COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

September 12, 2025

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

RE: Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program; CMS-1832-P

Submitted electronically to regulations.gov

Dear Administrator Oz,

Thank you for the opportunity to comment on the CY 2026 Medicare Physician Fee Schedule Proposal Rule. The Council for Affordable Health Coverage (CAHC, www.cahc.net) is a broad-based alliance with a singular focus: ensuring all Americans have access to affordable coverage. Our member organizations are pro-patient, pro-competition, and pro-innovation, and include employers, medical providers, patient groups, insurers, agents and brokers, technology companies, and pharmaceutical manufacturers.

CAHC has long supported reduced drug costs, greater access to drug therapies, and fostering innovation to help treat and cure disease. We have serious concerns that several provisions of the proposed rule fall short of the agency's statutory obligations and risk undermining program integrity, provider sustainability, and patient access to care in low-cost settings. We provide comments on the following areas in this letter:

1. 340B Statutory Requirements under the Inflation Reduction Act
2. Average Sales Price (ASP): Units Sold at Maximum Fair Price
3. Part B ASP Calculation: Bona Fide Service Fee
4. Addressing physician work time

340B Statutory Requirements Under the Inflation Reduction Act

CMS has made reporting to the 340B claims repository voluntary, yet without mandatory participation, the repository cannot fulfill the legal requirement to eliminate duplicate discounts. The Inflation Reduction Act of 2022 mandates that CMS exclude 340B units from Medicare Part D inflation rebate calculations to avoid duplicate discounts. CMS openly acknowledges that its exclusion methodology will not capture ADAP purchases, many contract pharmacy fills, and physician referrals. Those gaps will lead to precisely the duplicate discounts the agency is charged by law to eliminate, an outcome both unlawful and untenable under the IRA's anti-duplicate discount provisions.

Additionally, CMS will incur significant costs to build and maintain this repository; voluntary reporting undermines return on that investment and delays compliance with the Inflation Rebate statute. Under Social Security Act § 1847A(i), as added by the Inflation Reduction Act (Pub. L. 117-169), CMS is required to remove 340B-purchased units from rebate calculations. A mandatory system would ensure that CMS meets its obligations efficiently and effectively.

CMS has a clear statutory duty to exclude all 340B units from inflation rebate calculations under Social Security Act §1847A, as amended by the Inflation Reduction Act of 2022. We urge the agency to strengthen its proposal by mandating comprehensive data reporting and adopting robust, automated exclusion rules. These steps will serve patients, protect program integrity, and align with CMS's broader goals of efficiency and accountability.

***Recommendation*:** Approve and uniformly apply the 340B Rebate Guidance to all drugs subject to the Part D inflation rebate, not just Medicare negotiated (MFP) drugs, to ensure consistent, comprehensive exclusion of discounted units. Transform the 340B claims repository into a mandatory reporting mechanism for all covered entities. Requiring real-time, standardized data submissions will:

- Guarantee that all 340B purchases—regardless of dispensing site—are correctly flagged.
- Eliminate reliance on error-prone manual matches.
- Protect manufacturers and taxpayers by preventing illegal duplicate discounts.

Average Sales Price: Units Sold at Maximum Fair Price

In the proposed rule, CMS states to clarify that, under the IRA Medicare Drug Price Negotiation Program, units of selected drugs sold at maximum fair price (MFP) are included in the calculation of the manufacturer's ASP, effective January 1, 2026. In addition, CMS has indicated it will no longer publish ASP prices for MFP drugs. CAHC is concerned this would eliminate commercial pricing based on ASP and move the entire market to MFP price controls that are determined by bureaucrats and politicians, not markets.

In 2028, price limits on physician-administered drugs will cut reimbursement by 50%, leading to a $25 billion reduction, with $12 billion from oncology alone.[1] Large, metropolitan hospitals may absorb these reimbursement cuts, but smaller oncology practices in rural areas will suffer and may close or join the consolidation trend by joining a hospital. Access to proper care will become even more difficult for cancer patients. These changes will be devastating for community-based care and send more patients to the hospital, where taxpayers and beneficiaries will pay more, considering the current higher reimbursement for hospital-based care.

We also believe CMS lacks legal authority to include MFP discounts in ASP calculations. The Social Security Act ("SSA") § 1847A(c)(3) sets forth that ASP includes all sales to all purchasers in the U.S., including price concessions, but excluding sales excluded from Best Price. The Inflation Reduction Act does not explicitly state that CMS should include MFP in ASP calculations. The law does specifically include MFP in Best Price and excludes it from AMP. Had Congress intended to include MFP in ASP, it would have explicitly added it in the statute, which it did not. By including MFP in ASP, CMS is imposing a

[1] Avalere Health. (September 2024). *Commercial Spillover Impact of Part B Negotiations on Physicians.* https://advisory.avalerehealth.com/insights/commercial-spillover-impact-of-part-b-negotiations-on-physicians

significant economic and regulatory burden on physician practices and manufacturers without explicit statutory direction.

Finally, with respect to CMS no longer publishing separate ASPs for MFP drugs, CAHC believes the proposal is ill-advised. Many commercial payers use ASP as a benchmark for reimbursement purposes. Eliminating published ASPs will create new regulatory burdens on payers to adjust payments to providers and manufacturers. Second, if a generic or biosimilar product enters the market for an MFP drug, MFP no longer applies, but ASP would. CMS's proposal creates a gap in data that harms payer, provider, and manufacturer financial modeling and planning. Finally, MFP is a set price, while the statutory intent of Congress in creating ASP was to base reimbursement on a market-based mechanism. CMS is moving away from Congressional intent codified in SSA § 1847A(c)(3) and §1847A(b)(2) [the alternative payment pathway].

Recommendation: MFP should be excluded from ASP calculations because Congress did not specifically include it in law for the purposes of calculating ASP. CAHC asks that CMS continue to publish ASPs for MFP drugs, consistent with the statute and market-based pricing. We encourage you to work with stakeholders to continue to explore the best way to implement the IRA to help patients, to encourage access to quality care, and to keep patients out of high-cost settings.

Average Sales Price Calculations – Bona Fide Service Fees (BFSFs)

CMS is proposing to tighten the rules for excluding BFSFs from Medicare Part B ASP calculations. Under the new proposal, any service fee, especially those tied to drug price or volume, must meet novel and strict fair-market-value (FMV) calculations and non-pass-through tests before it can be excluded from ASP. We are concerned the proposed changes would impose significant administrative and financial burdens on the supply chain while increasing compliance costs.

CMS has not demonstrated the problem the proposal seeks to fix, nor has it defined the economic and regulatory costs associated with changing the BFSF methodology. In addition, the proposed rule creates different BFSF standards in ASP compared to the MDRP program. Manufacturers and distributors will now have to navigate an uncertain environment created through this regulatory disparity.

Recommendation: CMS should withdraw the BFSF proposal, produce a regulatory and economic analysis that shows the costs and benefits of changing the methodology, and only move forward if the benefits outweigh the costs. CMS should apply any changes evenly across programs.

Addressing physician work time

As MedPAC and others have identified, there are substantial problems with the current time measurements used in determining the resources used to calculate payments for work values in the physician payment formula. To establish the time component, the AMA surveys physicians to determine the length of time necessary to perform a service. Because the AMA's methodology tends to favor specialists, this approach has skewed reimbursements upward for specialty care and contributed to a growing specialist workforce, while the share of general practitioners and primary care providers has steadily declined. The surveys are also highly subjective and not exactly accurate. Some response rates to the current surveys are 10 percent or less, and call into question the survey's ability to accurately capture the actual time used to provide a service to a beneficiary. It is critical to ensure the time estimates

are accurate to ensure the accuracy of the fee schedule. Much is at stake as this survey data is applied to thousands of services totaling billions annually.

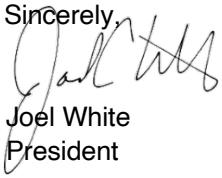
To address these distortions, CMS proposes to layer in an adjustment alongside the traditional survey and AMA inputs when calculating physician work values. Specifically, payments for services where direct patient contact plays a minimal role would be scaled back to reflect greater efficiency—efficiencies that AMA surveys and CMS's current formula have failed to capture. Implementation would rely on productivity benchmarks produced by CMS's Office of the Actuary. CMS is also proposing to change the way it calculates the MEI productivity adjustment, giving preference to empiric studies of time over low-response-rate survey data. The goal is to encourage greater primary care access and lower costs.

CMS solicited feedback on the approach and methods to collect empirical data. We suggest a technology-based approach. Objective, verifiable time data can be captured by using biometric timestamps at the start and end of each service. Both physician and patient would confirm the encounter's closure before any claim is submitted, and could be surveyed by provider type across different geographic areas. These precise, procedure-coded time records can then be aggregated, validated, and analyzed to produce accurate benchmarks for service duration by specialty, region, and provider efficiency. We believe a data validated approach is better than an adjustment based on an estimate of productivity through the Actuary because it would be based on actual physician behavior rather than guesses.

Conclusion

Thank you for your consideration. We stand ready to assist CMS in refining these policies to deliver on the promise of affordable, reliable drug coverage for Medicare beneficiaries.

Sincerely,



Joel White
President