

March 26, 2026

John Brooks
Deputy Administrator & Chief Policy and Regulatory Officer
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5545-P & CMS-5546-P
P.O. Box 8013,
Baltimore, MD 21244-8013
Submitted electronically

Re: CMS-10110 – Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals

Dear Mr. Brooks:

On behalf of the undersigned organizations, who are committed to improving and expanding access to provider-administered medications, we write to express concerns with *Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals and Supporting Regulations in 42 CFR 414.800–806 Information Collection Request (ICR)*.

Patients who receive infused medications typically have chronic, complex, or severe conditions such as chronic rheumatologic and musculoskeletal diseases, inflammatory bowel diseases, neurological disorders and rare diseases. These patients receive infused medications that cannot be taken orally either due to the patient's medical condition, response to previous medications, or the types of available medications on the market. Instead, these medications must be delivered directly by a health care provider to the patient intravenously. Infusions are commonly administered in hospitals, outpatient infusion centers/suites, physicians' offices or sometimes at home under medical supervision. Unlike small molecule drugs, which can be easily absorbed by the body in pill or tablet form, infused medications are typically complex biologics that require precise handling, storage, and delivery, making their administration more resource-intensive.

As the providers and administrators of these infused medications, we have recently been made aware of this ICR. While an ICR directed at manufacturers might not, at first blush, appear to impact physician practices, we are concerned that the ICR, along with recent frequently asked questions (FAQs) relating to the ICR, may have the unintended consequence of directly impacting the ASP. **We urge CMS to delay implementation of the certification requirement described in the ICR to avoid downstream implications to providers of Part B medications across the United States.**

CMS indicates in the FAQs that if a manufacturer *cannot* obtain a BFSF certification from the recipient, the fee cannot be considered a BFSF. Given the extremely short timeline manufacturers are under to obtain and submit these certifications, we see the unintentional inclusion of these fees within the ASP as a real threat and could cause an unwarranted drop in the ASP.

The medical practices that administer medications are extremely dependent on the ASP and the corresponding six percent add-on payment, which accounts for the drug acquisition cost and helps providers cover overhead costs such as intake and storage, equipment and preparation, staff, facilities, and spoilage insurance. This anticipated drop in the ASP would not reflect any actual changes in pricing, but rather

manufacturer's inability to comply with this very limited certification deadline. **Yet again, providers are stuck in the middle of the federal government and manufacturers, with a drop in provider reimbursement as collateral damage.** Uncertainty and fluctuations in the ASP put medical practices – arguably the safest and most cost-effective setting for administration of physician-administered drugs – at risk.

At a time when physician practices are faced with an onslaught of threats to the ASP, we hope CMS will consider a solution to this problem, which appears to be within its jurisdiction. We urge CMS to consider a delay of this BFSF certification requirement to help minimize the downstream impact on the ASP and provider reimbursement. We thank you for your consideration and are happy to further detail our comments upon request.

Respectfully,

National Infusion Center Association

American Gastroenterological Association

Association of Women in Rheumatology

Coalition of State Rheumatology Organizations

National Organization of Rheumatology Management

Spondylitis Association of America

CC: Ryan Howe, Acting Deputy Director, Center for Medicare