March 2, 2026

Via Electronic Submission File Docket ID: CMS-2025-1921

Re: Information Collection Request: Revision of a currently approved collection; Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals and Supporting Regulations in 42 CFR 414.800-806

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Oz:

The Part B Access for Seniors and Physicians Coalition ("ASP Coalition"), representing more than 300 patient advocacy organizations, physician groups and provider organizations across the U.S., submits the following comments in response to the Centers for Medicare & Medicaid Services (CMS) information collection request (ICR) entitled, "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)." Our comments address the Federal Register Notice, Supporting Statement – Part A, related ICR Forms (CMS-10110, OMB 0938-0921), and the agency's Frequently Asked Questions (CMS FAQs) regarding submission of the bona fide service fee certification form (BFSF Certification Form).[1]

Background and Summary of Coalition Comments: The ICR addresses new requirements adopted in the 2026 Medicare Physician Fee Schedule Final Rule, effective January 1, 2026, requiring manufacturers to submit BFSF certifications and reasonable assumptions when they report average sales price (ASP). The Coalition urges CMS to delay the requirement for manufacturers to submit BFSF certifications and reasonable assumptions when reporting ASP, given that the agency has not finalized the applicable reporting forms. A delay is necessary to avoid situations in which ASP is inappropriately impacted because of an administrative

[1] 90 Fed. Reg. 61154 (Dec. 30, 2025); CMS-10110, *available at* https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing-items/cms-10110; CMS, Medicare Program Bona Fide Service Fee Certification and Average Sales Price Reasonable Assumptions Frequently Asked Questions (Jan. 7, 2026), *available at* https://www.cms.gov/files/document/frequently-asked-questions-faqs-bfsf-certification-asp-reasonable-assumptions.pdf.

impediment to accurate reporting. Our concerns are grounded in our longstanding advocacy to protect provider reimbursement in Medicare Part B, on behalf of patients who rely on critical drugs for serious, complex and life-threatening conditions. These include Medicare beneficiaries with cancer and other serious and chronic conditions such as rheumatologic, autoimmune, and inflammatory conditions; and those living with blinding eye diseases, Crohn's disease and ulcerative colitis, other rare chronic diseases, and serious mental illness. Providers continue to face significant payment pressure in Medicare Part B and should not be subject to further reductions associated with reporting of BFSFs.

Timeline and CMS FAQs: The ICR is open for comment until March 2. As a result of the timeline, final information collection requirements have not been established. Further, CMS stated in a January 28, 2026 eNewsletter, that updated reasonable assumptions and BFSF certification fields would not be available in the ASP Data Collection System until April 1, 2026. The next ASP submission deadline is 30 days later.

This compressed timeline, along with CMS FAQs indicating that CMS expects manufacturers to obtain BFSF certifications on a per-product basis and upon any change to the underlying service contract, make it exceedingly difficult, if not impossible, to secure the relevant certifications.[2] The ASP Coalition is very concerned that this environment will have an adverse and inaccurate impact on reported ASPs for reasons that are unrelated to pricing changes.

Our concerns are worsened by Question 7 of the CMS FAQs – which states:

- "Q7. What if a service provider refuses to provide a certification? A7. If a service provider refuses to provide a certification, the fee cannot be considered a bona fide service fee."

Recommended Solution: To avoid an unnecessary and unwarranted disruption to reported ASPs, we urge CMS to provide manufacturers with more time after final approval of the information collection to collect and submit BFSF certifications to CMS. Specifically, we recommend that the CMS delay the requirement for at least two full quarters after approval of the information collection. Our recommendation is intended to avoid unintended but harmful consequences to provider payments, which risks disruptions to beneficiary access to treatment. We appreciate your consideration of our views and look forward to continued engagement with the agency.

cc: William N. Parham, III, Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs

[2] CMS FAQs, Q3 and Q4.