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

Intro

CMS received 17 public comments, including submissions from 11 manufacturers, three trade associations, and three advocacy organizations. Commenters raised issues related to the format and scope of the certification, estimated reporting burden, CMS's legal authority to require a certification, and implementation timing. CMS also received comments addressing the reasonable assumptions template. After careful consideration of these comments, CMS has revised the certification form, updated the burden estimates in the Supporting Statement, and clarified related guidance in the FAQs.

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

Certification Form

1. **Format and technical edits**

Comment: A few commenters recommended revisions to improve the usability and specificity of the certification, including:

- Delete prefatory language before Section 1.
- Name the agreement, the parties involved, and effective period of the certification in the form (above Section 1).
- Reformat Section 1 using a structured table to accommodate multiple products or manufacturers.
- Replace "certifying individual" with "signatory" in Section 2 for accuracy.
- Clarify ambiguous references to "conditions" in Section 2.
- Modify Section 3 to conform with language in final rule.

CMS Response: We appreciate the commenters' suggestions to enhance user-friendliness and reduce potential for confusion. Upon review, we agree that many of the recommended edits and will revise the form accordingly. However, CMS does not agree with the recommendation to delete the prefatory language. The prefatory language provides important context regarding the corresponding regulatory requirements and includes necessary submission instructions. CMS also does not agree with the recommendation to add "any and all additional Drug Names and NDCs added to the Agreement hereafter," as such language is inconsistent with the policy.

Action(s) Taken: CMS updated certification form.

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

Comment: Several commenters affirmed that requiring a separate certification for each product is impractical and unnecessarily burdensome, further stating that requiring a certification at the product level is inconsistent with the PRA which requires CMS to perform data collection in a manner that's least burdensome. Commenters urge CMS to finalize one certification per service fee arrangement, rather than per product. Additionally, some commenters noted an inconsistency between the FAQ document and the Certification Form, observing that the FAQ states that "a singular certification letter for each product is required to be submitted," whereas the Certification Form includes a table permitting the listing of multiple drug names and NDCs.

CMS Response: We thank the commenters for their feedback. CMS did not intend to require duplicative certifications where a single service fee arrangement encompasses multiple products under the same terms and conditions. Accordingly, CMS is clarifying that manufacturers may use a single certification per service fee arrangement. The certification may include multiple products in the designated table, consistent with its current structure.

Action(s) Taken: CMS revised FAQ language to align with the finalized policy and the structure of the certification.

Comment: Multiple commenters requested that CMS clarify that adding a new product to an existing agreement does not trigger a new certification requirement. Commenters generally argue that requiring a new certification each time a product or NDC is added would create an unnecessary procedural step without improving compliance, recordkeeping, or transparency. They contend that product additions are often administrative in nature and do not alter the underlying services or fee structure of the agreement. Several commenters recommended that CMS finalize language in the certification stating that newly added products are automatically incorporated into the existing certification. Many commenters also recommended that a new certification is required only when there is a material change to the agreements (e.g. changes to services, fees, fee calculation methodologies, or pass-through of service fees) and further suggested limiting the certification to no more than once annually. A few commenters also raised concerns that requiring multiple certifications for the same underlying agreement would create duplicative information collection and would not represent the least burdensome approach required by the PRA. Additionally, commenters noted that many service

agreements automatically renew unless terminated, and therefore should not trigger new certification obligations absent substantive changes.

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, we are maintaining the policy finalized in the CY 2026 Physician Fee Schedule (PFS) final rule and stated on the FAQ form that the 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 material changes that require a new certification.

Action(s) Taken: No action taken.

Comment: Many commenters opposed the requirement that manufacturers sign the certification. Commenters argue that a third-party signature should suffice, as manufacturers are not in a position to certify how the fee recipient uses the fee. One commenter also noted that the certification requirement set forth at 42 C.F.R. § 414.804(a)(5)(iii) specifies that certification must come from the fee recipient, not the manufacturer. Furthermore, others asserted that the signature is duplicative and unnecessary because manufacturers already certify the accuracy and completeness of ASP submissions. A few commenters recommended revising the language to state "acknowledged and accepted by manufacturer" and adding appropriate knowledge qualifiers to limit the scope of the manufacturer's attestation. Others requested CMS allow the certification form to be requirements signed by a manufacturer representative that meets the requirements of 42 C.F.R. § 414.804(a)(7).

CMS Response: We thank the commenters for their feedback. We are not removing the box for the manufacturer signature; however, we will insert the phrase "acknowledged and accepted by the manufacturer." We believe this revision appropriately clarifies that the fee recipient, not the manufacturer, is certifying that the fee is not passed on, while still reflecting the manufacturer's acknowledgment of the arrangement. We also clarify 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.

Action(s) Taken: CMS updated certification form and the FAQs.

Comment: A few commenters objected to reporting fee amounts, methodologies, and discount structures and raised concerns about disclosure of commercial strategies. They recommended limiting the certification strictly to information required under 42 CFR §

414.804(a)(5)(iii), avoiding duplicative information already submitted through reasonable assumptions, and adding a statement that the certification is reinforcing that only fees directly tied to part b drug sales are required for purposes of the certification.

CMS Response: As we stated in the final rule, regarding confidentiality, data collected through the ASP module will be protected from disclosure to the extent required by the law. We cannot release information about specific manufacturers or wholesalers or prices charged by such manufacturer or wholesaler for specific products due to statutory confidentiality provisions that limit the release of ASP data as specified in section 1847A(f)(2)(D) of the Act, and in section 1927(b)(3)(D) of the Act. However, we agree that reporting fee amounts, methodologies, and discount structures would be duplicative of information required in reasonable assumptions. Accordingly, we will remove this component on the certification.

Finally, with regard to the recommendation that we add a statement that the certification is only required for BFSFs directly related to a Part B Drug, we reiterate our statement in the FAQ: the certification requirement applies to BFSFs directly related to drug sales. A fee is "directly" related to a Part B drug 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: CMS updated certification form.

Comment: One commenter sought clarification on how to submit the signed certification in the ASP portal. The commenter stated that while the user guide mentions a text box for reasonable assumptions, it does not explain how the executed certification itself should be submitted, and the commenter asks whether there will be a dedicated upload function or another submission method within the portal.

CMS Response: We thank the commenter for bringing this issue to our attention. The instructions for submitting the certification are included in the Certifier User Guide in section 3.4 because the certifier is responsible for uploading the document.

Action(s) Taken: CMS updated the FAQs to clarify where to find instructions for submitting the signed certification.

3. **Burden**

Comment: Multiple commenters requested CMS reassess its burden estimates to more accurately reflect both ongoing and one-time compliance burden associated with the certification requirements. Regarding annual burden, commenters asserted that CMS's estimate does not account for the time required to review contracts, track amendments

and renewals, conduct legal analysis, and manage related documentation. Because fee recipients are not legally obligated to sign certifications, commenters anticipate substantial back-and-forth negotiations to complete and execute forms. Commenters also stated that CMS's estimate does not capture substantial one-time costs.

CMS Response: CMS agrees that we should reassess and revise its burden estimates to more accurately reflect ongoing compliance costs. With regard to one-time costs, this is outside the scope of the PRA. For purposes of the PRA process, only the average annual burden needs to be calculated. OMB's review is limited to the average annual burden associated with the information collection.

Action(s) Taken: Annual burden updated in Supporting Statement.

4. **Legal Authority and Practical Implications**

Comment: Several commenters objected to the certification requirement on legal and practical grounds, arguing that the certification exceeds CMS's statutory and regulatory authority and improperly expands reporting obligations without proper notice and comment. Commenters also requested CMS assess the practical implications of requiring manufacturers to obtain certifications from entities that may be unwilling to submit certifications, arguing that manufacturers do not have the ability to compel fee recipients to comply and this could have a downstream impact on provider reimbursement when manufacturers are forced to classify fees as price concessions. Commenters urged CMS to withdraw the certification requirement, make its use optional, or permit more flexible documentation alternatives, such as allowing flexibility in submitting certifications that are substantially similar to the required form.

CMS Response: We acknowledge the commenter's concerns. However, these comments are outside the scope of the PRA, as it requests that CMS reconsider a policy determination finalized in the CY 2026 PFS final rule. Furthermore, as stated in the final rule, absent evidence demonstrating that service providers are unwilling to furnish the required certifications, we do not find these concerns to be substantiated. Accordingly, the final rule establishes the policy going forward. Finally, we will not accept certifications that are substantially similar to the required form. Under the PRA, CMS may collect information only through forms that have been reviewed and approved through the PRA clearance process. If we have concerns with a manufacturer's certification, we may follow up with the manufacturer.

Action(s) Taken: No action taken.

5. **Implementation Timing**

Comment: A few commenters requested a delay of 1 – 2 quarters, citing concerns that CMS has significantly understated the burden associated with the submission process. They also note the limited time between the close of the comment period and the first ASP submission deadline. One commenter recommended a phased implementation approach, suggesting that CMS could prioritize collection of RAs during the initial quarter or establish a defined transition period during which similar certifications are sufficient. One commenter also asked when CMS anticipates releasing finalized templates following the close of the comment period. Finally, one commenter recommended CMS host a technical webinar, stakeholder education session, or written FAQs to address common scenarios and documentation expectation to promote uniform interpretation across manufacturers.

CMS Response: We acknowledge the commenters' concerns. With respect to the requested implementation delay, this recommendation falls outside the scope of the PRA, as it effectively seeks reconsideration of a policy determination finalized in the CY 2026 PFS final rule. In that rule, CMS established that the certification requirements apply to sales occurring on or after January 1, 2026; that data must be submitted to CMS by April 30, 2026; and that such data will be reflected in the July 2026 Medicare Part B Drug Payment Limit File.

As discussed above, we have revised the burden estimates to more accurately account for annual costs.

Regarding the timing of finalized templates, we are unable to provide a specific anticipated release date at this time. CMS will continue to share updates on the status of the PRA package as they become available.

Finally, CMS is hosting an ASP annual training on Tuesday, April 14, 2026 and we released BFSF/reasonable assumptions related FAQs earlier this year.

Action(s) Taken: No action taken.

Reasonable Assumptions

Comment: A few commenters raised concerns that requiring submission of the reasonable assumptions form with quarterly ASP submissions is inconsistent with existing ASP regulations and not authorized by law. They noted that current regulations require manufacturers to maintain and provide reasonable assumptions and related documentation, but do not mandate a specific format, fields, or standardized template. Accordingly, they urged CMS not to require use of the template. If CMS proceeds with the requirement, they recommend eliminating mandatory category fields and word limits, clarifying that manufacturers need not address every listed topic, and allowing attachments to provide additional context and detail. One commenter also recommended

CMS revise the burden required for manufacturers to comply with the template, including involvement from legal counsel, government pricing personnel, business colleagues, third-party vendors, outside counsel, and senior management.

CMS Response: We appreciate the commenter's feedback. However, whether the requirement to submit the reasonable assumptions template is consistent with existing ASP regulations or otherwise authorized by law is outside the scope of this PRA. As stated on the current reasonable assumptions form, if you do not have reasonable assumptions for a particular area, put "N/A" in the box. If you have additional verbiage for any of the areas, attach a cover letter when submitting the form. Finally, CMS agrees that we should reassess and revise its burden estimates to more accurately reflect ongoing compliance costs.

Action(s) Taken: Annual burden updated in Supporting Statement.