under the law. Infusion providers occupy a unique position as many of the products most likely to be considered for future negotiation are intravenous biologics that providers administer and bill under Medicare Part B. Congress specified the framework and limits for selecting drugs for negotiation. CMS should not use an expansive QSSD interpretation to extend negotiated pricing to additional products beyond those limits. For infusion providers, expanding the number of Part B drugs subject to the Maximum Fair Price (MFP) would also expand the number of therapies exposed to the program's unresolved reimbursement risks.

Impact of the MFP on Provider Reimbursement and Patient Access

In allowing CMS to bundle several formulations under the same QSSD, infusion practices will face an even greater challenge in navigating the Maximum Fair Price than what is statutorily prescribed in the *Inflation Reduction Act*. Non-hospital, community-based infusion practices source their medications through "buy-and-bill" in which the medical practice purchases medications in advance and later bills the health plan for the medication once administered to the patient. These practices must also cover clinical staffing, monitoring, supplies, and other administration costs while operating on narrow margins. Currently, the cost of these medications is based on the Average Sales Price (ASP), plus a six percent add-on payment which allows our members to account for acquisition costs, albeit under incredibly slim margins. However, according to the CY2026 Medicare Physician Fee Schedule, provider reimbursement for negotiated drugs will be calculated based on the Maximum Fair Price (MFP) plus a six percent add-on.

NICA has repeatedly expressed concerns about this new calculation, which according to a recent Avalere study,[1] could decrease the Part B add-on payment by 42-61% in Medicare and could cut reimbursement by 12-18% in the commercial market. Applying the MFP to additional drugs beyond the maximum number outlined in the law will exacerbate the impact of this underwater reimbursement for infusion centers, making it untenable for our members to provide these critical services to their patients.

Fixed-Dose Combination

The proposed rule also solicits comments on applying similar rationale to fixed-dose combination (FDC) products, under which CMS would treat an FDC as equivalent to a single-ingredient QSSD whenever the agency determines that one of the combination's active components is not biologically active against the condition being treated. We have serious concerns with this interpretation. Specifically, CMS should not adopt interpretations that allow the Agency to bring additional products within the negotiation program beyond the framework and limits Congress established at its discretion.

[1] Avalere Health. "Commercial Spillover Impact of Part B Negotiations on Physicians." September 2024.

Office-based and ambulatory infusion centers play a key role as the most efficient setting for drug administration, compared to hospital outpatient departments and, in many cases, even compared to the home. Thus, it is clearly beneficial to advance policies that support our nation's in-office drug administration capacity to further Congress and the Administration's goals to reduce the overall cost of prescription medications for both the federal government and for patients. Unfortunately, the effects of these broad interpretations within IPAY 2029 fall most heavily on infusion providers and the Medicare beneficiaries who depend on physician-administered therapies. We urge CMS to take corrective action on these provisions as we believe they were not the intended consequence of the *Inflation Reduction Act's* negotiation framework.

Thank you for the opportunity to comment on this important issue. We would welcome the opportunity to connect with you if we can provide any other information about our concerns. Please do not hesitate to contact me, should you have any questions or wish to further discuss this issue: Brian.nyquist@infusioncenter.org

Sincerely,

Brian Nyquist, MPH
Chief Executive Officer
National Infusion Center Association