Medicare Program

Bona Fide Service Fee Certification and Average Sales Price Reasonable Assumptions

Frequently Asked Questions

Policy: Effective January 1, 2026, manufacturers of drugs payable under Medicare Part B are required, as part of the submission of average sales price (ASP) data, to submit reasonable assumptions including fair market value (FMV) documentation for current, new, and renewed contracts, and certification from the recipient of a bona fide service fee (BFSF) that the fee is not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Resources:

2026 Physician Fee Schedule Final Rule (90 FR 49532 through 49542)

PRA Listing for CMS Form Number CMS-10110

Q1. Where can I find the BFSF certification and ASP reasonable assumption forms?

A1. The forms currently available were posted with the proposed rule. You can find both documents here: https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing-items/cms-10110 The final versions were updated to be consistent with the final rule and will be posted once they receive OMB approval. We will update this FAQ document with a link to the final versions when those forms are posted.

Q2. Is the determination of 'new' or 'prospective' contracts based on the contract's execution date, such that only contracts executed after January 1, 2026 are considered 'new' or 'prospective'?

A2. New or prospective contracts is based on the contract's execution date, such that only contracts executed after January 1, 2026 are considered 'new' or 'prospective', or if it is renewed on or after that date. Contracts executed before January 1, 2026 but with an effective date on or after January 1, 2026 would not be considered 'new' or 'prospective' for certification purposes.

Q3. How often are certification letters required to be obtained during the course of a contract for a bona fide service? Are manufacturers required to submit a certification for each product or one certification across products?

A3. A singular certification letter for each product is required to be submitted for the length of the term of the contract or until a subsequent amendment or renewal (see next question for additional detail on what constitutes an amendment to a contract). Manufacturers do not need to submit the certification every quarter, only when the contract is new or renewed.

Q4. If terms change for an existing contract for bona fide service, does this qualify as new?

A4. Yes, the certification requirement is triggered by *any* change to an existing contract. For example, adding a new product, such as a new package size, a newly acquired product, or a new product launch, along with changes in the fee amount or adjustments to the contract term are considered amendments that triggers a new certification.

Q5. What will CMS require in the reasonable assumptions in terms of assumptions on the current (not new) contracts?

A5. CMS requires a brief summary of all current bona fide service contracts in the reasonable assumptions. The reasonable assumption form submitted with the proposed rule is available at the link above. We reiterate that the final version of the form aligns with the final rule. Once OMB approval is obtained, the final form will be posted, and this FAQ document will be revised to reflect its availability.

Q6. Is the certification only required for BFSFs directly related to a Part B drug?

A6. Yes, 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.

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.

Q8. Are there any frequency requirements for the FMV reassessments?

A8. To clarify, FMV documentation is not due quarterly; effective January 1, 2026, manufacturers must document the methodology used to determine FMV for all current, new, and renewed contracts. For example, all FMV determinations for current contracts are due by April

30, 2026 with their submission of ASP for first quarter of sales in 2026. If a service arrangement is newly signed or renewed between January 1, 2026 through March 31, 2026, the FMV determination data is also due by April 30, 2026.

Q9. What does CMS require for the documentation of FMV?

A9. We will accept well-detailed summaries of FMV methodologies that clearly describe the data sources, assumptions, and rationale supporting the determination.

Q10. Can manufacturers submit a summary for bundled arrangements and reallocation approach rather than for each distinct bundled arrangement.

A10. Manufacturers may submit a summary of bundled arrangements and the reallocation approach. CMS will notify manufacturers directly if we need further information regarding bundled sales arrangements.

Q11. Will restating ASP for temporal bundles impact reimbursement for providers? Will the restatement timeframe be modified based on the Final Rule?

A11. Please refer to the ASP Restatement Policy Overview document here: https://www.cms.gov/files/document/average-sales-price-asp-restatement-policy-overview-updated-06/16/2025.pdf

Q12. How should manufacturers describe reasonable assumptions related to maximum fair prices (MFPs)/Medicare volume?

A12. Assumptions pertaining to the MFP should be provided in the 'Other' box on the reasonable assumptions form.