NATIONAL INFUSION CENTER ASSOCIATION

The Nation's Advocacy Voice for In-Office

3307 Northland Dr, Ste 160 ▪ Austin, TX 78731
www.infusioncenter.org ▪ info@infusioncenter.org

February 20, 2026

Administrator Oz, MD
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5545-P
P.O. Box 8013,
Baltimore, MD 21244-8013
Submitted electronically

Re: CMS-5545-P – Global Benchmark for Efficient Drug Pricing Model ("GLOBE Model")

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 reduce healthcare spending and 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.

We appreciate the opportunity to provide comments on the Global Benchmark for Efficient Drug Pricing Model ("GLOBE Model"), which implements a new test payment model for Medicare Part B drugs. While notable improvements have been made from past iterations of this policy, NICA remains concerned about the Model and encourages CMS to withdraw the Model from consideration.

Removing Providers from the Middle
We would like to thank CMS for making considerable improvements from past Most-Favored Nations drug pricing models for Part B drugs by removing health care providers from the center of these drug pricing negotiations with manufacturers. In past iterations, CMS policy influenced the Average Sales Price (ASP), which is in turn used to determine provider reimbursement for drug administration services. While we have concerns about the Model as a whole, NICA greatly appreciates CMS's adjustments in this test model to avoid reimbursement cuts for infusion providers. This will allow providers to remain whole and continue providing the drug services patients need.

Exacerbating White Bagging
Within the proposal, CMS acknowledges that the model may incentivize the increased use of "white bagging," where drugs are reimbursed under Part D instead of through the Part B medical benefit. While

a minor comment within the overall proposed rule, this could have significant consequences for infusion centers and their patients.

Through white bagging, the patient's health plan and pharmacy benefit manager (PBM) require the patient to obtain their medications from a specialty pharmacy instead of directly from their infusion provider. The specialty pharmacy then ships the drug directly to a healthcare provider's office, hospital, or clinic for administration. This process differs from the traditional "buy-and-bill" model, where providers purchase and manage their own drug inventory.

White bagging can disrupt patient care, increase healthcare costs, and undermine the financial viability of community-based infusion centers. NICA is very concerned with the impact on patient care quality and safety. Shipping and processing issues often cause delays, preventing timely administration of medications. For patients with serious or time-sensitive conditions, these delays can result in severe health consequences. Additionally, many medications require precise dosing based on a patient's weight. Policies that embolden health plans, PBMs, and their specialty pharmacies to mandate white bagging put health care providers in a compromised situation. These providers lack the flexibility to adjust doses at the time of administration, forcing them to either delay treatment or administer suboptimal doses, both of which can compromise patient outcomes.

While white bagging may move the patient's prescription from the medical benefit to the pharmacy benefit, white bagging has been proven to increase healthcare costs and waste. When providers are required to source medications from a specialty pharmacy, they lose the ability to make immediate changes, such as adjusting dosage or switching medications. When medications are dispensed but cannot be used due to treatment changes or incorrect dosing, it leads to unnecessary waste and high costs for both patients and insurers. In fact, in a recent NICA and Avalere study, infusion centers reported administrative costs associated with white bagging waste to range from $35,000 to $652,000 per center per year.[1] These medications are often paid for by the patient and their insurer, but the patient does not receive the medication. The medications cannot be returned or used for another patient; they must be disposed of and repurchased. According to the study, 46% of infusion centers indicated that they have experienced instances where patients paid a copay for a regimen/dosage that was not administered due to complications from white bagging.[2]

Furthermore, the financial viability of providers is at risk under white bagging mandates. Administering specialty medications involves complex preparation, administration, and post-treatment care, which can require 2-3 hours of additional labor per patient. However, white bagging does not provide adequate reimbursement for these added costs—and in fact, puts providers underwater on the drug service—making it difficult for non-hospital infusion centers to sustainably offer white-bagged drugs. As a result, providers may be forced to send patients to more expensive hospital settings, further increasing healthcare costs.

Finally, white bagging reduces flexibility in patient care. Under the buy-and-bill model, providers can offer payment plans, spreading the costs for patients and making expensive treatments more accessible. White bagging often requires patients to pay for medications upfront, which could prevent some from receiving treatment. Moreover, the loss of flexibility in adjusting treatments and dosages in real time limits

[1] Avalere. "Payer White-Bagging Requirements: Considerations for Access to Infusion Care." June 2024.

[2] Ibid.

providers' ability to deliver personalized care, which could lead to reduced access to services and even the closure of community-based infusion centers.

NICA strongly discourages CMS from pursuing models that incentivize white bagging over the traditional buy-and-bill model. NICA urges CMS to monitor whether GLOBE drives an increase in white bagging policies outside of the Model to compensate for lost revenue within the Model. White bagging mandates create significant barriers to patient care, increase overall healthcare costs, and threaten the financial health of non-hospital providers. Protecting the buy-and-bill model ensures that patients continue to receive timely, personalized, and affordable care in the most cost-effective setting: community-based infusion centers.

Reference Countries

CMS will benchmark GLOBE pricing based on the lowest price from a set of non-U.S. reference countries. OECD member countries with a real GDP per capita that is at least 60 percent of the U.S. real GDP per capita and an annual real GDP of at least $400 billion. According to CMS, this includes: Australia, Austria, Belgium, Canada, Czechia, Denmark, France, Germany, Ireland, Israel, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden, Switzerland and the United Kingdom.

NICA discourages CMS from adopting drug prices for Part B medications from these nations, which operate government-run health systems, as they do not acquire prescription drugs in a comparable supply chain to the United States. More specifically, none of these countries rely on pharmacy benefit managers (PBMs) as third-party intermediaries to determine drug access and formulary design. NICA has been very vocal in its concerns about flagrant PBM abuses that drive up the cost of prescription drugs in the United States. Without considerable regulation, these middlemen will continue to drive up the price of medication in the United States even after the list price is set at a Most Favored Nations price.

PBMs play a significant role in determining drug access as well as drug pricing. PBMs dictate in-network providers, set drug formularies, determine copays, and even control prior authorization rules—giving them ultimate control over which medications patients can access and where they can get them. This happens in the private commercial insurance market, Medicare Advantage, and Managed Medicaid. Meanwhile, PBMs are making a fortune in the process.

PBMs profit at nearly every stage of the supply chain, reaping significant profits from drug manufacturers, pharmacists, and even patients, and they will continue to make superfluous profits – driving up the cost of prescription drugs – even if the Model is implemented. PBMs dictate preferred placement on a health plan's formulary, or the list of covered drugs, based on the manufacturer rebates offered—not based on the most affordable medications. In fact, drug pricing and premium trends over the last decade demonstrate that whatever savings PBMs negotiate are mostly absorbed by the PBMs themselves—not the patient. In fact, for every rebated dollar, the list price of the medication increases by $1.17.[3] That hurts the patient, who typically pays coinsurance on the list price before rebates are applied.

To make matters worse, PBMs are deeply embedded throughout the healthcare system thanks to widespread vertical integration. The three largest PBMs – CVS Caremark, Express Scripts, and OptumRx – are owned by major insurance companies and healthcare conglomerates, giving them enormous control over drug pricing, insurance coverage, and even dictating which pharmacies patients can use and which

[3] USC Leonard D. Schaeffer Institute for Public Policy & Government Service. "The Association Between Drug Rebates and List Prices." February 2020.

providers they can see. According to the Federal Trade Commission, these three giants alone process around 80% of all prescription drug claims in the U.S.[4] That kind of market power means they can dictate prices and limit patient choice while boosting their own bottom line.

Unlike the OECD countries identified in the proposed rule, the United States is the only country that relies on these middlemen in its drug supply chain. For these reasons, NICA strongly urges CMS to reconsider benchmarking U.S. drug pricing on countries that do not have PBM intermediaries and where governments or public insurers directly negotiate drug prices and manage formularies.

Impact to Beneficiaries

NICA would like to thank CMS for recognizing that health plan designs for Medicare Part B beneficiaries have caused patients to face substantial cost-sharing liability associated with each administration, including monthly Part B premiums, the annual Part B deductible, Part B coinsurance, and premiums and cost sharing under supplemental coverage. These costs can be extremely challenging for infusion center patients, who typically require recurring, regular treatments with complex specialty drugs.

NICA is concerned that CMS' beneficiary protections and quality measures are not robust enough for evaluating the impact on access to GLOBE Model Drugs. To that end, we urge CMS to reconsider unless safeguards can be incorporated that reflect the financial realities of office-based buy-and-bill practices by closely monitoring whether ASP-based payment amounts fall below provider acquisition costs and whether alternative drug distribution arrangements, such as white- and brown-bagging, are increasing, and by assessing the resultant impacts on patient access and site of care.

Omission of Biologics

Finally, NICA would like to thank CMS for removing biosimilar and reference biologic products from the test model. Providers currently struggle with challenges surrounding adequate reimbursement for biosimilar products due to the over-rebating of these products. The Medicare Part B drug payment methodology, which relies on average sales prices (ASPs) reported by manufacturers, is no longer adequate to support access to provider-administered biosimilars in the office-based infusion center setting. This is because the ASP is calculated using manufacturers' net sales across all purchasers, and factors in rebates, discounts, and other price concessions. These manufacturer rebates—perversely incented to secure "fail first" or preferred status on a health plan's formulary—artificially depress the ASP without lowering providers' actual acquisition cost, which results in "underwater" reimbursement. When this occurs, providers are forced into untenable positions: either administer the medication at a loss, which is increasingly unsustainable given persistently low reimbursement under the Medicare Physician Fee Schedule, or refer patients to HOPDs, where care is more costly for both Medicare and beneficiaries, and poses greater safety risks for immune-compromised patients. These access barriers increase the risk of disease progression or hospitalization—costly outcomes that could often be avoided with timely, office-based treatment.[5] Given the unstable market conditions surrounding biosimilar products among infusion center providers, we appreciate that these are excluded from the GLOBE model.

Thank you for the opportunity to comment on this important issue. NICA remains concerned about the Model and encourages CMS to withdraw the Model from consideration. We would welcome the

[4] Federal Trade Commission. "FTC Releases Interim Staff Report on Prescription Drug Middlemen." July 2024.

[5] Aliment Pharmacol Ther. "Real-world assessment of therapy changes, suboptimal treatment and associated costs in patients with ulcerative colitis or Crohn's disease." April 2014.

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