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

**Intro**

The Centers for Medicare and Medicaid Services (CMS) received nine public comments, including submissions from six manufacturers and three trade associations. Commenters raised issues related to the format and scope of the bona fide service fee (BFSF) certification, estimated reporting burden, CMS's legal authority to require a certification, and implementation timing. CMS also received comments addressing the reasonable assumptions template as well as submission procedures. After careful consideration of these comments, CMS has clarified related guidance in the Frequently Asked Questions (FAQs) and updated the Certifier and Submitter User Guides. There are no changes to the BFSF certification or reasonable assumptions forms.

The following is a summary of the comments we received and our responses.

**Certification Form**

**1. Scope and Content of the Certification Requirement**

**Comment**: Multiple commenters urged CMS to clarify that BFSF certifications should remain valid when contracts are updated with additional products, package sizes, or National Drug Codes (NDCs), so long as the underlying fee structure, services, and methodology remain unchanged. They further noted that many agreements already include automatic updates under state contract law that do not create new contracts, and that requiring re-certification for non-substantive amendments could discourage appropriate contract management and is overly burdensome. A few commenters also expressed confusion whether only amendments related to Part B drug service fees would require a new form.

**CMS Response:** We appreciate the commenters' concerns that requiring a new certification each time a product is added could introduce an additional procedural step without meaningfully improving compliance, recordkeeping, or transparency. However, as set forth in the FAQ 4, and consistent with the Calendar Year 2026 Physician Fee Schedule (PFS) final rule , the BFSF certification requirement is triggered by any change to the terms of an existing

contract. Amendments, including the addition of a new product (for example, a new package size, a newly acquired product, or a new product launch), changes to fee amounts, or revisions to the contract term, constitute changes that require a new certification.

We reiterate our statement in FAQ 7: the certification requirement applies to BFSFs directly related to drug sales. A fee is "directly" related to a drug payable under Medicare Part B when it is paid for services specifically associated with that product, such as distribution and logistics, administrative functions, or data reporting specific to the drug.

**Action(s) Taken:** No action taken.

**Comment:** One commenter stated that CMS has not clearly defined the term "service fee arrangement," creating uncertainty about whether separate certifications are required for each fee within a single contract. They explained that contracts often contain multiple service fees under one agreement and argue that requiring separate certifications for each fee would create significant administrative burden. The commenter requested clarification that a single certification per contract may cover all applicable BFSF arrangements under that agreement.

**CMS Response:** CMS appreciates the commenter's feedback regarding the use of the term "service fee arrangement." We clarify that separate certifications are not required for each individaul fee within the same contract. A single certification may cover multiple services included within the same agreement.

**Action(s) Taken:** CMS updated FAQ 3 to clarify that one certification can contain multiple BFSFs.

**Comment:** Commenters stated that manufacturers should not be required to certify elements of BFSF arrangements that are outside their control, particularly how fee recipients use or allocate fees. Several commenters recommended eliminating the manufacturer signature requirement altogether, noting that service providers, not manufacturers, have direct knowledge of whether fees are passed through to clients or customers. If CMS retains the signature requirement, stakeholders urged greater flexibility by allowing authorized delegates to sign on behalf of the manufacturer, rather than limiting signatory authority to senior

executives reporting to the chief Executive Officer (CEO) or Chief Financial Officer (CFO). They emphasized that permitting delegation to appropriate personnel, such as contracting or functional leaders, would reduce unnecessary administrative burden while still ensuring accountability and timely certification.

**CMS Response:** We thank the commenters for their feedback. While the box for the manufacturer signature will remain on the form,  60-day Information Collection Request (ICR) revision, we inserted the phrase "acknowledged and accepted by the manufacturer". This addition clarifies that manufacturers have acknowledged and accepted the form from the fee recipient, and does not signify that the manufacturer has any direct knowledge of whether the fee is passed on outside of the service provider's attestation on the BFSF certification form. We also clarified that, consistent with 42 C.F.R. § 414.804(a)(7), an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO may sign the certification. We believe these revisions strike an appropriate balance between reducing administrative burden and maintaining program integrity.

**Action(s) Taken**: No action taken.

**2. Burden**

**Comment:** Many commenters asserted that CMS has significantly underestimated the burden associated with the certification form requirements. Overall, commenters are concerned that CMS estimates do not account for the volume of fee arrangements that will require certifications, the frequency of re-certifications, and other compliance activities including triggering even monitoring and tracking, engagement with fee recipients, systems updates, and impacts to government price calculations. Furthermore, one commenter claimed that CMS' estimate does not take into account the hours of work required by manufacturers' government price reporting personnel.

**CMS Response:** CMS appreciates the commenters' feedback regarding burden estimates associated with the certification requirements. CMS believes the current burden estimates appropriately account for the personnel, time, and resources necessary to complete and maintain the required certifications and related documentation. In developing these estimates, CMS considered the activities

associated with reviewing, preparing, and submitting the required materials, as well as the personnel typically involved in those processes. In addition, CMS considered the anticipated volume of fee arrangements requiring certification, the potential need for re-certifications, and associated compliance activities, including monitoring and tracking certifications, engagement with fee recipients, system modifications, and assessment of any impacts on government price reporting and calculations, and believes these considerations are appropriately reflected in the burden estimates. CMS therefore does not believe additional revisions to the burden estimates are warranted at this time.

**Action(s) Taken:** No action taken.

**Comment:** One commenter highlighted that the certification requirements compound other recent drug price reporting programs, including the Inflation Reduction Act's Medicare Drug Price Negotiation Program maximum fair price requirements, the recent most-favored nations pricing agreement with the Trump Administration, and CMS' Global Benchmark for Efficient Drug Pricing Model and Guarding U.S. Medicare Against Rising Drug Costs Model proposed models. The commenter claimed that collectively, these administrative burdens stand in stark contrast to the Trump Administration's important deregulatory agenda to eliminate "unnecessary regulatory burdens placed on the American people."

**CMS Response**: CMS appreciates the commenter's concerns regarding the cumulative administrative burden associated with various drug pricing and reporting initiatives. While CMS recognizes that manufacturers may be subject to multiple reporting obligations across different programs, other drug pricing initiatives are outside the scope of this PRA. CMS believes the information collection associated with the BFSF certification requirement is necessary to promote accurate ASP reporting, consistent with the Administration's priorities of lowering drug prices.

**Action(s) Taken**: No action taken.

**Comment**: A few commenters requested that CMS reduce burden and increase flexibility in the BFSF certification process by allowing manufacturers to download a blank certification form and complete the form offline with input from the service provider. One commenter noted that the final rule describes criteria for the

certification requirement but does not expressly require use of the certification form or prescribe a specific format for recipient attestations. This commenter recommended CMS permit alternatives such as reliance on certifications in contracts or recipient-provided attestations.

**CMS Response**: CMS appreciates the commenters' suggestions regarding additional flexibility in the BFSF certification process. CMS believes the standardized certification form and submission process are appropriate to promote consistency, completeness, and administrative efficiency in the collection of information necessary to support accurate ASP reporting. CMS disagrees with the commenter's assertion that the certification requirements were required to be expressly included in the final rule. CMS believes the BFSF certification form requirements are consistent with and supported by the final rule. At this time, we will not permit alternatives to the certification form.

**Action(s) Taken**: No action taken.

**3. Legal Authority and Practical Implications**

**Comment:** Many commenters stated that CMS lacks statutory authority to require submission of the certification, asserting that the ASP statute provides an exclusive list of required data elements and does not authorize additional data requirements. They contended that CMS failed to adequately address these concerns in the final rule. Commenters also claimed that CMS has not complied with procedural requirements under the Paperwork Reduction Act (PRA) and Administrative Procedure Act (APA). Regarding the PRA, commenters claimed that CMS has not fully followed the requirements of the two approval pathways laid out in the statute. Concerning the APA, commenters claimed that CMS failed to adequately justify a significant reversal of its longstanding policy and did not explain why fee recipient would cooperate.

**CMS Response**: We acknowledge the commenters' concerns. CMS's policy to require reporting of the BFSF certification was finalized in the CY 2026 PFS final rule and is outside of the scope of this PRA package. CMS has complied with the applicable requirements of the PRA and APA. The proposed reporting requirement was first subject to notice-and-comment via the Notice of Proposed Rulemaking (NPRM) that published in the Federal Register on July 16, 2025 (90 FR 32352). While

the rule provided the public with  60-days to comment on the proposed provisions, the NPRM had mistakenly stated that we would use the standard non-rule PRA process for public notice/comment and OMB approval. This was corrected in an August 14, 2025 (90 FR 39155) NPRM correction that identified the error and specified that we would use the rulemaking process for public notice/comment and OMB approval. Because of inadvertent issues with posting the collection of information's materials for public review/comment, we published a notice on December 30, 2025 (90 FR 61154) that provided the public with an additional 60-days to review the collection's materials and to comment. As required by the PRA, we also published a subsequent 30-day notice on April 7, 2026 (91 FR 17657). Comments were due on/by May 7, 2026.

]  However, we reiterate that for a fee to be considered a BFSF, it must meet all of the requirements of the definition, including that the fee not be passed on.

**Action(s) Taken**: No action taken.

**Comment**: Commenters highlighted practical and legal concerns, including that service providers have no obligation or incentive to sign certifications, which could lead to misclassification of legitimate fees, as well as potential conflicts with state laws. Additionally, the commenter argues that the requirement may negatively impact provider payments and patient access, and does not meaningfully enhance transparency, considering the certification is confidential and conveys no information to the public or CMS beyond what manufacturers' own ASP calculations already reflect. Additionally, one commenter added that CMS' statement that this policy could lower drug prices is not relevant because that is not the purpose of the ASP statute which requires manufacturers to report ASP accurately, not to minimize it. To that extent, a commenter requested CMS clarify how it intends to use the information from the certification to improve ASP accuracy.

**CMS Response**: As discussed in the final rule and responses to comments from the 60-day ICR, CMS considered concerns that the certification requirement could affect providers' willingness to furnish services. However, to date, we have not seen evidence demonstrating that service providers are unwilling to furnish the required certification. Based on the information available, we do not find sufficient

support to conclude that the requirement will result in the anticipated access or participation issues.

With respect to concerns about potential conflicts with state laws, commenters did not identify any specific state-law requirements that would prevent compliance with the certification requirement. Based on the information available, CMS is not aware of any conflict between the certification requirement and applicable state laws.

CMS disagrees with the assertion that this policy does not improve transparency. The certification requirement enhances transparency by providing CMS as well as the public with assurance that fees are being appropriately classified in accordance with applicable requirements.

Finally, CMS' discussion of potential effects of the certification policy on drug prices is relevant in describing the anticipated impacts of improved ASP reporting accuracy. We stated in the final rule that the goal of these proposals was to avoid inaccurate calculation of the manufacturer's ASP that is used to determine Part B drug payment limits (90 FR 49533) and we reiterated the importance of ASP calculation accuracy throughout the final rule.

**Action(s) Taken**: No action taken.

**4. Implementation Timing**

**Comment**: One commenter requested additional guidance regarding whether certifications must be obtained and submitted for contracts that were executed or in effect during the first quarter of 2026, or whether the requirement applies only prospectively to contracts executed or amended after the effective date of the finalized PRA materials. Several commenters also urged CMS to delay implementation to allow stakeholders adequate time to establish compliance processes.

**CMS Response**: CMS appreciates the commenters' requests for additional guidance and additional implementation time. The CY 2026 PFS final rule established that certifications are required for contracts executed and/or amended on or after January 1, 2026, consistent with the final rule, and that such certifications were due to CMS not later than April 30, 2026. Due to delays in

approval of the PRA package to implement the requirement to submit reasonable assumptions and certification forms for BFSFs, we were unable to collect this data for the first sales quarter of 2026. Therefore, requirements as described in 42 CFR 414.804(a)(5)(ii) and (iii) are waived for the first sales quarter of 2026. We will provide updates regarding the availability of the forms and future reporting as they become available.

**Action(s) Taken**: No action taken.

**Reasonable Assumptions**

**Comment:** Several commenters argued that requiring manufacturers to enter reasonable assumptions into multiple free-text fields is unnecessarily burdensome and increases the risk of error compared to submitting a single document. They contended that CMS has not justified this requirement and suggested allowing a single comprehensive document that includes all required reasonable assumptions and supporting detail.

**CMS Response**: CMS appreciates the commenters' feedback regarding the format for submitting reasonable assumptions. In reviewing reasonable assumptions that have been voluntarily submitted to date, we observed a wide variety of organization in the documents, types of information, and level of detail provided. Analyzing and compiling a single document with various formats from each manufacturer reduces the quality of the data collected and reduces CMS's ability to effectively analyze the information. CMS believes that collecting information through structured free-text fields supports consistency, improves organization, and facilitates a more efficient review of submitted information. Therefore, any additional burden is outweighed by the benefits of a consistent structured format.

**Action(s) Taken**: No action taken.

**Comment**: Commenters noted that certain data elements may have been removed from the certification form on the premise that this information would be captured within reasonable assumptions, including fee amounts or fee-structure data, and that this expectation is inconsistent with longstanding practice and that neither the final rule nor associated guidance explicitly requires the inclusion of detailed, contract-level data. Commenters expressed that reasonable assumptions should explain how BFSFs are generally determined. Moreover, one commenter

noted that a BFSF is not a "discount," and assume CMS' guidance to provide information on the "discount structure" in connection with a BFSF is an error and should be omitted. A few commenters requested clarification on what is required for the summary of BFSFs in the reasonable assumption submission. Other commenters recommended CMS clarify that reasonable assumptions should be limited to high level methodological descriptions and suggested adding a free-text "BFSF description" field and removing the current free text field.

**CMS Response**: We appreciate commenters feedback regarding information requested in reasonable assumptions for BFSFs. Reasonable assumptions support accurate ASP reporting and CMS oversight and collecting contextual information about BFSFs is consistent with that purpose. We agree with the commenter that the reasonable assumptions description of the BFSF should explain how the fee is determined, including the fair market value analysis. The amount of the BFSF is not required to be included in the description of the reasonable assumptions. Finally, we agree with the commenter that CMS's guidance to provide information on the "discount structure" is an error and should be omitted.

**Action(s) Taken**: CMS updated FAQ 6 to clarify the expectations regarding reporting BFSFs in manufacturers' reasonable assumptions.

**Comment**: One commenter suggested CMS reevaluate whether submission of the FMV methodology should be required as part of ASP reporting given that it is not a direct input into the ASP calculation.

**CMS Response**: CMS disagrees with the commenter's suggestion. Information regarding fair market value (FMV) methodologies may be relevant to CMS's evaluation of whether a fee qualifies as a bona fide service fee for ASP reporting purposes. We stated in the CY 2026 PFS final rule that we will use reasonable assumptions to better understand the scope and frequency of FMV reassessments, and this information will aid with informing future policy development (90 FR 49538).

**Action(s) Taken**: No action taken.

**Comment**: Multiple commenters raised concerns about the operational impact given the large number of service arrangements and amendments and questioned whether CMS has adequately accounted for this increased burden in its estimates.

In particular, one commenter expressed that the current instructions are unclear whether CMS means to say that each of these amendments potentially would need to be cataloged and reported in the BFSF assumptions document insofar as any fee amount changed.

**CMS Response**: CMS appreciates the commenters' feedback regarding the operational impact associated with the reasonable assumptions requirement. CMS updated the burden estimates associated with reasonable assumptions submissions in response to the 60-day ICR to account for the time and effort necessary to prepare and maintain the required information. CMS believes the current burden estimates reasonably reflect the administrative resources required to comply with the reporting requirements. We are persuaded by commenters that the fee amount is not required to be included in the reasonable assumptions and, therefore, would not need to be updated if the fee amount changes.

**Action(s) Taken**: CMS updated FAQ 6 to clarify the expectations regarding reporting BFSFs in manufacturers' reasonable assumptions.

**Submission Procedures and User Guides**

**Comment**: A few commenters recommended CMS align responsibility for uploading the Certification form with existing ASP submission processes by assigning this task to the ASP data submitter, rather than the ASP certifier. They emphasized that while the certifier should retain ultimate accountability for reviewing and certifying submissions, requiring them to handle document uploads creates unnecessary administrative burden.

**CMS Response**: We thank the commenters for their feedback. CMS will provide functionality within the ASP Portal for both the submitter and certifier to be able to upload the certification.

**Action(s) Taken**: CMS updated the Submitter and Certifier User Guides and updated FAQ 9.

**Comment**: One commenter stated that requiring BFSF certifications and reasonable assumptions to be submitted at the labeler code level creates unnecessary duplication, since these policies and methodologies are established at the manufacturer (parent company) level. They request that CMS allow

consolidated submissions across labeler codes or provide a mechanism to avoid duplicative reporting where the information is identical, in order to reduce administrative burden.

**CMS Response**: CMS recognizes that affiliated entities may use the same reasonable assumptions, methodologies, or certification practices across multiple labeler codes. Under section 1847A of the Social Security Act and the implementing regulations at 42 CFR part 414, ASP reporting obligations are tied to the drugs reported under a specific national drug code (NDC), which contains the labeler code of the product. Because of the various complex business structures of drug manufacturers, including frequent buying and selling of drugs and/or subsidiaries, if submissions of reasonable assumptions and BFSF certifications were not tied to the labeler code, CMS would not be able to clearly ascertain which NDCs the submitted forms applied to. Collecting the information at the labeler-code level ensures that the data collected are clearly associated with the applicable reporting entity and the drugs for which ASP data are being reported. Accordingly, we are maintaining the current reporting structure.

**Action(s) Taken**: No action taken.

**Comment**: One commenter noted that the current Certifier User Guide is outdated and references prior from elements that are no longer applicable.

**CMS Response**: We thank the commenter for bringing this to our attention. We agree that certain references in the current Certifier User Guide are outdated and we will revise accordingly.

**Action(s) Taken**: CMS updated the Certifier User Guide.