



515 KING STREET, ALEXANDRIA VA 22314

MEMORANDUM

**To: Hon. Robert F. Kennedy, Jr., Secretary, US Department of Health and Human Services
Dr. Mehmet Oz, Administrator, Centers for Medicare and Medicaid Services**

From: Andrew Langer, Director, Center for Regulatory Freedom

Date: March 2, 2026

Re: Comments to US Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS) in response to Notice CMS-10110 (Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals), Docket #CMS-2025-1921, Fed. Reg. 2025-23924, Published December 30, 2025

Below are comments of the American Conservative Union Foundation's (d/b/a. Conservative Political Action Coalition Foundation) (hereinafter "CPAC Foundation") Center for Regulatory Freedom (hereinafter "CRF"), in response to CMS-10110 (Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals), Docket #CMS-2025-1921, Fed. Reg. 2025-23924, published December 30, 2025.

CRF is a project of the CPAC Foundation, a non-profit, non-partisan 501(c)(3) research and education foundation. Our mission is to inject a common-sense perspective into the regulatory process, to ensure that the risks and costs of regulations are fully based on sound scientific and economic evidence, and to ensure that the voices, interests, and freedoms of Americans, and especially of small businesses, are fully represented in the regulatory process and debates. Finally, we work to ensure that regulatory proposals address real problems, that the proposals serve to ameliorate those problems, and, perhaps most importantly, that those proposals do not, in fact, make public policy problems worse.

INTRODUCTION

The Center for Regulatory Freedom (CRF) supports the Centers for Medicare & Medicaid Services' (CMS) ongoing efforts to ensure that Average Sales Price (ASP) reporting under Medicare Part B is accurate, transparent, and economically sound. The ASP system is foundational to Part B drug reimbursement, and its integrity directly affects beneficiary affordability, provider reimbursement predictability, and overall program stability. Clear and

reliable pricing inputs are essential to maintaining confidence in Medicare payment methodologies and to avoiding unintended distortions in reimbursement rates.

CRF recognizes that CMS's recent revisions to ASP submission requirements are intended to formalize documentation standards and enhance clarity surrounding the treatment of bona fide service fees and manufacturer pricing assumptions. Requiring consistent submission of reasonable assumptions documentation and certification letters reflects a legitimate interest in improving uniformity and reducing ambiguity in price reporting practices. When implemented properly, clear documentation expectations can support transparency and strengthen compliance consistency across the marketplace.

However, the Paperwork Reduction Act requires more than policy coherence; it demands disciplined calibration of information collection requirements. Agencies must demonstrate that each collection is necessary for the proper performance of agency functions, that it has practical utility, and that the burden imposed is accurately estimated and minimized to the greatest extent practicable. PRA discipline requires agencies to consider how compliance operates in the real world—across complex contracting arrangements, multi-product portfolios, and enterprise-level compliance systems—not simply how a form appears on paper.

In this proceeding, several concerns warrant careful attention before OMB approval is granted. First, the burden estimates associated with the certification and documentation requirements appear to understate the operational complexity and senior-level oversight necessary to ensure compliance. Second, the requirement that manufacturers obtain certifications from third-party fee recipients raises questions about the scope of manufacturer responsibility where they lack legal control over downstream actors. Third, aspects of the certification structure risk misclassifying legitimate bona fide service fees as price concessions based solely on documentation mechanics rather than economic substance. Finally, certain elements of the form design and submission structure may generate unnecessary redundancy and compliance friction.

CRF's objective is not to weaken ASP transparency or to dilute accountability standards. Rather, our goal is to ensure that CMS's documentation framework remains aligned with statutory boundaries, accurately reflects real-world compliance burdens, and avoids unintended distortions to ASP calculations. Regulatory integrity is strengthened—not compromised—when compliance mechanisms reflect operational reality and legal authority.

An information collection regime that overestimates manufacturers' ability to compel third-party certifications, or that automatically penalizes the absence of documentation irrespective of substantive compliance, risks undermining the very pricing accuracy CMS seeks to protect. Documentation requirements should support accurate economic reporting, not create structural incentives for defensive overclassification or artificial price concession treatment that could reverberate through Part B reimbursement calculations.

CRF therefore urges CMS and OMB to ensure that the final information collection approval reflects rigorous PRA standards, respects statutory limits, and incorporates implementation flexibility consistent with operational realities. Accurate ASP reporting is essential to Medicare integrity. Achieving that goal requires a documentation framework that is disciplined, legally

sound, and economically grounded.

EXECUTIVE SUMMARY

CMS's effort to enhance transparency and documentation surrounding Average Sales Price (ASP) calculations reflects a legitimate interest in preserving Medicare Part B payment integrity. However, the current information collection framework risks overstating compliance feasibility while understating the economic and operational consequences of implementation. Without recalibration, the certification and documentation requirements may impose burdens that exceed those contemplated under the Paperwork Reduction Act and create compliance structures that do not fully reflect statutory boundaries or real-world contracting dynamics. We offer the following:

- **CMS materially underestimates the compliance burden associated with certification collection, internal workflow redesign, monitoring of triggering events, system modifications, and senior-level legal and executive review.**
- **Manufacturers lack legal authority to compel independent third-party fee recipients to execute certifications, yet the framework effectively conditions compliance treatment on the actions of entities outside the manufacturer's control.**
- **Misclassification of legitimate bona fide service fees solely due to missing certifications—irrespective of economic substance—could distort ASP calculations and reverberate through downstream Medicare payment determinations.**
- **CMS must clarify whether certifications are required at the product level or entity level and should explicitly permit a single certification covering multiple products under a unified service arrangement to avoid duplicative reporting.**
- **Certifications should accommodate subsequently added National Drug Codes under unchanged fee arrangements without triggering redundant administrative cycles or unnecessary recertification events.**
- **The requirement that manufacturers sign a certification concerning downstream fee treatment is inappropriate and legally unnecessary, as manufacturers cannot attest to facts outside their knowledge or control.**
- **CMS should permit certifications that are substantially similar to the prescribed format in order to prevent unnecessary resubmissions, operational bottlenecks, and compliance gridlock.**
- **The implementation timeline is unrealistic relative to enterprise-level compliance realities and the timing of final template availability, warranting transitional flexibility.**

CRF supports disciplined transparency in ASP reporting and recognizes CMS’s responsibility to safeguard pricing integrity. At the same time, transparency mechanisms must remain consistent with statutory limits, accurately reflect compliance burdens, and be operationally feasible. We therefore urge CMS and OMB to recalibrate the information collection to ensure it advances accountability while minimizing unnecessary burden and preserving economic accuracy.

I. THE PAPERWORK REDUCTION ACT REQUIRES REALISTIC BURDEN ESTIMATION

The Paperwork Reduction Act requires agencies to estimate the real-world burden imposed by an information collection, not merely the time required to complete and upload a form. Burden under the PRA encompasses the total time, effort, and financial resources expended by affected entities to generate, review, verify, and maintain the required information. This includes systems changes, legal review, internal governance processes, and monitoring mechanisms necessary to ensure compliance. An estimate that captures only clerical submission time does not satisfy the statute’s mandate to assess the full compliance impact of a regulatory requirement.

In the context of ASP documentation and certification requirements, it is critical to distinguish between “submission time” and “compliance time.” Submission time refers narrowly to the act of entering data or uploading documentation. Compliance time, by contrast, includes the contracting analysis, fee classification review, internal auditing, and executive oversight necessary before a submission can be made with confidence. The latter represents the overwhelming share of real-world burden. Conflating these two categories materially understates the operational demands imposed on manufacturers.

The certification requirement alone triggers substantial operational activity. Manufacturers must identify all relevant fee arrangements, evaluate whether each arrangement qualifies under applicable standards, determine whether certifications are required, engage with counterparties to obtain those certifications, and track their status across potentially hundreds or thousands of agreements. Each of these steps involves contract review, legal interpretation, and coordinated internal decision-making. These are not ministerial tasks; they require subject-matter expertise and judgment.

Moreover, legal and compliance teams must evaluate whether individual arrangements meet definitional criteria and whether any modifications to contracts trigger new certification obligations. Executive-level review may be required to validate compliance approaches and risk tolerance. Internal controls must be designed or modified to ensure that documentation is obtained, tracked, stored, and retrievable for audit purposes. These activities impose measurable labor costs that extend well beyond administrative staff.

System redesign and workflow restructuring represent additional burdens that must be reflected in PRA modeling. Manufacturers may need to modify pricing systems, document management platforms, and internal reporting tools to incorporate certification tracking and flag certification-triggering events. Monitoring mechanisms must be established to identify contract amendments, product additions, renewals, and other changes that could require updated documentation. These

system adjustments require coordination across legal, compliance, information technology, and pricing analytics teams.

Certification-triggering events further compound the burden. Contract amendments, new product launches, additions of National Drug Codes, changes in fee structures, and term extensions may each necessitate review and potential recertification. Tracking these events across multi-product, multi-counterparty portfolios is resource-intensive. The burden is not static; it is dynamic and ongoing, tied to the lifecycle of commercial arrangements rather than to a single reporting event.

The compliance burden also persists across quarters. Because ASP submissions occur quarterly, the documentation framework must operate continuously. Certifications must be monitored for validity, updated where necessary, and reconciled with current pricing data before each submission cycle. The recurring nature of the process multiplies the resource commitment. What might appear modest in isolation becomes significant when replicated four times annually across a national portfolio of products and counterparties.

These tasks require specialized personnel, including legal counsel, contract managers, compliance officers, and pricing analysts. Senior-level staff involvement is often necessary to resolve interpretive questions and approve compliance positions. The PRA requires agencies to account for the labor categories and expertise required to perform compliance functions. Estimating burden based primarily on administrative-level effort does not reflect the actual resource intensity of enterprise-level compliance systems.

Underestimating burden not only affects affected entities; it also undermines the integrity of OMB review. The PRA framework is designed to ensure that agencies rigorously evaluate necessity, practical utility, and burden minimization before imposing information collections. If the underlying burden assumptions fail to capture real-world compliance dynamics, OMB cannot meaningfully assess whether the collection satisfies statutory standards.

CRF therefore urges CMS to recalculate its burden estimates using an enterprise-level modeling approach. Such modeling should account for contracting review time, internal governance processes, system modifications, monitoring mechanisms, and quarterly repetition. Only with a realistic burden assessment can CMS and OMB determine whether the information collection is properly calibrated to achieve its objectives without imposing unnecessary or excessive compliance costs.

In short, adherence to the Paperwork Reduction Act requires recalibration before approval. Accurate ASP reporting is a legitimate objective. Ensuring that the documentation framework reflects realistic compliance burdens is an equally essential requirement of sound administrative governance.

II. STATUTORY LIMITS AND THIRD-PARTY CERTIFICATION AUTHORITY

The revised documentation framework places manufacturers in the position of obtaining certifications from downstream fee recipients concerning the treatment of bona fide service fees.

As a threshold matter, manufacturers do not control the internal business practices, accounting decisions, or downstream pricing conduct of independent fee recipients. These entities are separate commercial actors operating under their own governance structures, compliance frameworks, and legal obligations. Any regulatory structure that conditions a manufacturer's compliance status on the independent conduct of third parties must carefully account for these institutional boundaries.

While commercial contracts may contain representations, warranties, and cooperation clauses, contractual leverage is not equivalent to operational control. Manufacturers cannot compel execution of a certification where a counterparty declines to provide one, particularly if the counterparty disputes the form language, timing, or legal implications of certification. Even where agreements provide cooperation obligations, enforcement of such provisions may require renegotiation, litigation, or termination—none of which is practical or proportionate in the context of routine pricing documentation. The PRA does not authorize agencies to presume perfect contractual compliance across complex, multi-party commercial ecosystems.

Moreover, the certification in question pertains to facts uniquely within the knowledge and control of the fee recipient—specifically, whether a fee is passed through in whole or in part to a downstream client or customer. Manufacturers do not have visibility into the fee recipient's internal accounting practices, pricing decisions, or downstream cost allocation methodologies. A regulatory regime that conditions compliance treatment on information outside the manufacturer's knowledge base raises fundamental questions about both fairness and feasibility.

To the extent the framework effectively requires manufacturers to secure third-party attestations as a precondition to proper fee classification, it risks exceeding the statutory design of ASP reporting requirements. The statutory scheme focuses on manufacturer reporting obligations and price concession definitions. It does not contemplate deputizing manufacturers as enforcement intermediaries responsible for securing independent certifications from unrelated entities. Expanding compliance obligations beyond statutory reporting responsibilities warrants careful scrutiny.

There is also a meaningful risk of penalizing manufacturers who act in good faith but encounter refusal or delay from counterparties. If a legitimate bona fide service fee is treated as a price concession solely because a certification was not obtained—despite substantive compliance with definitional criteria—the manufacturer bears the regulatory consequence of another entity's decision. This shifts compliance risk in a manner that may be inconsistent with statutory intent and sound administrative practice.

The resulting asymmetry of liability is particularly concerning. Fee recipients face no comparable regulatory consequence if they decline to provide certification, yet manufacturers may face altered pricing treatment or reporting consequences based solely on that refusal. Such asymmetry creates structural imbalance and may incentivize defensive classification decisions rather than economically accurate reporting. Regulatory frameworks should align accountability with control.

Regulatory structures that create practical impossibility—where compliance depends on factors outside a regulated entity’s authority—undermine both legitimacy and enforceability. Sound administrative governance requires agencies to calibrate obligations to what regulated parties can realistically accomplish. Conditioning proper ASP treatment on third-party cooperation without providing safe harbors or alternative documentation pathways risks creating avoidable compliance dead ends.

CRF therefore recommends that CMS confirm that good-faith efforts to obtain certification, combined with contemporaneous contractual representations and documentation, will suffice where third-party execution cannot be secured despite reasonable diligence. A framework that recognizes documented, good-faith compliance efforts would better align with statutory boundaries while preserving transparency objectives.

Ultimately, enforcement mechanisms must reflect practical authority boundaries. Manufacturers can and should be responsible for accurate reporting within their knowledge and control. Extending liability to encompass independent third-party conduct, without corresponding authority, risks overextension. Ensuring that certification requirements operate within realistic legal and operational limits will strengthen—not weaken—the integrity of ASP reporting.

III. RISK OF MISCLASSIFICATION AND DISTORTION OF ASP

A bona fide service fee is generally understood to be a payment for legitimate services actually performed, that reflects fair market value, and that does not function as a price concession. The defining characteristic is economic substance: the fee compensates the recipient for specified services and does not reduce the net price realized by the purchaser. The distinction between a service fee and a price concession is therefore grounded in function and effect, not merely in the presence or absence of a particular document.

It is important to distinguish between substantive compliance and documentation mechanics. A fee arrangement may satisfy all definitional criteria for treatment as a bona fide service fee under governing standards, yet lack a specific certification form at a particular point in time. The absence of documentation does not, by itself, transform the economic character of the transaction. Regulatory enforcement mechanisms should be designed to capture economic reality, not to redefine it based on procedural formality.

If the framework effectively requires manufacturers to treat a fee as a price concession solely because a certification was not obtained, it risks conflating documentation gaps with substantive noncompliance. A service that meets all substantive requirements does not become a discount merely because a counterparty declines to execute a prescribed form. Automatic reclassification based on documentation status elevates procedural compliance above statutory definition.

Such automatic misclassification could artificially inflate the amount of reported price concessions. Treating legitimate service fees as price reductions would alter the net sales figure used in ASP calculations. Even marginal shifts in reported price concessions can affect payment

benchmarks when aggregated across large product portfolios and repeated quarterly. Over time, these distortions could materially affect reported ASP values.

Because ASP serves as the basis for Medicare Part B reimbursement calculations, distortions at the reporting stage reverberate downstream. Provider reimbursement amounts are derived from ASP-based methodologies, and shifts in reported net pricing can influence payment rates. In addition, pricing benchmarks are often referenced in broader rebate or inflation-related frameworks. Misclassification at the documentation stage can therefore have cascading financial consequences beyond the immediate reporting quarter.

The statutory framework governing ASP is built on economic definitions of price concessions and service fees. Documentation requirements are tools to support accurate reporting; they are not substitutes for the statutory definitions themselves. Enforcement mechanisms should reinforce the definitional framework, not displace it. When documentation rules operate in a way that overrides economic substance, they risk undermining the integrity of the reporting system they are intended to protect.

A more balanced approach would employ a rebuttable presumption structure. Where certification is not available despite documented, good-faith efforts, manufacturers should be permitted to rely on contemporaneous contractual representations, internal compliance review, and other substantiating documentation to support proper classification. This approach would preserve CMS's ability to audit and verify arrangements while avoiding automatic reclassification detached from economic substance.

CMS should also consider establishing documentation safe harbors. For example, clear guidance that contractual language meeting specified criteria, combined with documented outreach efforts to obtain certification, satisfies reporting expectations would provide predictability. Safe harbors reduce compliance uncertainty and encourage accurate reporting rather than defensive reclassification.

Ultimately, ASP integrity depends on aligning reporting treatment with economic reality. Documentation requirements should enhance transparency and auditability, but they should not operate as rigid triggers that override substantive compliance. Preserving the distinction between procedural documentation and economic classification is essential to maintaining both fairness and accuracy in Medicare payment calculations.

IV. CERTIFICATION STRUCTURE MUST MINIMIZE REDUNDANCY

To promote both compliance accuracy and burden minimization, the certification structure should operate at the entity or agreement level rather than at the individual product level. Where a single service arrangement governs multiple products or National Drug Codes, a unified certification covering all products under that arrangement reflects commercial reality. Service agreements are typically negotiated at the enterprise level, with pricing and service terms applying across portfolios. Requiring separate certifications for each product artificially fragments a unified contractual relationship.

A product-level certification requirement would generate substantial operational burden without corresponding compliance benefit. Manufacturers would be required to prepare, track, collect, store, and reconcile multiple certifications tied to a single agreement, even when the underlying fee structure and service terms remain identical. This duplication increases administrative workload while adding no incremental transparency regarding whether a fee is passed through.

The scale implications are significant. Many manufacturers maintain portfolios spanning dozens or hundreds of products, often subject to the same service arrangements. In large commercial ecosystems, a single service provider may interact with multiple manufacturers and multiple product lines. Requiring separate certifications per product could multiply the volume of required forms exponentially, creating logistical strain for both manufacturers and counterparties. High-volume certification requirements increase the likelihood of delay, non-response, or clerical error.

The certification framework should also expressly accommodate the addition of new National Drug Codes or package configurations under an unchanged service agreement. In practice, product portfolios evolve over time due to new launches, line extensions, or packaging changes. Where the underlying fee arrangement remains materially unchanged, requiring a new certification solely because an additional NDC is included creates unnecessary churn. A well-drafted certification can reasonably encompass future additions under the same contractual terms.

Recertification should be triggered only by material changes to the fee arrangement itself, such as modifications to the fee calculation methodology, substantive amendments to service scope, or extension of the agreement's term. Routine operational developments, including product additions within the same agreement framework, should not automatically require new certifications. Limiting recertification to material contractual changes aligns the documentation requirement with economic substance.

Redundant certification cycles do not reduce compliance risk; they may increase it. Excessive documentation volume can create bottlenecks, tracking errors, and confusion regarding which certifications are operative at a given time. When compliance systems are burdened with duplicative inputs, the risk of inadvertent misalignment rises. Streamlining documentation requirements enhances accuracy by focusing attention on substantive compliance rather than repetitive administrative tasks.

Clarity and alignment between guidance documents and the certification form itself are equally important. Any ambiguity regarding whether certifications must be product-specific or agreement-specific should be resolved in favor of consistency with commercial practice and operational feasibility. Clear alignment between agency guidance and form structure will reduce interpretive uncertainty and facilitate uniform implementation.

The Paperwork Reduction Act expressly requires agencies to avoid unnecessary duplication in information collection. Requiring multiple certifications for the same underlying agreement, absent substantive change, risks creating duplicative collection that does not materially enhance

oversight. Minimizing redundancy is not a relaxation of standards; it is an application of statutory burden discipline.

A streamlined, agreement-level certification structure—permitting coverage of multiple products and future additions under unchanged terms—would better serve CMS’s transparency objectives while reducing unnecessary administrative complexity. By aligning documentation requirements with contractual and operational realities, CMS can enhance compliance accuracy and preserve ASP integrity without imposing avoidable duplication.

V. FORM DESIGN AND SIGNATURE REQUIREMENTS MUST REFLECT REALITY

The certification form must reflect the practical realities of commercial relationships and the allocation of knowledge between contracting parties. Requiring a manufacturer signature on a statement attesting that a fee “is not passed on” is inappropriate where the underlying fact concerns the conduct of an independent fee recipient. Manufacturers do not control, observe, or direct how a counterparty treats fees in its downstream transactions. Imposing a manufacturer certification on matters outside its knowledge risks compelling an attestation that cannot be independently verified.

The certification should therefore be executed solely by the fee recipient, who is uniquely positioned to attest to the downstream treatment of the fee. The manufacturer’s role is to collect and retain the certification as part of its reporting documentation. Shifting the attestation burden to the party with actual knowledge aligns the form with commercial and legal realities. It also avoids creating artificial liability exposure based on representations that a manufacturer cannot substantiate.

If CMS believes some form of manufacturer acknowledgment is necessary for administrative completeness, the form should clearly distinguish between attestation and acknowledgment. Language such as “acknowledged and accepted by manufacturer” would reflect that the manufacturer has received the certification without implying that it is independently certifying the truth of statements made by another entity. Clear differentiation between certification and acknowledgment reduces ambiguity and protects the integrity of both parties’ representations.

The form should also clearly identify the governing agreement to which the certification applies. Including a specific reference to the relevant service arrangement—by name and date—will provide precision and limit confusion regarding scope. Explicit linkage between the certification and the underlying agreement enhances auditability and ensures that all parties understand the contractual framework being addressed.

In addition, the form would benefit from a structured table format to capture product names, National Drug Codes, and manufacturer identifiers in a clear and organized manner. A tabular format improves usability, particularly where multiple products are covered under a single arrangement. Clarity in presentation reduces the likelihood of incomplete or inconsistent entries and supports more accurate recordkeeping.

Ambiguous terminology within the form should also be clarified to avoid interpretive disputes. References to undefined “conditions” or vague descriptions of fee variability can create uncertainty for signatories. Replacing imprecise language with clearer descriptions of fee metrics and calculation methods will improve comprehension and reduce hesitation among fee recipients asked to execute the certification.

CMS should further confirm that certifications that are substantially similar to the prescribed format will be accepted. In practice, minor variations in formatting, sequencing, or non-substantive wording are likely to occur, particularly during initial implementation phases. Rejecting certifications based on immaterial deviations would create unnecessary administrative churn without advancing transparency objectives. Flexibility in accepting substantially similar certifications supports both compliance efficiency and accurate reporting.

Excessive rigidity in form design risks undermining ASP integrity rather than strengthening it. When documentation frameworks become overly prescriptive, they may discourage timely certification, increase friction between contracting parties, and elevate procedural technicalities over economic substance. A form that reflects practical realities, allocates responsibility appropriately, and permits reasonable flexibility will better serve CMS’s objective of ensuring accurate and reliable ASP reporting.

VI. IMPLEMENTATION TIMELINE AND TRANSITION FLEXIBILITY

The implementation timeline for the revised ASP documentation and certification requirements warrants careful reconsideration. The proximity between finalization of form requirements and the first reporting deadline leaves limited time for manufacturers to operationalize enterprise-level compliance systems. ASP reporting is not a discrete filing exercise; it is the culmination of layered internal review, data reconciliation, and certification collection processes. Compressed timelines heighten the risk of avoidable error and administrative bottlenecks.

Uncertainty surrounding final templates and submission mechanics further compounds this challenge. Where forms, portal instructions, or guidance documents are not fully stabilized well in advance of the reporting deadline, manufacturers must either delay preparation or proceed based on provisional assumptions. Neither outcome promotes reporting accuracy. A stable documentation framework should precede mandatory compliance by a sufficient margin to allow orderly system adjustments.

Enterprise compliance changes require significant lead time. Manufacturers must identify all affected agreements, revise internal policies, update contract templates where appropriate, redesign workflow processes, modify information systems, train relevant personnel, and engage counterparties to obtain certifications. These steps occur across legal, compliance, pricing, information technology, and operational functions. Even under expedited conditions, such cross-functional coordination cannot be completed instantaneously.

CRF therefore urges CMS to exercise transitional enforcement discretion during the initial implementation period. Where manufacturers demonstrate documented, good-faith efforts to

comply—particularly with respect to certification collection and documentation format—CMS should avoid punitive reclassification or rejection of submissions based solely on technical deficiencies. Transitional flexibility promotes cooperation and improves long-term compliance outcomes.

A phased implementation approach would further support orderly adoption. For example, CMS could prioritize collection of reasonable assumptions documentation in the initial quarter while allowing additional time for full certification integration across all affected arrangements. Alternatively, CMS could establish a defined transition window during which substantially similar certifications and reasonable documentation substitutes are deemed sufficient.

First-quarter flexibility is especially important given the operational scale of the change. Initial submission cycles will reveal unanticipated technical issues, workflow bottlenecks, and interpretive ambiguities. Allowing for measured adjustment during this period will enable CMS and manufacturers to refine processes collaboratively. A rigid enforcement posture at the outset may discourage transparency and prompt defensive compliance behavior rather than substantive accuracy.

These recommendations are consistent with broader regulatory burden reduction principles. The Paperwork Reduction Act and sound administrative governance favor implementation strategies that minimize disruption while preserving policy objectives. Transparency and accountability are not advanced by compressed rollouts that overwhelm compliance infrastructure.

Successful implementation of the revised ASP documentation framework depends on calibrated rollout and practical transition safeguards. By aligning timelines with operational realities and providing measured flexibility during the initial reporting cycles, CMS can enhance compliance accuracy, preserve program integrity, and ensure that documentation reforms achieve their intended purpose without unnecessary disruption.

CONCLUSION

CRF reiterates its support for transparent and accurate Average Sales Price reporting as a cornerstone of Medicare Part B integrity. Reliable pricing inputs are essential to predictable reimbursement, beneficiary affordability, and public confidence in federal healthcare programs. Documentation reforms that enhance clarity and auditability can strengthen these objectives when properly calibrated.

At the same time, the Paperwork Reduction Act requires agencies to ensure that any information collection is necessary for the proper performance of agency functions, has practical utility, and minimizes burden to the greatest extent practicable. Compliance structures must reflect real-world operational dynamics rather than theoretical administrative exercises. Accurate burden estimation and disciplined calibration are not peripheral considerations; they are statutory requirements.

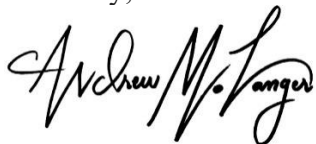
Third-party certification obligations must also remain aligned with legal authority and practical control. Manufacturers cannot compel independent counterparties to execute certifications concerning facts uniquely within those counterparties' knowledge. A regulatory framework that conditions compliance outcomes on conduct outside the regulated entity's control risks exceeding statutory design and creating avoidable compliance friction.

CRF is particularly concerned that rigid documentation triggers could result in economic misclassification of bona fide service fees based solely on procedural deficiencies. When documentation mechanics override substantive economic reality, ASP calculations may be distorted, with downstream consequences for provider reimbursement and related payment structures. Transparency objectives are best served when economic substance—not technical formality—drives classification outcomes.

We therefore urge CMS to revisit its burden estimates, refine certification mechanics to minimize redundancy, clarify signature and agreement-level structures, and incorporate safe harbors that recognize good-faith compliance efforts. A recalibrated framework that aligns documentation requirements with operational feasibility will better protect ASP integrity while satisfying PRA discipline.

Finally, CRF recommends transitional flexibility and a measured implementation approach to ensure that enterprise-level compliance systems can be responsibly deployed. A calibrated rollout, coupled with reasonable accommodation for initial implementation challenges, will advance transparency without unnecessary disruption. CRF remains committed to disciplined, economically grounded Medicare regulatory governance that safeguards program integrity while avoiding unnecessary compliance burdens on regulated entities.

Sincerely,

A handwritten signature in black ink that reads "Andrew M. Langer". The signature is written in a cursive, flowing style.

Andrew M. Langer
Director
CPAC Foundation Center for Regulatory Freedom