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https://www.regulations.gov/docket/CMS-2025-1921

William Parham
CMS, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Information Collection Request for Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals and Supporting Regulations in 42 CFR 414.800–806 (CMS–10110; OMB Control Number 0938–0921)

Viatris Inc. ("Viatris") is pleased to provide comments in response to the Centers for Medicare & Medicaid Services ("CMS") *Information Collection Request for Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals and Supporting Regulations in 42 CFR 414.800–80* ("ICR").[1]

Viatris Inc. is a global healthcare company uniquely positioned to bridge the traditional divide between generics and brands, combining the best of both to more holistically address healthcare needs globally. With a mission to empower people worldwide to live healthier at every stage of life, we provide access at scale, currently supplying high-quality medicines to approximately 1 billion patients around the world annually and touching all of life's moments, from birth to the end of life, acute conditions to chronic diseases. With our exceptionally extensive and diverse portfolio of medicines, a one-of-a-kind global supply chain designed to reach more people when and where they need them, and the scientific expertise to address some of the world's most enduring health challenges, access takes on deep meaning at Viatris. We are headquartered in the U.S., with global centers in Pittsburgh, Shanghai and Hyderabad, India.

We appreciate that CMS has provided stakeholders an opportunity to provide comment on the proposed form for reporting reasonable assumptions for calculating the manufacturer's

[1] 90 Fed. Reg. 61154 (Dec. 30, 2025).

Average Sales Price ("ASP") and the proposed Certification Form from the recipient of a service fee as evidence that the fee was not passed on in whole or in part ("Certification Form").

1 Viatris has Experience Inquiring into Customers' Pass-Through Practices and Negotiating Written Representations, and Wishes to Share the Benefit of That Experience with CMS

Viatris appreciates the transparency and certainty associated with the concept of written certification of customer pass-through practices. Even prior to the promulgation of the certification requirement in the 2026 Physician Fee Schedule Final Rule ("Final Rule"),[2] Viatris had a policy in place where Viatris asks the customer whether they pass on any part of the fee to their customers or clients, makes contemporaneous notations of the response, and asks the customer if it would be willing to make a written representation in the contract. We wish to share the benefit of that experience with CMS.

We are concerned that if CMS finalizes the Certification Form as proposed, in conjunction with some statements in its Frequently Asked Questions regarding the Bona Fide Service Fee Certification and Average Sales Price Reasonable Assumptions ("FAQs"),[3] the process will be unduly burdensome to manufacturers as well as to our supply chain partners, resulting in bona fide service fees ("BFSFs") being incorrectly treated as price concessions, thereby artificially depressing provider reimbursement.

Accordingly, we have focused our comments on areas in which we believe it is particularly important that CMS provide operational clarity and reduce unnecessary burdens to the drug supply chain in connection with the collection of Certification Forms from service fee recipients, to help facilitate the accurate reporting of ASP in accordance with statutory requirements, and to avoid underpayment of providers for Medicare Part B drugs and biologicals.

We have also provided a proposed Certification Form at Attachment 1 which is consistent with our comments.

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[2] 90 Fed. Reg. 49266, 49542 (Nov. 5, 2025).

[3] 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/medicare/payment/part-b-drugs/asp-education-outreach/faqs-bfsf-certification-asp-reasonable-assumptions.

2 CMS Should Require a Separate Certification Letter for each Service Fee Arrangement—Not Each Product

a. A Separate Certification Letter for Each Product is Burdensome, Impracticable and Makes it Less Likely that Customers will Provide Certification—Even Where the Fee is in Fact Not Passed On

In its FAQs, CMS provides "A singular Certification Form for each product is required . . ." Given the size of the Viatris portfolio and the number of products it has subject to service fee arrangements, a single Certification Form for each product is impractical and has no transparency or compliance benefit to the pass-through prong of the BFSF test.

Viatris currently reports MDRP pricing for over 1,350 NDC-11s and ASP for over 250 NDC-11s. While the requirement to obtain a Certification Form confirming no pass through of service fees only applies to ASP-reportable drugs, a single service fee under a single contract (e.g., a pick pack and ship fee under a wholesaler distribution services agreement) frequently applies to both ASP-reportable and ASP-non-reportable drugs.

For certain of its customers, Viatris has over 1,000 price-reportable NDC-11s on contract, of which almost 200 are ASP-reportable. If a separate Certification Form were required for each product, whenever Viatris and the customer amend any of the service descriptions or corresponding fees, Viatris would ask the customer to execute 1,000 separate certifications. Even if Viatris were only to seek certifications for its ASP-only reportable drugs, almost 200 Certification Forms per contract or amendment would still be required. This is burdensome, impracticable and imposes unnecessary challenges to the company's relationships with customers and risks the customer will decline to execute the forms, even if the fee is in fact not passed on, resulting in artificially depressed ASP-based provider reimbursement.

Accordingly, CMS should require a separate Certification Form for each service fee arrangement—not each product.

b. Viatris' Experience is that Customers Make Pass-Through Representations for the Fee as a Whole, not on a Product-Specific Basis

Prior to the Final Rule, CMS allowed a manufacturer to presume that service fees were not passed through in absence of evidence to the contrary. Nonetheless, as explained above, Viatris has had a stricter policy in place for years whereby for new or revised services or corresponding fee, Viatris asks the customer whether they pass on any part of the fee to their customers or clients, makes contemporaneous notations of the response, and asks the customer if it would be willing to make a written representation in the contract.

In over 350 "pass through" queries made in the last 8 years, never once has a customer replied that its pass-on practice was product-dependent. In all cases, the pass-through representation was fee-specific.

A product-specific certification is inconsistent with industry pass-through practices. Accordingly, CMS should require a separate Certification Form for each service fee arrangement—not each product.

c. Viatris Revenue Management System, Used by Numerous Manufacturers, Cannot Manage Product-Specific Government Price Reporting Treatment

At contract execution or amendment, Viatris makes a determination that a service fee or other financial flow associated with a contract is a Price Concession (included in government price reporting ("GP")) or a BFSF (excluded from GP), and it assigns a GP treatment-consistent transaction classification code to that financial flow (called a "Price Group" in the system). This is an industry-specific system designed to operationalize complex contracts common to the pharmaceutical industry and used by many other manufacturers. At the close of each period (e.g., month or quarter) the system identifies all sales or utilization for all products that serve as the base of the fee, applies the fee calculation methodology, creates a payment transaction for the total fee amount and attaches the corresponding GP treatment transaction classification code. The system has no mechanism to assign different product-specific transaction classification codes to different parts of the fee payment transaction. Thus, a product-specific Certification Letter also is not implementable on a systematic basis. The system is designed for fee-specific treatment.

3 Regarding Contract Amendments, CMS Should Require Certification Letters Only Where the Amendment Changes the Description of Services or the Corresponding Fee—But Not for Every Product Change

In the preamble to the 2026 Physician Fee Schedule Final Rule ("Final Rule"), CMS states that "the proposed certification requirement applies to new contracts."[4] In its FAQs however, CMS states:

> 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.

[4] 90 Fed. Reg. 49266, 49542 (Nov. 5, 2025).

This approach would be infeasible for Viatris, given the size of our product portfolio and the nature of contracting for generics. Even where the underlying services and corresponding fees in our contracts remain unchanged, products go on and off contract frequently and prices change frequently.

For example, for distribution service agreements with wholesalers, Viatris generally only puts new products on contract at launch, removes products when discontinues, and only makes price changes where there is a WAC change. Yet this still results in near constant changes. In 2025 alone, between newly launched NDC-11s, discontinuations and WAC changes, Viatris would have had over 250 changes triggering new certifications under CMS's proposal. Some of these NDCs are on contract with over 20 wholesalers. Under CMS's proposal, every one of these 250 changes per year (or at least the significant portion associated with ASP-reportable products) would require securing new certifications for up to 20 wholesalers, even if the underlying distribution services provided by the wholesaler did not change.

As to GPO contracts, Viatris has a significant generic injectables portfolio, almost all of which are ASP-reportable, and for which Viatris offers discounts to healthcare provider-member GPOs. While Viatris has a smaller number of NDC-11s on contract with each GPO than it does with wholesalers, there is a higher frequency of price changes and products going on and off contract including for example, over 500 changes in one year in connection with just one arrangement. Under CMS's proposed rule, every one of these 500 changes (or at least the high ASP-reportable portion) would require securing new Certification Forms from the GPO, even if the underlying service description and fee calculation did not change.

A requirement to obtain hundreds if not thousands of Certification Forms per year for changes unrelated to the contracted services and corresponding fees would discourage price competition (by discouraging contract price changes) and risk artificially depressing ASP and resulting provider reimbursement where service providers are unable or unwilling to provide all of these letters on a timely basis. Such a requirement would also put Viatris at a competitive disadvantage in the fast-paced awards process with burdensome administrative process.

Accordingly, when issuing the final Certification Form, CMS should make clear that for contract amendments, new Certification Forms are only required upon execution of an amendment that that changes the description of the services or the corresponding fee—not for every price or product change.

4 CMS Should Revise the Certification Form to Avoid Suggesting that the Manufacturer also Executes the Certification, Because the Manufacturer is the Recipient of the Certification Form, Not the Certifier

Section 3 of the proposed Certification Form contains a certification that "that the fee is not passed on in whole or in part to a client or customer of an entity" and includes a "Manufacturer Signature" and a "Fee Recipient Signature." It is unclear why this Section includes a manufacturer signature, as the manufacturer is the recipient of the Certification Form, not the certifier. Nor would manufacturers be in a position to certify the service provider's pass-through practices (which are solely within the control of the service provider). Viatris' proposed revised Certification Form in Attachment 1 thus clarifies that only a signature is required from the service provider. If CMS nevertheless insists on including a manufacturer certification, the Certification Form should specify that the manufacturer is certifying solely to the accuracy of the information in the portions of the form completed by the manufacturer.

Thank you for the opportunity to provide comments regarding the Initial Guidance. We would be happy to provide further information regarding these comments at your convenience. Should you have any questions, please contact me at Christopher.Lewis@viatris.com.

Respectfully,

Christopher M. Lewis
Head of Government Pricing and Reporting

Attachment 1
Viatris Proposed Form of Certification

Manufacturer Letterhead
Name of Manufacturer
Address

Date

Service Provider Addressee
Name and Address

Subject: Manufacturer Request to Service Provider For Certification Pursuant to 42 C.F.R. § 414.804(a)(5)(iii)

Section 1: Manufacturer Request to Customer for Certification	
Sample Language	Dear Service Provider: Regarding the Contract/Amendment referenced below, effective on or about xxx date (Effective Date), Manufacturer requests that Service Provider execute and return this certification to Manufacturer at <<contact>> before the Effective Date. Failure of Service Provider to return the executed certification prior will result in the fees identified below to be treated as price concessions by Manufacturer. Manufacturer will submit a copy of this certification to the Centers for Medicare and Medicaid Services ("CMS") as required by 42 C.F.R. § 414.804(a)(5)(iii).

Section 2: Identification of Contract. This Certification Applies to the Following Contract	
Sample Language	Distribution Services Agreement, effective as of XXXX, made by and between XXXXX (hereinafter "Manufacturer") and [XXXXXX] (hereinafter "Service Provider"), as amended (the "Agreement") [and Amendment No. XX, effective xxxxxx (the "Amendment")].

Section 3: Identification of Service Fee Arrangements. This Certification Applies to the Following

Sample Language

	Name/Description of Services	**Contract Citation**	**Name/Description of Corresponding Fee**	**Contract Citation**
1	Pick, pack and ship; Inventory Days on Hand	Paragraph 30	Distribution Service Fee	Paragraph 31
2	Chargeback Services	Section 6(a)	Financial Fee	Section 6(b)

Attachment 1
Viatris Proposed Form of Certification

Section 4: Identification of Products. This Certification Applies to the Following Products	
Sample Language	All products to which the above-referenced service fees apply in accordance with the terms and conditions of the above-referenced contract, including products currently on contract, products added to the contract at any later time, and irrespective of any product price changes. This certification remains in full force and effect throughout the contract term, unless and until Service Provider notifies Manufacturer pursuant to the notification provision of the Contract. Service Provider acknowledges that Manufacturer relies on this certification to comply with 42 C.F.R. § 414.804(a)(5)(iii),

Section 5: Identification of Service Provider. This Certification is Made on Behalf of the Following	
Sample Language	Service Provider Name Address City, State Zip Phone number Fax Company website

Section 5: Certification **I certify that the fee is not passed on in whole or in part to any client or customer of Service Provider.**	
Sample Language	Service Provider Certifying Individual Signature Service Provider Certifying Individual Name Service Provider Certifying Individual Title

Thank you for your cooperation

Name
Title