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VIA ELECTRONIC FILING – http://www.regulations.gov

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1832-P
P.O Box 8016
Baltimore, MD 21244-8016

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

Dear Administrator Oz:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to respond to the proposed rule published by the Centers for Medicare & Medicaid Services (CMS) concerning calendar year (CY) 2026 revisions to payment policies under the physician fee schedule, other changes to Part B payment and coverage policies, and the Medicare Prescription Drug Inflation Rebate Program. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are laser-focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than $850 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.[1]

PhRMA's positions and recommendations on the proposals contained in the proposed rule, for which we provide more detail below, are summarized as follows:

- CMS should use its authority to exclude the Maximum Fair Price (MFP) for drugs selected for price setting under the Inflation Reduction Act (IRA) from the calculation of Average Sales Price to prevent significant harm to both physician and patient access to physician administered drugs.
- PhRMA is disappointed that CMS is not yet moving forward with mandatory covered entity reporting to a 340B claims data repository in order to identify and exclude 340B units from Part D inflation rebates. However, we believe the "Prescriber-Pharmacy" claims-based estimation approach laid out in the proposed rule is a better methodology for identifying 340B units than CMS' prior estimation proposal. We recommend that CMS make a number of critical changes to the "Prescriber-Pharmacy" estimation approach to improve its accuracy before implementing it.

[1] PhRMA. (July 2025). 2025 PhRMA Annual Membership Survey. Available at: https://cdn.aglty.io/phrma/Report%20-%20PhRMA%202025%20Annual%20Membership%20Survey%20-%20July%202025.pdf

- CMS should withdraw its proposal that Drugs Covered as Preventative Services (DCAPS) under Part B meet the definition of Part B rebatable drugs for purposes of the Part B inflation rebate program. DCAPS are covered under Part B as services, not as separately payable drugs. As such, they do not meet the definition of a Part B rebatable drug.

- PhRMA supports CMS' efforts to harmonize the treatment of bundled arrangements across average sales price (ASP) and Medicaid Drug Rebate Program (MDRP) reporting wherever feasible. Accordingly, CMS should adopt modifications to the proposed definition of bundled arrangements to conform to the MDRP regulations and revise certain remarks on reallocation of bundled discounts that are inconsistent with the MDRP. We also support CMS' proposal not to incorporate language on value-based arrangements from the MDRP regulations into the ASP regulations due to differences between the Medicaid rebate program and the Part B drug payment system.

- CMS should not move forward with its proposals on bona fide service fees (BFSFs) until it has conducted additional fact-finding to assess the significant operational and contractual burdens and costs these policies would entail and has undertaken a more thorough evaluation of relevant service arrangements and valuation practices through additional research and stakeholder engagement. This will allow CMS to propose, and explain in adequate detail, flexible and efficient policies that would better achieve CMS' and manufacturers' shared goal of ensuring ASP accuracy while avoiding unnecessary administrative and financial burden.

- Because a compliance date of January 1, 2026, is infeasible, if CMS finalizes its BFSF price reporting proposals, these provisions should have an effective date at least eight full quarters following publication of the final rule and should apply only to new contracts entered into after that effective date.

- CMS should not adopt its ASP proposals related to tissue collection for autologous cell-based immunotherapies and gene therapies. Furthermore, CMS provides no reasoned explanation for its proposal to arbitrarily exclude tissue collection fees from BFSF status even when those payments meet the definition of BFSFs.

- The Center for Medicare and Medicaid Innovation (CMMI) should strictly follow statutory evaluation and expansion protocols rather than creating new mandatory models that have not been fully evaluated under the statutory criteria, with respect to existing models and the proposed Ambulatory Specialty Model (ASM); CMMI must not finalize a Phase I model with mandatory participation given the agency's goal of *testing* models.

- In response to CMS' Request for Information on the prevention and management of chronic disease, PhRMA is encouraged by the agency's focus on addressing the root causes of chronic disease. CMS should consider opportunities to advance prevention and management, such as integrating pharmaceutical and lifestyle interventions, improving medication adherence, and strengthening person-centered care through community partnerships and care coordination.

- PhRMA appreciates CMS' efforts to prioritize mental health care for older adults by expanding access to evidence-based, individualized treatment approaches and innovative tools, such as Prescription Digital Therapeutics (PDTs). CMS should support appropriate coverage and reimbursement for these therapies, as well as strengthen care coordination across the continuum, in order to meet the complex behavioral health needs of the Medicare population.

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I. Excluding MFP from the Calculation of ASP

The IRA calls for the Agency to set MFPs for certain "selected drugs," including, beginning in 2028, certain drugs covered under Medicare Part B. In the proposed rule, CMS states that the calculation of ASP for a selected drug covered under Medicare Part B will include units sold at the MFP. As PhRMA has previously outlined to the Agency,[2] we strongly believe this decision will harm providers who administer Part B selected drugs and could jeopardize patient access to medically important treatments. Given the significant implications of CMS' decision for key stakeholders, ***we urge CMS to 1) withdraw its statement that ASP includes MFP, and 2) explicitly confirm the exclusion of MFP from ASP.***

In the sections below, we provide detailed comments in support of this position, including:

- Including MFP in ASP calculations for Part B selected drugs would drastically reduce reimbursement across Medicare, Medicaid, the commercial market, and in other public health programs —especially harming specialty providers as well as small and rural providers— thereby reducing patient access and leading to an increase in closures and consolidation.
- Since MFP is excluded from the average manufacturer price (AMP) under the IRA, it should also be excluded from ASP to ensure the pricing benchmarks remain comparable and the pricing metrics for both the Part B and Part D inflation rebates are treated consistently.
- Because Congress did not authorize including MFP in ASP, CMS *lacks* the legal authority to make such a change, which would have sweeping and lasting negative effects on provider payments and patient access.
- Conversely, CMS can exclude MFP-priced units from the calculation of ASP for Part B selected drugs, using its statutory "counting units" authority—previously used for units sold under the Competitive Acquisition Program—to protect reimbursement and patient access.
- The Agency's "clarification" that manufacturers must include MFP in the calculation of ASP beginning January 1, 2026 goes against the clear structure of the IRA that limits the Program's impact in Part B to 2028 and beyond, as it would result in MFPs affecting the ASP of selected drugs with Part B utilization starting in the third quarter of 2026.

Including MFP in ASP Negatively Impacts Providers and Patients Across Markets

CMS' decision to include MFP in the calculation of ASP for selected Part B drugs will have dramatic and sustained adverse effects on healthcare providers and patients across the Medicare fee-for-service (FFS), Medicare Advantage (MA), and commercial markets. Including MFP in ASP would substantially reduce ASP for Part B selected drugs, which would likely impact (1) MA and commercial plan payments for selected drugs, both during and after the drug is selected; and (2) Medicare FFS payments, for up to an 18-month period after deselection, due to the two quarter lag in ASP reporting and the 12-month average of lagged price concessions. This ASP erosion would occur even while costs necessary to administer products in-office remain the same.

Indeed, research suggests that ASP serves as a payment benchmark for a wide swath of payers outside of Medicare FFS. A recent survey of commercial insurers showed that they reimburse for 63 percent of covered lives in the physician office based on a medicine's ASP.[3] As a result of commercial insurer reliance on ASP as a reimbursement metric, inclusion of MFP in the calculation of ASP could lead to a decrease in provider payments,

[2] PhRMA Comments on IPAY 2028 Draft Guidance. (June 2025). Available at: https://phrma.org/resources/phrma-comments-on-draft-guidance-of-medicare-drug-price-negotiation-program

[3] Avalere Health. (January 2025). Estimating the Spillover Impact of IRA Part B Negotiation. Available at: https://advisory.avalerehealth.com/insights/estimating-the-spillover-impact-of-ira-part-b-negotiation

including up to an 18 percent reduction in add-on payments for provider-administered selected drugs in the commercial market and MA.[4] Moreover, ASP is also the basis of reimbursement for provider-administered medicines in many state Medicaid programs as well as other public health programs. Reduced Medicaid reimbursement could further reduce provider participation in Medicaid, which on average already pays significantly below Medicare rates.[5] Cuts to provider reimbursement as a result of ASP erosion will occur in addition to the significant payment cuts for Part B selected drugs in Medicare itself, which are estimated to total a decrease of up to 61 percent representing up to $18 billion in losses.[6] Providers have indicated that renegotiating reimbursement contracts with commercial payers is unlikely to revert reimbursement to financially viable rates based on ASP or ASP alternatives, with only 6 percent of providers indicating that it is a "very likely" outcome.[7]

If providers face significant reimbursement cuts for Part B drugs as a result of a declining ASP, with erosive effects rippling through various payer channels, providers—particularly independent and community providers—may find themselves unable to offer Part B medicines that are subject to price setting. This may lead to reduced patient access to drugs, including some of the most highly utilized drugs in Medicare Part B. Given the importance of these drugs for the treatment of serious illnesses, such as cancer, CMS' decision to incorporate MFP in the calculation of ASP could eventually harm seniors' health.

Aside from the potentially significant consequences for patient health, CMS' decision is likely to cause patient access issues, and lead to practice closures and consolidation, reducing patient access to community providers and increasing Medicare program costs. Community-based cancer providers have already sounded the alarm, saying that "The cuts to Medicare drug reimbursements under the IRA, if left unchecked, threaten to disrupt cancer care for millions of patients and increase costs across the healthcare system."[8] In particular, small and rural providers, which typically operate on slimmer margins than large health systems, would be least able to absorb the reimbursement cuts triggered by the inclusion of MFP in the calculation of ASP. These effects will have real impacts on patient access to medicines and their health outcomes: 92 percent of community providers surveyed in a recent analysis indicate that their practices would be likely to stop stocking selected Part B medicines when faced with IRA reimbursement cuts, and 79 percent of providers anticipate a moderate or severe impact to patient access to Part B medicines.[9] When faced with the anticipated payment cuts under the IRA, 81 percent of providers indicate that they would refer more patients to costlier hospital outpatient departments.[10]

CMS Should Align the Treatment of ASP with the IRA's Exclusion of MFP from AMP

Under the IRA, MFP is explicitly excluded from the calculation of AMP, and sales data captured in AMP are a subset of data included in ASP. Specifically, AMP represents the average price paid to the manufacturer by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacy purchases directly from the manufacturer, while ASP represents manufacturer sales of a drug to all eligible purchasers,

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[4] *Ibid.*
[5] MACPAC. (January 2025). Evaluating the Effects of Medicaid Payment Changes on Access to Physician Services. Available at: https://www.macpac.gov/wp-content/uploads/2025/01/Evaluating-the-Effects-of-Medicaid-Payment-Changes-on-Access-to-Physician-Services.pdf
[6] *Ibid.*
[7] Avalere Health. (September 2025). Provider Perspectives on Medicare Drug Price Negotiation: Implications for Part B Beneficiary Access, Practice Operations, and Reimbursement. Available at: https://advisory.avalerehealth.com/insights/white-paper-provider-survey-on-part-b-negotiation-impacts
[8] Community Oncology Alliance. (September 2024). Analysis: Oncologists Could Face Over $12 Billion Cut in Medicare and Commercial Part B Payments Due to IRA Negotiation. Available at: https://mycoa.communityoncology.org/news-updates/press-releases/analysis-oncologists-could-face-over-12-billion-cut-in-medicare-and-commercial-part-b-payments-due-to-ira-negotiations
[9] Avalere Health. (September 2025). Provider Perspectives on Medicare Drug Price Negotiation: Implications for Part B Beneficiary Access, Practice Operations, and Reimbursement. Available at: https://advisory.avalerehealth.com/insights/white-paper-provider-survey-on-part-b-negotiation-impacts
[10] *Ibid.*

inclusive of sales in retail settings. Since the IRA explicitly excludes MFP from AMP reporting, it is necessary to exclude MFP from ASP reporting as well, since it would create a distortion across these comparable pricing benchmarks to exclude MFP from retail sales reported under AMP but not require such exclusion of MFP under ASP.

Moreover, when Congress established ASP as the basis for Part B drug reimbursement, it also provided a mechanism for monitoring market prices and adjusting ASP-based payments in certain situations. Specifically, section 1847A(d)(3)(C) of the Social Security Act (SSA, the Act) states that if the Office of Inspector General (OIG) finds that the ASP for a drug exceeds its AMP by more than a certain threshold, the lower of 103 percent of AMP or the widely available market price (if any) is substituted as the basis of provider reimbursement for that drug. As Congress envisioned comparability between ASP and AMP as outlined above, we believe it is critical, and logically consistent, to maintain similar exclusions from ASP and AMP to ensure such comparisons are done on an "apples to apples" basis.

Furthermore, since MFP is expressly excluded from AMP, Part D rebatable drugs continue to have inflation rebates calculated on a metric that excludes MFP while they are selected under the Program. By excluding MFP from ASP, CMS would be aligning the treatment for Part B rebatable drugs, whose inflation rebate obligations remain based on ASP while they are selected,[11] as well as once they are deselected. Excluding MFP from ASP is also important for program integrity under the Part B inflation rebate program. If MFP is included in the calculation of ASP, this could cause a spike in ASP once a drug is no longer selected, as there will no longer be sales at MFP flowing into the calculation. Thus, drugs coming off the selected drug list may be more likely to be subject to Part B inflation rebates even when there has been no underlying change in market prices.

Under the Major Questions Doctrine, CMS Cannot Construe the IRA's Silence on ASP as Delegating Authority to Include MFP in ASP

PhRMA continues to maintain that CMS lacks the authority to include MFP in the calculation of ASP. The IRA explicitly includes MFP in Best Price and excludes MFP from AMP,[12] but is silent on whether MFP is included in ASP. Under the major questions doctrine, statutes are not interpreted as authorizing federal agencies to make decisions with "vast economic and political significance" unless the statute does that explicitly.[13]

In enacting the IRA, Congress was well aware of the significance and unprecedented nature of the Drug Price Negotiation Program (the "Program"): HHS said, "[f]or the first time… Medicare is able to negotiate the prices of prescription drugs."[14] The Agency's policy to require that manufacturers include MFP pricing in their ASP calculations will change ASP from a market-based metric—what Congress intentionally created in the 2003 Medicare Modernization Act—to a metric dominated by a single CMS-set price, which, as noted above, is likely to cause major repercussions for providers and patients who rely on physician-administered drugs.

Moreover, selected and deselected drugs may seem uncommon today, but their number will quickly mount, as CMS will choose 20 new selected drugs every year from 2029 forward.[15] Eventually, selected and deselected drugs could account for most covered Medicare drugs. Congress would not have silently permitted CMS to decide whether to trigger such a major, across-the-board, and potentially long-lasting deterioration of price in the marketplace for physician-administered drugs, impacting provider payment rates, patients' access to critical

[11] SSA §1847A(i)(3)(A)(ii).
[12] SSA §1927(c)(1)(C)(ii)(V), (k)(1)(B)(i)(VI).
[13] *Util. Air Regul. Group v. EPA,* 573 U.S. 302, 324 (2014) (internal quotations omitted).
[14] HHS. (August 2023). HHS Selects the First Drugs for Medicare Drug Price Negotiation. Available at: https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html
[15] SSA § 1192(a).

medicines, and with implications for clinical decision making. ***Accordingly, CMS lacks authority to require that manufacturers include MFP in their ASP calculations.***

CMS Has Existing Authority to Exclude MFP from ASP

Under the SSA, the Secretary may establish ASP "units" for manufacturers to report and methods for "counting units" included in ASP for years after 2004.[16] Indeed, CMS previously relied on this authority to exclude units sold to vendors through the Part B Competitive Acquisition Program (CAP) from the calculation of ASP to prevent distortion of the ASP.

Congress established the CAP as an alternative payment methodology to ASP for Part B drugs. A physician could acquire certain Part B drugs either under the traditional buy and bill model or from CAP vendors under contract with CMS. In a 2005 interim final rule, CMS revised the definition of "unit" to state that "the method of counting units excludes units of CAP drugs … administered to a beneficiary by a participating CAP physician."[17]

CMS could invoke this same "counting units" authority to exclude MFP units from ASP to avert the impact of reduced reimbursement rates on providers and patient access. CMS could then amend the definition of a "unit" in 42 C.F.R. § 414.802 to specify that for selected drugs, "units" also excludes units priced at MFP (or for which the manufacturer provided a refund to reduce the provider's net price to MFP) to meet the MFP access requirements under the IRA.

Requiring the Inclusion of MFP in ASP Prior to 2028 is Inconsistent with the IRA's Design

CMS' position that MFP is included in ASP effective as of January 1, 2026 is not only inconsistent with its own clarification that the Part B payment limit for a selected drug for 2026 and 2027 with Part B utilization "will not be based on the MFP unless it is selected for renegotiation . . . and there is an agreed-upon renegotiated MFP," but also is inconsistent with the design of the program, which provides for a two-year delay before Part B drugs are subject to MFPs.[18] Two of the Part D drugs selected for initial price applicability (IPAY) 2026 – Stelara and Novolog – also have Part B utilization. Thus, under the Agency's policy, provider reimbursement for these drugs under Part B will be impacted beginning in the third quarter of 2026, long before Congress intended for MFPs to apply to Part B drugs in IPAY 2028. ***We strongly urge CMS to, at a minimum, clearly state that MFP units are excluded from ASP in this circumstance.***

II. Medicare Inflation Rebate Program – Identification and Exclusion of 340B Units from Part D Inflation Rebate Calculations

PhRMA appreciates the opportunity to provide comments on the Agency's revised proposed approach to identifying and excluding units of Part D rebatable drugs subject to an agreement under Section 340B of the Public Health Service Act (340B units) from the Part D inflation rebate calculation. While we are disappointed that CMS is not yet moving forward with mandated covered entity reporting to a 340B claims data repository given the statutory requirement for CMS to exclude all 340B units from Part D inflation rebate calculations,[19] we believe the "Prescriber-Pharmacy" claims-based estimation approach laid out in the proposed rule, with some

[16] SSA § 1847A(b)(2)(B); after 2004, "[t]he Secretary may establish the unit for a manufacturer to report and methods for counting units as the Secretary determines appropriate to implement this section."
[17] 70 Fed. Reg. 70478, 70481 (Nov. 21, 2005) (amending 42 C.F.R. § 414.802).
[18] 90 Fed. Reg. 32352, 32545 (July 16, 2025).
[19] SSA § 1860D-14B(b)(1)(B). "…beginning with plan year 2026, the Secretary shall exclude from the total number of units for a dosage form and strength with respect to a part D rebatable drug, with respect to an applicable period, <u>*units of each dosage form and strength*</u> of such part D rebatable drug for which the manufacturer provides a discount under the program under section 340B of the Public Health Service Act" (emphasis added).

critical changes, is a better approach to identifying 340B units than the CMS' prior estimation proposal.[20] ***However, to encourage meaningful participation in the voluntary claims data repository and to be able to meaningfully test the repository's ability to exclude 340B units from Part D inflation rebate calculations, we urge CMS to set a clear date in the future when it intends to issue a regulation making reporting to the repository mandatory for all covered entities.*** As noted above, CMS has a statutory requirement to exclude each 340B unit from Part D inflation rebate calculations – the "Prescriber-Pharmacy" claims-based estimation approach, while an improvement, does not meet this obligation. As such, CMS should move with all swiftness towards mandatory reporting to the repository.

PhRMA also notes that broadening the recently announced 340B rebate model pilot[21] to include all Part D drugs would provide a clear and simple path to accurately excluding 340B units from the Part D inflation rebate. CMS could then utilize claims-level data reported by covered entities to manufacturer rebate platforms to populate claims-level data in the repository. ***We urge CMS to work with colleagues in the Office of Pharmacy Affairs and urge them to expand the 340B rebate model pilot as quickly as possible.***

CMS Should Establish a Clear Date Upon Which Reporting to the Repository is Mandatory

As noted above, PhRMA is disappointed that CMS is not yet moving forward with mandatory covered entity reporting to a 340B claims data repository. A claims repository with mandatory reporting and oversight for covered entities would provide a more accurate way for CMS to identify and exclude 340B units from Part D inflation rebate calculations than the proposed estimation approach, including by capturing referrals that would otherwise be missed. As we have commented previously to the Agency, CMS has clear authority to engage in rulemaking under sections 1102(a) and 1871(a)(1) of the Act to require covered entities to submit data on 340B units dispensed to Part D beneficiaries (or to have a third party acting on their behalf submit this data to a repository). CMS could also require covered entities to report such data to the repository as a condition of their Medicare enrollment.

Despite CMS' statement that the Agency will "strongly encourage" covered entities to report claims data to the repository for testing, PhRMA is highly skeptical that many, if any, covered entities will choose to voluntarily report data. CMS has offered no incentives for covered entities to participate in the repository, and covered entities will need to develop data submission and certification processes in order to participate. Needless to say, poor participation in the claims repository will make it very difficult for CMS to test whether the repository is a reliable and accurate method for identifying and excluding 340B units.

To better encourage actual participation, we strongly urge CMS to adopt a regulation, effective no later than October 1, 2027, requiring all covered entities to report data to the repository. If the repository is expected to be up and running at some point in 2026, we recommend that CMS require that mandatory reporting by all covered entities begin for the Part D inflation rebate period beginning October 1, 2027. This sends a clear signal to covered entities that mandatory reporting is expected while still allowing time for covered entities to develop reporting processes. Indeed, CMS has used a similar approach historically for other new reporting requirements. For example, CMS issued guidance in December 2022 extending the requirement to utilize 340B modifiers on Part B claims to covered entities not paid under the Outpatient Perspective Payment System (OPPS) effective January 1, 2024.[22] This allowed impacted covered entities just over a year to prepare their systems to begin using 340B modifiers, but still made clear when mandatory modifier usage was expected.

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[20] 89 Fed. Reg. 61596, 61969 (July 31, 2024). Available at: https://www.govinfo.gov/content/pkg/FR-2024-07-31/pdf/2024-14828.pdf
[21] 90 Fed. Reg. 38165 (August 7, 2025). Available at: https://www.federalregister.gov/documents/2025/08/07/2025-14998/340b-program-notice-application-process-for-the-340b-rebate-model-pilot-program-correction
[22] CMS. (December 2022). Part B Inflation Rebate Guidance: Use of the 340B Modifiers. Available at: https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf

Furthermore, PhRMA encourages CMS to take advantage of the recently announced 340B rebate model pilot[23] in order to populate claims-level data in the repository for pilot participating drugs. Specifically, CMS could utilize claims-level data reported by covered entities to manufacturer rebate platforms, allowing CMS to utilize the claims repository to exclude 340B units from Part D inflation rebate calculations for pilot participating drugs prior to the start of mandatory covered entity reporting. ***We also recommend that CMS align the data fields for the claims repository with the data fields utilized under the 340B rebate pilot to allow for more seamless reporting across programs.*** While similar, the 340B rebate pilot program data fields are more extensive than those proposed by CMS for the claims repository and include the addition of:

- Date Prescribed;
- Quantity Dispensed;
- Prescriber ID;
- 340B ID;
- Rx Bank Identification Number (BIN); and
- Rx Processor Control Number (PCN).[24]

In addition, we also strongly encourage CMS to add a requirement for covered entities to report the original purchase date of the units dispensed.

Finally, PhRMA is disappointed by the Agency's statement in the proposed rule that data submitted to the repository, "would not be made available to external parties, including manufacturers…."[25] Manufacturers need access to data submitted to the repository for assurance that covered entities are submitting information on all Part D claims. As such, ***we strongly urge CMS to allow manufacturers to view repository data for their own drug products.***

Critical Changes are Needed to the Prescriber-Pharmacy Claims-Based Estimation Approach

While the proposed Prescriber-Pharmacy claims-based approach will likely result in more accurate identification of 340B units within Part D than previous CMS proposals, it still suffers from some critical weaknesses that CMS must address before finalizing this approach. As CMS itself notes, the claims-based estimation approach is not well-suited for drugs dispensed to beneficiaries with support from AIDS Drug Assistance Programs (ADAPs) and can miss drugs dispensed through covered entity-owned pharmacies and in-house pharmacies. In addition, the Prescriber-Pharmacy claims-based estimation approach will not capture 340B units on claims stemming from provider referrals.[26] And on the other side of the ledger, the Prescriber-Pharmacy claims-based estimation approach may incorrectly identify some claims as 340B by not appropriately accounting for physicians providing care at multiple facilities (some of which may be 340B covered entities and others not).

To better capture 340B units dispensed to Part D beneficiaries through in-house or other covered entity-owned pharmacies, PhRMA recommends that CMS expand its proposed geolocation methodology beyond pharmacies listed in the Health Resources & Services Administration's (HRSA) Office of Pharmacy Affairs Information System (OPAIS) contract pharmacy database. Measured at 340B prices, across the full 340B program less than

[23] 90 Fed. Reg. 38165 (August 7, 2025). Available at: https://www.federalregister.gov/documents/2025/08/07/2025-14998/340b-program-notice-application-process-for-the-340b-rebate-model-pilot-program-correction
[24] 90 Fed. Reg. at 38167.
[25] 90 Fed. Reg. at 32642.
[26] While PhRMA has concerns that covered entities may be inappropriately collecting 340B discounts on units prescribed as a result of referrals, to the extent those 340B discounts are claimed, these units should be excluded by CMS from Part D inflation rebate calculations.

20% of spending went through contract pharmacies as of 2021.[27] Thus, it is critical to ensure the Agency's methodology captures in-house and covered-entity-owned pharmacies. To do this, CMS should compare the name and address fields for all pharmacies reported to the National Council for Prescription Drug Programs (NCPDP) with all addresses associated with covered entities, including shipping addresses, for all covered entities registered with HRSA. ***In the future, PhRMA also recommends that CMS and HRSA require 340B covered entities to report the National Provider Identifier (NPI) for their in-house, covered entity-owned, and contract pharmacies and the Drug Enforcement Administration number and Health Industry Number for their in-house pharmacies.***[28] This would allow CMS to more easily identify applicable pharmacies without needing to geolocate addresses.

ADAPs are unique among 340B covered entities and already utilize a rebate model for manufacturers to provide access to 340B pricing. To capture 340B units dispensed to beneficiaries with support from ADAPs, we recommend that CMS take advantage of this existing rebate model and have ADAPs report 340B units dispensed to Part D beneficiaries to CMS. CMS should also encourage ADAPs, as with all 340B covered entities, to begin reporting data to the 340B claims repository. However, CMS should be aware that the current timelines for ADAP 340B rebate agreements can exceed the timeline for Part D inflation rebates laid out under the Inflation Reduction Act. For example, based on our understanding, ADAPs may have up to 12 months after the end of each calendar quarter to report rebate claims to manufacturers, with manufacturers having a further quarter to then reconcile the claims. This means that not all data on 340B utilization could be reported to CMS or the repository within the 9-month timeframe following the end of each Part D applicable period, as some utilization cannot be validated until outside the nine-month applicable period. Additionally, ADAPs may be limited in which fields they can report to the repository for units where they are not the dispensing entity. ***We recommend that CMS adjust manufacturer Part D inflation rebate obligations for subsequently received data on 340B units dispensed to beneficiaries with support from ADAPs through the established reconciliation process for Part D inflation rebates.***

Finally, PhRMA supports the Agency's proposal to augment the prescriber NPI and Medicare Provider Number (MPN) file under the "Prescriber-Pharmacy" estimation approach by using NPI when the NPI is listed in the 340B OPAIS database but an MPN is not. We believe this appropriately handles situations where a covered entity does not have an MPN.

CMS Should Not Use the "Beneficiary-Pharmacy" Estimation Approach at this Time

PhRMA has significant concerns that the Beneficiary-Pharmacy approach described in the proposed rule will lead to a significant undercounting of 340B units dispensed to Part D beneficiaries. Particularly for medications that are taken on a recurring basis, identifying 340B units by looking at monthly covered entity service and pharmacy pairings for a beneficiary could miss refill prescriptions that occur in the months following the provider visit.

Utilizing the fill number to link prescriptions over a period of time, such as one year, back to one provider visit would help to address this shortcoming. ***However, we urge CMS not to move forward with the Beneficiary-Pharmacy estimation approach without refinement and the opportunity for further comment.***

III. Medicare Inflation Rebate Program – Part B Drugs Covered as Preventative Services

PhRMA disagrees with the Agency's statement in the proposed rule that "[t]he current set of drugs covered as [Drugs Covered as Preventative Services (DCAPS)] drugs meets the definition of a Part B rebatable drug under

[27] CBO. (September 2025). Growth in the 340B Drug Pricing Program. Figure 13. Available at: https://www.cbo.gov/publication/61730#_idTextAnchor030

[28] For in-house pharmacies, the NPI may be unique to the facility but not the individual pharmacy. Adding the DEA and HIN numbers would allow CMS to link in-house pharmacies to a covered entities 340B ID.

section 1847A(i)(2) of the [Social Security] Act," and that therefore, "CMS intends to identify DCAPS drugs as Part B rebatable drugs as defined in section 1847A(i)(2) of the Act."[29]

DCAPS are covered under Part B as additional preventative services, not as separately payable drugs. As such, they do not meet the definition of a Part B rebatable drug. Indeed, in establishing payment for DCAPS, CMS noted that the "authority at section 1833(a)(1)(W)(ii) of the Act provides for payment for additional preventive services, including drugs. This authority differs from the authority used to pay for drugs that are separately paid as drugs and biologicals under other Part B payment authorities. Specifically, payment for most drugs separately payable under Part B is authorized at section 1833(a)(1)(S) of the Act and outlined at section 1842(o)(1)(C) of the Act… because [DCAPS] are not described in section 1842(o)(1)(C) of the Act, provisions under section 1847A of the Act would not apply…."[30] And CMS choosing to base payment for DCAPS on Average Sales Price (ASP) does not convert what are services into separately payable drugs.

We therefore urge CMS to withdraw its proposal and clearly state that DCAPS do not meet the definition of Part B rebatable drugs under section 1847A(i)(2) of the Act.

IV. Average Sales Price: Bundled Arrangements and Bona Fide Service Fees

PhRMA shares CMS' commitment to ensuring accurate ASP reporting and appreciates CMS' attention to these issues. We recognize CMS' efforts in the proposed rule to establish regulations that clearly define ASP-calculation requirements and manufacturer obligations — these are important steps toward promoting consistency, transparency, and precision in ASP reporting across the industry. At the same time, we are concerned that CMS has not fully considered the operational burden and cost that many of these proposals would impose, or whether the agency's policy goals could be achieved through more flexible standards. Many of the proposed requirements would introduce extensive procedural obligations with no clear added value. By proposing rigid mandates, CMS risks diverting manufacturer and other stakeholder resources towards costly compliance activities that do little to improve data accuracy or program integrity and do not account for certain realities of pharmaceutical contracting. We urge CMS to consider whether these proposals may inadvertently hinder, rather than advance, the Trump Administration's goals of promoting economy and efficiency while reducing administrative bloat. As the President has cautioned, federal regulations have become an "ever-expanding morass" that often "further increas[e] compliance costs and the risk of non-compliance."[31] Without refinements to produce a more balanced approach, these proposals could undermine the President's efforts to "reduce[] unnecessary, burdensome, and costly Federal regulations" by introducing inefficiencies and discouraging innovation.[32]

As our comments below describe, the burden associated with many of the proposed requirements could potentially lead manufacturers to default to treating certain non-discount transactions, such as bona fide service fees, as price concessions. CMS should seek a measured approach that supports accurate ASP reporting without introducing complexities that may force manufacturers to calculate ASPs that arguably are understated or

[29] 90 Fed. Reg. at 32635.
[30] 89 Fed. Reg. 97710, 98221 (Dec. 9, 2024). Available at: https://www.govinfo.gov/content/pkg/FR-2024-12-09/pdf/2024-25382.pdf
[31] *See* Exec. Order No. 14192, *Unleashing Prosperity Through Deregulation*, 90 Fed. Reg. 9065 (January 2025).
[32] The White House, *Fact Sheet: President Donald J. Trump Launches Massive 10-to-1 Deregulation Initiative.* (January 2025). Available at: https://www.whitehouse.gov/fact-sheets/2025/01/fact-sheet-president-donald-j-trump-launches-massive-10-to-1-deregulation-initiative/; *see also* Exec. Order No. 14192, *Unleashing Prosperity Through Deregulation*, 90 Fed. Reg. 9065 (January 2025) ("The ever-expanding morass of complicated Federal regulation imposes massive costs on the lives of millions of Americans, creates a substantial restraint on our economic growth and ability to build and innovate, and hampers our global competitiveness. . . . It is the policy of my Administration to significantly reduce the private expenditures required to comply with Federal regulations to secure America's economic prosperity and national security and the highest possible quality of life for each citizen.").

overstated in order to comply with CMS' BFSF test.[33] It also could disrupt market forces by under-reimbursing providers and skewing clinical decisions away from necessary therapies.

Additionally, the proposed rule lacks clarity in key areas, and in some instances, the preamble appears to conflict with the regulatory text. Further, as discussed below, certain CMS proposals are ill-defined and seem to rely on ideas about how certain fees work that are not clearly explained in the proposed rule. It will be helpful for CMS to take additional time to study these issues and ultimately develop proposals that are well-grounded in a comprehensive understanding of the policies in question and supported by a clear and articulated rationale.

Finally, CMS proposes that many of the ASP-related proposals take effect on January 1, 2026. With comments due by September 12, 2025, CMS would have less than two months to consider stakeholder input, incorporate feedback and issue a final rule with a prospective start date that satisfies the Congressional Review Act's minimum requirement of a 60-day delay between the publication of a "major rule" in the *Federal Register* and its effective date.[34] This timeline would leave manufacturers very little time to prepare for implementation. Given the scope and complexity of the proposed changes and the substantial operational and contractual modifications they would entail, this timeline is not feasible. PhRMA urges CMS to take the time required to engage in a meaningful review of stakeholder comments, including additional fact-finding to evaluate more fully the rationale for certain proposals, the burdens they may impose, and the potential alternatives. ***PhRMA strongly recommends that, to ensure that manufacturers have adequate time for planning, system updates, and compliance readiness, these provisions should apply only to new contracts entered into after the effective date for any BFSF provisions adopted in the final rule, which should be at least eight full quarters following publication of the final rule.***

a) Bundled Sales Arrangements

CMS Should Adopt a Definition of "Bundled Arrangement" that Mirrors the Medicaid Drug Rebate Program (MDRP) Definition to Ensure Consistency and Minimize Ambiguity

In the proposed rule, CMS proposes to adopt the following definition of "bundled arrangement":

> Bundled arrangement means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or biological or other drugs or biologicals or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary, purchasing patterns, prior purchases), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs or biologicals been purchased separately or outside the bundled arrangement.[35]

CMS indicates that its proposal upholds its "intent to remain consistent, as appropriate, with Medicaid's policy for calculating AMP."[36]

PhRMA generally supports CMS' proposal to define "bundled arrangement" in a manner consistent with the MDRP definition of "bundled sale," at 42 C.F.R. § 447.502. Historically, CMS has prioritized alignment across

[33] 90 Fed. Reg. at 32543.
[34] 5 U.S.C. § 801(a)(3).
[35] 90 Fed. Reg. at 32542, 32849 (proposed 42 CFR § 447.802).
[36] 90 Fed. Reg. at 32542.

Medicare and Medicaid pricing methodologies where feasible,[37] and PhRMA agrees that consistency across programs is critical to promoting clarity and reducing administrative burden and the risk of error.

However, CMS' proposed definition of a bundled arrangement falls short of this objective. Specifically, CMS includes "purchasing patterns" and "prior purchases" in the parenthetical list of examples of performance requirements that may give rise to a bundled arrangement, without defining the terms or explaining their relevance. These terms do not appear in the MDRP definition of a "bundled sale" at 42 C.F.R. § 447.502. CMS does not explain why it proposes to add these words — or even acknowledge that they are not found in the MDRP regulatory definition, thus creating significant ambiguity. PhRMA is concerned that the inclusion of undefined and unexplained terminology will introduce confusion and result in inconsistent application, undermining CMS' goals of regulatory alignment across the MDRP and Part B frameworks and consistent ASP treatment across manufacturers. ***Accordingly, we recommend that CMS delete these phrases from its proposed definition of a "bundled arrangement."***

Requiring Reallocation of Non-Contingent Discounts is Inconsistent with MDRP Standards

PhRMA urges CMS not to require the reallocation of non-contingent discounts in bundled arrangements. We raise this issue because the proposed rule preamble (but not its regulatory text) suggests that non-contingent discounts must be reallocated. This approach deviates from the MDRP regulatory requirements and current AMP and best price (BP) calculation practices, and would impose unnecessary complexity and compliance burdens on manufacturers. Additionally, reallocating non-contingent discounts could potentially distort ASP calculations in some cases by producing prices that diverge from the commercial intent behind a bundled arrangement.

In the proposed rule, CMS proposes to amend 42 C.F.R. § 414.804(a)(2) to add substantively the same language that appears in the MDRP definition of "bundled sale" regarding how manufacturers should reallocate discounts under bundled arrangements:

> (iii) The discounts in a bundled arrangement as defined at § 414.802, <u>including those discounts resulting from a contingent arrangement</u>, are allocated proportionately to the dollar value of the units of all drugs or products sold under the bundled arrangement.
>
> (iv) For bundled arrangements where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs or products in the bundle.[38]

CMS asserts that this regulatory language and the preamble guidance in the 2016 MDRP Final Rule supports the view that "the 'unbundling' of both contingent <u>and non-contingent discounts</u> is appropriate because 'all the discounts' in the bundled arrangement should be proportionally allocated."[39] CMS states in the proposed rule that it would adopt this approach for the ASP calculation "because of our stated intent for consistency with policies for AMP."[40]

CMS is incorrect that the 2016 MDRP Final Rule preamble clearly requires the reallocation of non-contingent discounts. The regulatory text discussed above was the subject of extensive commentary in the 2016 MDRP Final

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[37] 72 Fed. Reg. 38122, 38151 (Jul. 12, 2007) ("[W]e believe incorporating appropriate consistencies across the calculations of ASP and AMP, as allowable by statute, is rational . . . [and] will result in a lower potential for error and more accurate calculations of both prices."); 72 Fed. Reg. 39142, 39159 (Jul. 17, 2007) ("We believe a consistent methodology for addressing bundled sales in the Medicaid and Medicare Part B programs will reduce the burden and likelihood of errors for manufacturers calculating and reporting Medicaid rebate prices and ASP.").

[38] 90 Fed. Reg. at 32542, 32849 (emphasis added).

[39] 90 Fed. Reg. at 32542–43 (emphasis added).

[40] 90 Fed. Reg. at 32543.

Rule preamble, in which CMS explained that it removed proposed regulatory language in response to numerous stakeholder comments advocating that only contingent discounts within a bundle should be reallocated, and not non-contingent discounts. Originally the 2012 MDRP proposed rule proposed to revise the bundled sale definition by adding the underlined phrase to the language discussed above:

> The discounts in a bundled sale, including but not limited to those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement.[41]

However, in the 2016 MDRP Final Rule, CMS stated that "[s]everal commenters expressed concern that the phrase 'including but not limited to' will require manufacturers to allocate noncontingent discounts provided on drugs included in bundled sales (as well as any contingent discounts on those drugs) across all products in the bundled sale. The commenters indicated that non-contingent discounts are not part of bundled arrangements and should not be subject to allocation."[42] In response, CMS stated that "[w]e understand the commenters' concerns regarding the proposed language 'but not limited to' in the definition as proposed at § 447.502, and therefore, in this final rule, we are not finalizing that proposed language."[43]

The clear implication from this exchange is that CMS deliberately revised its proposed regulatory language to avoid requiring the reallocation of non-contingent discounts. If CMS intended to include non-contingent discounts within the scope of reallocation, it is unclear why it would have so explicitly narrowed the regulatory language.

Thus the 2016 MDRP Final Rule preamble and text support the conclusion that manufacturers are not required to reallocate non-contingent discounts. If anything, the absence of explicit direction in the regulatory language on this point allows manufacturers to adopt reasonable assumptions regarding non-contingent discount allocations.[44] The 2016 finalized regulatory language, which does not clearly require the reallocation of non-contingent discounts, was deliberately edited by CMS to exclude language that would have imposed such a reallocation requirement in the MDRP context. This same language is now proposed by CMS in the Part B context, yet CMS now indicates it has a different meaning.

Accordingly, to accomplish CMS' stated goal of maintaining consistency with the MDRP regulations, CMS should not interpret its proposed regulatory text to require reallocation of non-contingent discounts. If CMS believes the ASP context warrants a different standard, CMS should first propose regulatory language clearly requiring the reallocation of non-contingent discounts, and second, provide a reasoned explanation for the difference in policy so that stakeholders have adequate notice and an opportunity to provide meaningful comment for the agency's consideration. As it stands, CMS offers no justification for departing from MDRP principles (and does not appear to understand that its proposal would do so). Arbitrarily imposing a different standard in the ASP context would introduce unnecessary complexity and compliance burdens for the manufacturers that otherwise treat bundled arrangements consistently across programs. Such a shift could require manufacturers to reconfigure government pricing systems to treat the same non-contingent discounts differently across ASP and AMP/Best Price — creating operational inefficiencies, regulatory discord, and confusion in both ASP and Medicaid rebate calculations, all without a clear rationale or offsetting benefit.

Finally, beyond diverging from MDRP standards for no stated reason, requiring the reallocation of non-contingent discounts in ASP calculations could also be problematic from a policy perspective. The financial impact of doing so would not consistently increase or decrease ASPs; rather, the impact would vary entirely based on the

[41] 81 Fed. Reg. 5170, 5181 (Feb. 1, 2016).
[42] 81 Fed. Reg. at 5182.
[43] 81 Fed. Reg. at 5182 (emphasis added).
[44] *See*, *e.g.*, 83 Fed. Reg. 12770, 12785 (Mar. 23, 2018) (instructing manufacturers to make reasonable assumptions in the calculation of AMP and Best Price, in the absence of specific statutory or regulatory law).

particular arrangement and the actions of individual customers. However, this approach could inadvertently amplify the influence of bundled arrangements on ASP by incorporating discount dollars that are not directly tied to the intent of the bundle. Expanding the scope of bundled arrangements to include such unrelated discounts could potentially reduce the precision of ASP calculations in some cases, and manufacturers should not be required to take this approach. ***Accordingly, we recommend that in the final rule, CMS make clear that it is not adopting a requirement for reallocation of non-contingent discounts.***

CMS' Decision to Exclude Value-Based Arrangements from the ASP Bundled Arrangement Definition Appropriately Reflects Structural Differences Between the Medicare and Medicaid Frameworks

In the 2020 MDRP Final Rule, CMS updated the MDRP "bundled sale" definition to add that "[v]alue-based purchasing (VBP) arrangements may qualify as a bundled sale."[45] In the proposed rule, however, CMS declined to add this language to the ASP regulations because it continues to evaluate how VBP arrangements — and, more broadly, discounts associated with bundles across time periods — should be considered for drugs payable under Medicare Part B.[46] To that end, CMS solicits comments on how discounts associated with sales that may be considered bundled across time periods could be accounted for in the ASP calculation.[47]

PhRMA supports CMS' proposal not to adopt the portion of the MDRP bundled sale definition that addresses VBP arrangements. While PhRMA generally agrees that harmonization between MDRP and ASP pricing methodologies is appropriate where feasible, differences in the structure, objectives, and statutory frameworks of the MDRP and Part B program warrant some distinctions. CMS acknowledges this principle, noting that "although ASP and AMP serve similar, but not identical, purposes, differences between these calculations provide a rationale for, and in some instances may require, minor differences between the final policies adopted in Medicaid and Medicare regulations."[48] The treatment of discounts bundled across time periods is one such area where divergence is warranted.

In the MDRP context, manufacturers report pricing metrics that determine rebate obligations to state Medicaid programs. The MDRP framework includes a well-established mechanism for revising prior price reports, allowing for alterations based on updated data — including adjustments resulting from VBP arrangements or other time-based bundled discounts (within 12 quarters of the initial report). These amounts are automatically reconciled through rebate transactions with state Medicaid programs.

By contrast, the ASP calculation serves a different purpose of establishing a (typically) one-time reimbursement amount for providers. Unlike the MDRP, Part B payments are not supported by a routine mechanism ensuring ASP revisions are reflected in adjusted payments. Specifically, CMS' ASP Restatement Policy Overview makes clear that restatements of ASP-based payment limits are permitted only in narrowly defined circumstances when multiple criteria are met.[49] Moreover, even when CMS publishes restated payment limits, its guidance does not

[45] 42 C.F.R. § 447.502.
[46] 90 Fed. Reg. at 32543.
[47] 90 Fed. Reg. at 32543
[48] 72 Fed. Reg. at 66257; *see also* 90 Fed. Reg. at 32542 (stating CMS' "previously stated intent to remain consistent, as appropriate, with Medicaid's policy for calculating AMP" (emphasis added)).
[49] CMS. (June 2025). Average Sales Price (ASP) Restatement Policy Overview. Available at: https://www.cms.gov/files/document/average-sales-price-asp-restatement-policy-overview-updated-06/16/2025.pdf ("If corrected data are received from manufacturers after the correction deadline or if the ASP pricing files have been published, CMS will analyze the impact of the corrected data on payment limits to determine if a restatement is needed based on two timeframes . . . Because restating payment limits in these circumstances imposes a substantial administrative burden on [MACs] to potentially reprocess claims and retest systems, CMS does so only when the price change would meet three or more of the following criteria . . . .").

require Medicare Administrative Contractors (MACs) to adjust provider payments retroactively unless a provider specifically requests such an adjustment.[50]

These structural and operational differences underscore why CMS' decision not to adopt the MDRP's treatment of value-based arrangements within the ASP framework is appropriate. There is no apparent purpose for applying time-based discounting concepts to ASP without an automatic mechanism for retrospective reconciliation. ***PhRMA urges CMS to continue evaluating this issue carefully and to avoid incorporating time-based bundled discount concepts into ASP calculations unless it establishes a robust, automated payment adjustment process that accounts for revised ASP values stemming from intertemporal bundled discounts.***

b) Bona Fide Service Fees (BFSFs)

PhRMA appreciates CMS' efforts to respond to stakeholder concerns and provide greater clarity regarding the treatment of BFSFs. We support CMS' goal of promoting consistency in BFSF determinations and welcome its engagement on these important issues.

However, the proposals outlined in the proposed rule are underdeveloped, largely unexplained, and if finalized would impose significant new burdens on manufacturers and many other stakeholders without adequate justification — and without any payoff in terms of improving the accuracy of ASP calculations. The proposals appear to lack an understanding of the types of fees manufacturers pay, the operational realities of service arrangements, and the practices manufacturers use to confirm service fees are within fair market value (FMV) ranges. ***We urge CMS to conduct further research and analysis before finalizing new requirements related to BFSFs. We recommend that CMS review studies of the pharmaceutical marketplace that may be instructive in understanding the types of fees frequently paid by manufacturers, including the Federal Trade Commission's ongoing investigation into the role and impact of PBMs.[51] CMS should not move forward with its ASP proposals until it has conducted a more thorough evaluation of the relevant service arrangements and valuation practices through additional research and stakeholder engagement.***

In any event, as further discussed below, given the substantial new burdens that these proposals would impose on manufacturers and other stakeholders, as well as the problems they would engender, CMS would need to adopt a reasonable implementation period to ensure adequate time for planning, system updates, and compliance readiness in the event it decides at some point to finalize these proposals.

Finally, CMS' BFSF proposals include several new requirements related to the submission of proprietary information. ***Although PhRMA opposes certain of these initiatives, we urge CMS to confirm that any such information would be treated as confidential, consistent with the requirements of 42 U.S.C. § 1396r-8(b)(3)(D).*** Safeguarding proprietary data is essential to maintaining trust in the ASP reporting process and ensuring compliance with statutory confidentiality obligations.

CMS Should Clarify the Scope of Fees Subject to BFSF Analysis

As a threshold matter, we recommend that CMS not finalize its proposed changes to the BFSF provisions until it provides clear guidance regarding the types of fees that are — and are not — subject to the BFSF analysis. In the proposed rule, CMS introduces changes to the definition of BFSF that would significantly impact how manufacturers determine FMV and assess whether a fee meets the "not passed on" criterion.[52] However, CMS

[50] See, e.g., CMS. (October 2018). CMS Manual System, Pub 100-04 Medicare Claims Processing 6. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4154CP.pdf (standard instruction to MACs stating "[t]he contractors shall not search and adjust claims that have already been processed unless brought to their attention").
[51] Fed. Trade Commission. Pharmacy Benefit Managers. Available at: https://www.ftc.gov/terms/pharmacy-benefits-managers-pbm.
[52] 90 Fed. Reg. at 32543–45, 32849.

never specifies which categories of services fees are subject to the BFSF test, creating substantial uncertainty regarding the scope of CMS' proposed requirements.

Pharmaceutical manufacturers enter into a wide array of services arrangements with various parties, many of which do not involve entities that purchase or pay for pharmaceutical products and/or are wholly unrelated to such purchases and payments. These include fees for services such as tax preparation, clinical trial support, data analytics, and contract manufacturing of active pharmaceutical ingredients (API). Without clear guidance on the scope of the BFSF analysis, there may be confusion and inconsistency among manufacturers regarding which service fees must be analyzed under the BFSF test for purposes of ASP calculations. In light of the many additional burdens that CMS proposes to impose on manufacturers to determine whether a fee qualifies as a BFSF, it is important that the BFSF analysis be limited to fees that are directly related to the sale of drugs and that, absent the BFSF analysis, would properly be considered a price concession under the ASP framework.

CMS has previously recognized, in the context of the MDRP, that not all fees to any entity must be subject to the BFSF test. Specifically, CMS explained that for purposes of the MDRP, "certain fees unrelated to the sale of a drug or drugs but rather to the overall business of the manufacturer, such as tax preparation services," do not need to be analyzed under the BFSF test because "the transactions to such entities (tax preparers) would not be included in the determination of AMP or best price."[53] However, CMS declined to amend the regulation to note the fees that are subject to the BFSF analysis (or not) for purposes of the MDRP, and CMS provided no clarifying information in the proposed rule. CMS should take this opportunity to provide such clarity in the context of ASP reporting.

Because the scope of fees subject to the BFSF analysis fundamentally determines the reach and impact of CMS' proposed changes, it is imperative that CMS provide clear guidance on this issue before imposing new valuation and submission requirements.

The Proposed FMV Methodology is Overly Rigid and Burdensome

CMS' proposed FMV standards and methodologies under proposed 42 C.F.R. § 414.802 mark a substantial departure from current regulatory requirements for pharmaceutical manufacturers and raise concerns about feasibility, cost, and operational burden.

In the proposed rule, CMS proposes to require for the first time that manufacturers apply specific methodologies for FMV analyses. Under the proposed regulatory text, for fees that do not vary directly with the amount or price of the drug, manufacturers would be required to determine FMV based on "comparable market transactions that generally reflect current market conditions or the cost of the service plus a reasonable markup to the total cost."[54] For fees that do vary directly with the amount or price of the drug, CMS proposes that the "fair market value assessment must be conducted by an independent third-party valuator" and that the FMV must be determined using the cost of the service plus a reasonable markup to the total cost.[55] For both types of fees, CMS proposes that if the service arrangement is ongoing, the "fair market analys[i]s must be updated at a frequency no less than the renewal frequency of the agreement."[56]

PhRMA shares CMS' goal of ensuring BFSFs are correctly identified. At the same time, we are concerned that the proposed FMV methodology requirements are overly rigid and burdensome. Mandating third-party valuations for each new service arrangement where the fee varies with the amount or price of the drug and requiring reassessments at every contract renewal would introduce substantial inefficiencies and costs, without a clear

[53] 81 Fed. Reg. at 5179.
[54] 90 Fed. Reg. at 32849.
[55] 90 Fed. Reg. at 32849.
[56] 90 Fed. Reg. at 32849.

benefit to ASP accuracy. Further, CMS' proposal lacks clarity regarding what would constitute a valuation that meets the proposed requirements for a FMV assessment or reassessment. ***We urge CMS to adopt a more flexible framework that allows manufacturers to use a variety of validated approaches (which may include using a combination of methodologies to assess FMV) to support accurate — and efficient — FMV assessments.***

CMS appears to have an incomplete understanding of how manufacturers currently ensure FMV compliance and the associated costs and burdens of such compliance. We encourage CMS to conduct further fact-finding on this issue, with particular attention to the increased cost and operational burden associated with independent FMV reports. In particular, PhRMA understands that more complex FMV reports covering multiple services types and geographic areas can cost upwards of $100,000. In light of these costs — and the volume of service agreements that manufacturers may enter into — some manufacturers engage independent third-party valuators to establish FMV ranges for common service types (e.g., distribution services). These ranges are then used by in-house personnel to guide contract negotiations and renewals for the applicable service type, ensuring fees remain within the FMV range without requiring a new valuation for each agreement involving similar types of services and vendors.

The cost and operational burden of FMV assessments would increase dramatically if CMS required manufacturers to obtain a standalone FMV report from an independent third-party valuator for each service agreement involving a fee that varies with the amount or price of the drug. CMS' proposal to require independent-third party valuation already is problematic in light of the relatively small number of firms with the experience, expertise, and current capacity to handle a substantial increase in volume of work. Requiring that the valuator also have no financial relationship with either party to the fee arrangement other than the FMV analysis is overly restrictive and would unnecessarily exclude parties capable of conducting these analyses, including accounting, actuarial, or transfer pricing firms already engaged by manufacturers for other services. These firms, which typically silo their operations across different departments to permit the exercise of independent judgment despite the existence of broader relationships, can, and should be permitted to, conduct independent FMV analyses even if they perform other services for the parties to the fee arrangement. ***While many of CMS' proposals regarding FMV assessments need more flexibility, at a minimum, we urge CMS to clarify that manufacturers may rely on FMV ranges established by third-party evaluators for common service types and may apply existing FMV assessments to new contracts involving substantially similar services and vendors. We further urge CMS not to adopt the policy that a valuator have no financial relationship with parties to the fee arrangement other than the FMV analyses and instead clarify that FMV can be assessed by valuators exercising independent judgment.***

Additionally, requiring fair market analyses to be updated at least as frequently as the renewal of the agreement (i.e., annually for annual renewals) would impose a recurring and unnecessary administrative burden on manufacturers. Many service arrangements remain materially unchanged from year to year even if they are annually renewed, and requiring a new FMV assessment for each renewal would result in duplicative costs and effort. ***For ongoing service arrangements, we recommend that CMS clarify that manufacturers may rely on existing FMV reports to assess whether updated fees remain within an inflation-adjusted FMV range. We further recommend that CMS allow manufacturers to rely on such FMV reports for a reasonable period (e.g., three to five years), unless there is a material change in the scope or costs of the services provided or a significant shift in market conditions.*** This approach would balance the interest in ensuring accurate FMV assessments, shared by CMS and manufacturers, with the need to avoid unnecessary administrative and financial burden.

Finally, the proposed FMV requirements also conflict with FMV frameworks under other laws in CMS' purview. For example, with respect to the Physician Self-Referral Law (Stark Law), CMS expressly declined to affirm a specific valuation methodology and stated that it "intend[s] to accept any [fair market value calculation] method

that is commercially reasonable and provides [the agency] with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm's-length transactions that are not in a position to refer to one another."[57] CMS' proposed FMV standards and methodologies for BFSFs would create intra-agency confusion and create needless regulatory uncertainty. CMS has not explained why requiring specific methodologies for FMV analyses for BFSFs is uniquely warranted for such fees, in contrast to the other FMV frameworks deployed by CMS in other contexts. At a minimum, CMS should fully consider all of the factors described above, based on an adequate understanding of industry realities, to satisfy its fundamental obligation to avoid arbitrary and capricious decision-making. To date, it has not done so.

CMS Should Not Finalize the Proposal that BFSFs May Not Be Passed On to "Affiliates"

In the proposed rule, CMS proposes that to qualify as a BFSF, a fee must not be passed through to a customer or client of the fee recipient — which is currently the case — or to an "affiliate" of the fee recipient.[58] CMS states that adding "affiliate" to the list of entities to whom a BFSF must not be passed on would "more comprehensively address the type of arrangements that may exist between certain entities."[59] However, CMS has not articulated a clear reason for this proposal nor has it explained what types of affiliate arrangements it believes may be inappropriately classified as BFSFs. CMS also has not explained how such arrangements are not already addressed by the existing "client or customer" standard or why the insertion of "affiliate" is necessary.

CMS' proposed expansion of the "not passed on" prong of the BFSF definition is overly broad and risks unintended consequences. For example, the proposal fails to account for situations in which an affiliate of the fee recipient (such as an entity that is in the same corporate consolidated group for U.S. tax reporting purposes as the fee recipient) performs some or all of the services for which the fee is paid. A member of the corporate consolidated group of the fee recipient generally would be treated as an "affiliate" for legal purposes. Under the corporate consolidated group rules, it is common for members of the same group to provide intercompany services to members within the group, which may ultimately benefit unrelated third parties. The Treasury regulations include detailed rules to track such intercompany services and to ensure that the related revenue and expenses are allocated to the applicable member performing the services (e.g., the member providing the services should receive the related fee). In such cases, where an affiliate that is a member of the corporate group of the fee recipient receives all or part of the fee because it performed all or part of the work involved on behalf of a member of its group, there is no reason to foreclose the fee from qualifying as a BFSF. Disqualifying such arrangements would ignore the economic reality of the transaction and conflict with established tax principles that recognize the legitimacy of intercompany service arrangements and income and cost allocations within consolidated groups.

Moreover, CMS' circular definition of "affiliate" as "the affiliate of an entity that is receiving the fee that is providing the service" fails to provide practical guidance to regulated parties about what the term is intended to cover. [60] That vagueness would leave stakeholders uncertain as to which entities fall within CMS' understanding of an "affiliate," and worse still may lead many fee recipients to refuse to provide the certification letters that CMS seeks to collect. As discussed below, PhRMA anticipates that manufacturers will have immense difficulty obtaining these letters from many fee recipients, as CMS has not proposed any legal requirement for fee recipients to provide such reports. The addition of the word "affiliate" to the "not passed on" criterion introduces uncertainty and reduces the manufacturer's prospects of obtaining a certification from the fee recipient stating that the fee is not passed on — particularly in cases where the fee recipient is part of a larger corporate structure or lacks

[57] 85 Fed. Reg. 77492, 77556 (Dec. 2, 2020).
[58] 90 Fed. Reg. at 32849.
[59] 90 Fed. Reg. at 32544.
[60] 90 Fed. Reg. at 31541, n.102.

visibility into the ownership and operational details of related entities. The proposed "affiliate" requirement also is ambiguous and would needlessly introduce inconsistency into manufacturers' BFSF determinations.

Given the many challenges associated with the addition of the term "affiliate," we recommend that CMS maintain the current requirement that a BFSF must not be passed on to a "client or customer" and not expand this requirement to include affiliates.

The Proposed Requirement for a Certification that a Fee Is "Not Passed On" Would Inappropriately Place a Burden on Manufacturers Rather Than Fee Recipients

In the proposed rule, CMS proposes requiring manufacturers to submit a warranty or certification from the recipient of a service fee stating that the fee is not passed on, in whole or in part, to an affiliate, client, or customer of the fee recipient.[61] This proposal appears to be premised on the assumption that manufacturers can easily obtain these certifications from fee recipients, despite CMS placing no legal obligation on those recipients to submit the certification. That assumption is incorrect.

At the outset, we note that there is inconsistency between the proposed regulatory text and the preamble language regarding the certification requirement. The proposed regulatory text provides that manufacturers must submit a "certification letter" from the fee recipient as evidence that the fee is not passed on.[62] Yet in the preamble, CMS refers to manufacturers submitting a "certification *or warranty*" from the fee recipient.[63] ***Given the considerable burden that CMS is proposing to place on manufacturers, we request that CMS define its proposed submission requirements with greater clarity.***

PhRMA is also concerned that CMS' approach would inappropriately place regulatory responsibility for submission of the certifications on manufacturers rather than fee recipients. We understand that CMS is proposing this submission requirement to improve ASP reporting, which is done by manufacturers. However, CMS' proposal places the full burden of securing the required certifications on manufacturers, while imposing no corresponding obligations on fee recipients to provide them. Moreover, the certification relates to whether the fee recipient passes on all or part of the fee to certain third parties: information that generally is uniquely in the possession of the fee recipient. Service providers may be reluctant to provide such certifications for any number of reasons that have nothing to do with the substance of the certification itself, including the increased operational and cost burdens for providing such certification. If a manufacturer cannot obtain the certification from the fee recipient, its only option might be to treat the fee as a price concession — even if there is no reason to believe the fee is actually passed on. PhRMA anticipates that manufacturers will face significant challenges in obtaining such certifications absent an enforceable legal obligation that applies to fee recipients. This requirement also could introduce ambiguity into manufacturers' BFSF determinations, undercutting the precision and consistency of reporting BFSF arrangements that CMS intends.

Given the expected difficulty in manufacturers obtaining such certifications, PhRMA anticipates that CMS' proposal would result in many fees for legitimate services — that are not in fact passed on — nevertheless being classified as price concessions solely due to the absence of the required certification. The resulting misclassifications could lead to ASPs that are understated, which in turn could cause underpayment of providers and skew clinical decision-making. As CMS has recognized, understated ASPs could also incorrectly reduce manufacturers' inflation rebate obligations.[64]

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[61] 90 Fed. Reg. at 32849.
[62] 90 Fed. Reg. at 32849.
[63] 90 Fed. Reg. at 32544. *See also* 90 Fed. Reg. at 32541 ("We propose that manufacturers must also submit a warranty or certification from the recipient of the fee that is not passed on in whole or in part to an affiliate, client, or customer of an entity.") (emphasis added).
[64] 90 Fed. Reg. at 32543.

CMS should carefully consider its legal authority to impose an obligation to provide certification letters on third-party fee recipients, who are the more appropriate target of such a regulation, as they are the only parties that can make the certification. CMS should also assess the practical implications of requiring manufacturers to obtain certifications from entities that may be unwilling to submit the certifications, as well as the possible impact on ASP-based payments to providers should manufacturers be forced to classify fees as price concessions solely because they cannot obtain the certifications. ***We recommend that CMS delay adopting a certification requirement until it has conducted further analysis of these issues and sought further comment from stakeholders. In the interim, CMS should maintain its current standard that manufacturers may assume that fees are not passed on absent evidence to the contrary.***

Similarly, to the extent that CMS' BFSF proposals are intended to reform fee arrangements directly linked to drug prices or quantities, we have concerns with CMS seeking to do so by imposing additional requirements on manufacturers (instead of directly regulating fee recipients such as PBMs, GPOs or other intermediaries). The proposed rule does nothing to affect the incentives or obligations of PBMs, GPOs or other intermediaries; it would allow them to continue seeking fees directly linked to drug costs, and thus does not address the perverse incentives for intermediaries to favor higher list price medications. Instead of imposing requirements on manufacturers, we encourage CMS to analyze its authority to stop intermediaries from seeking and obtaining the linked fees that CMS wishes to discourage.

PhRMA Welcomes the Requirement to Submit Reasonable Assumptions

CMS proposes requiring manufacturers to submit any reasonable assumptions they use for ASP calculation.[65] PhRMA supports CMS collecting and reviewing manufacturers' reasonable assumptions related to ASP calculation on a prospective basis, and our member companies look forward to more dialogue with CMS to address and promptly resolve any questions or concerns related to manufacturers' reasonable assumptions.

The Additional Submission Requirements Are Unclear

The preamble to the proposed rule provides that manufacturers must maintain and submit to CMS "a copy of the FMV analysis, confirming it was conducted in a timely manner" and "documentation (such as a mutual representation in the relevant services agreement) that both parties have agreed to represent the payment as a BFSF in a consistent manner to all third parties, including any affiliates, clients, and governmental agencies."[66] However, CMS has not included any corresponding language in the proposed regulatory text that would establish these submission requirements, nor has it identified any rationale for imposing them. Further, CMS does not explain what it means for parties to represent a fee as a BFSF "in a consistent manner to all third parties" or how such documentation would improve the accuracy or integrity of ASP reporting. Consequently, imposing these requirements could generate liability risks solely due to the ambiguity of the representations that manufacturers and fee recipients would be expected to make. The inconsistency between the preamble and the proposed regulatory text also creates uncertainty for manufacturers as to whether CMS intends to impose these burdensome submission requirements. ***If CMS does intend to impose these requirements — and we would urge CMS not to do so — CMS must propose them in a future rulemaking in which it explains the scope and purpose of the proposal, including the meaning of the proposed representation, and seeks additional stakeholder feedback.*** At this juncture, this proposal is too poorly developed even to permit meaningful comment.

CMS Must Delay Implementation of the New BFSF Requirements to Ensure Compliance Readiness

[65] 90 Fed. Reg. at 32849.
[66] 90 Fed. Reg. at 32544.

CMS proposes that its new requirements with respect to BFSFs would take effect beginning January 1, 2026.[67] As discussed above, PhRMA recommends that CMS take the time necessary to conduct a meaningful review of stakeholder comments, and to engage in additional fact-finding to obtain a better understanding of what these proposals might realistically accomplish, how they could be structured most effectively, and the magnitude of the burdens they would impose on manufacturers and other stakeholders. ***To the extent that CMS finalizes any of its proposals related to BFSFs, we urge CMS to apply them only to new contracts entered into after the rule's effective date, which should be at least eight full quarters following publication of the final rule.***

A January 1, 2026 effective date is not feasible given the scope and complexity of the proposed changes, as well as the fact that many of these proposals would be difficult to implement due to their ambiguities. The new requirements would necessitate significant operational adjustments, including the review and potential renegotiation of multitudes of existing service arrangements, as well as the potential preparation of a substantial number of new FMV reports by third-party valuators, which may overwhelm the limited number of third-party valuators. Manufacturers would also need considerable time to interpret certain of these requirements and to educate internal teams and external partners, revise internal FMV assessment protocols, and implement new documentation and reporting systems. Implementing these changes correctly in a short period following publication of the final rule would be impracticable, given the scale of the operational adjustments required and the volume of impacted service arrangements. Moreover, rushed implementation could lead to misclassification of legitimate service fees, and over- or understatement of ASP, with the accompanying risks of incorrect provider reimbursement and incorrect inflation rebate assessments.

CMS' Commentary on Distribution and Data Sharing Service Fees Lacks Clarity and Creates Uncertainty Around the Treatment of Fees that May Satisfy the BFSF Definition

In the proposed rule, CMS offers commentary on how certain categories of service fees — such as distribution and data sharing fees — should be treated in the ASP calculation. CMS states that it is "proposing a non-exhaustive list of certain fees that we either do not consider [to be] BFSFs or may not be in line with FMV." However, the accompanying discussion is vague and lacks specificity or factual support. For example, CMS suggests that "certain" distribution service fees "appear to be price concessions" because they "appear to exceed the FMV for the service," but does not identify which fees or under what circumstances. Similarly, CMS questions the legitimacy of "certain" data sharing fees that "appear to exceed the FMV for the service or are not bona fide services" when the data is required for legal compliance or audit purposes — again, without offering a clear rationale for why it seems to consider the fees in question suspect.

PhRMA is concerned that CMS' commentary reflects generalized skepticism rather than a well-defined policy position grounded in factual observations and described with sufficient clarity to enable consistent application of the BFSF definition. Indeed, CMS has not proposed any corresponding regulatory text addressing these fee categories, leaving stakeholders uncertain about what, if anything, is actually being proposed. While CMS raises vague concerns about the cost or nature of certain service fees, it fails to identify why fees for distribution services or data could not qualify as BFSFs under the definition. For example, CMS offers no rationale for its suggestion that data sharing services that otherwise satisfy the four-part test — including, e.g., fees for services that are actually performed on behalf of the manufacturer and that the manufacturer would otherwise perform or contract for — might not be considered "bona fide" simply because the data is required under the terms of an agreement.

To enable meaningful stakeholder engagement, PhRMA urges CMS (in a new proposed rule) to identify specific service fees it has concerns about in a clear manner, explain the basis for its concerns, and — where appropriately justified — propose corresponding regulatory language that commenters can address directly.

[67] 90 Fed. Reg. at 32544.

Alternatively, CMS should pose targeted questions to solicit input on areas where further understanding is needed. At this point, we emphasize that when distribution or data sharing fees satisfy the four-part BFSF test, there is no legal basis to exclude them from BFSF treatment. The current four-part BFSF standard provides a well-established framework for identifying legitimate service fees exchanged for necessary, bona fide services. We do not want to foreclose improvements in the current BFSF test, but improvements will only come about through a rulemaking process in which CMS' concerns and the rationale for any proposals are laid out clearly, allowing stakeholders to meaningfully respond to CMS' concerns and any proposals it makes to improve the BFSF test. PhRMA and its member companies would welcome such a dialogue. At this juncture, however, CMS should reaffirm its commitment to the existing BFSF definition rather than introducing ambiguities that risk undermining routine, commercially necessary arrangements and creating unwarranted compliance uncertainty.

c) Autologous Cell-Based Immunotherapies and Gene Therapies

In the proposed rule, CMS proposes guidance on how manufacturers of an autologous cell-based immunotherapy or gene therapy should account for fees paid in connection with cell collection procedures for purposes of ASP reporting. First, CMS proposes that "any preparatory procedures for tissue procurement" required for manufacturing the product that are paid for by the manufacturer should "be included in the calculation of the manufacturer's ASP."[68] CMS asserts that this approach aligns with its proposal that preparatory procedures for such therapies "be included in the payment for the product itself."[69] Second, CMS proposes that "any payment by the manufacturer to an entity" for such tissue procurement cannot be considered a BFSF, reasoning that such procedures are "an integral part of the manufacturing process" for these therapies and "should be included in the price of the product."[70]

As a threshold matter, PhRMA is concerned that these proposals conflict with the ASP statute, given that tissue procurement is a manufacturing cost, not a price concession.[71] The ASP statute requires manufacturers to calculate ASP by dividing their U.S. "sales to all purchasers" by the total units of the drug or biological sold during the relevant timeframe.[72] Congress did not direct manufacturers to add in (or subtract) specific manufacturing expenses when reporting ASP. ASP is not a measure of the cost of manufacturing a drug, but of the average price at which the manufacturer sells the drug.

In addition, the proposed rule does not address why a payment for tissue procurement services that satisfies all four conditions of the BFSF definition cannot be treated as a BFSF under the regulatory criteria CMS itself has established. There is no apparent reason why a payment by the manufacturer to an entity for tissue procurement could not :(1) represent FMV (2) for a bona fide, itemized service actually performed on behalf of the manufacturer (3) that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and (4) meet the requirement that the fee not be passed on to a client or customer of the fee recipient. CMS provides no justification for excluding payments that otherwise meet these criteria.

Under CMS' proposal, if a payment by a manufacturer to an entity for tissue procurement cannot be a BFSF, the implication is that it may represent a price concession for ASP purposes. Yet CMS does not explain why a

[68] 90 Fed. Reg. at 32547.
[69] 90 Fed. Reg. at 32547.
[70] 90 Fed. Reg. at 32547.
[71] By CMS' own description, these services are "an integral part of the manufacturing process," which makes them part of the cost of production. 90 Fed. Reg. at 32545. As further evidence that tissue procurement costs are production costs, tissue procurement is highly regulated under FDA's current good tissue practice requirements, which govern sterility, contamination control, documentation, and other safeguards related to the recovery and processing of cells and tissues intended for cellular- and tissue-based therapies prior to distribution.
[72] SSA §1847A(c)(1)(A)-(B).

payment for a service that is "an integral part of the manufacturing process" for a therapy should be automatically disqualified from BFSF status.

CMS should not adopt the ASP proposals related to tissue collection. The rationale for these proposals has not been explained, and they would arbitrarily exclude fees that meet the definition of BFSF from BFSF status.

Appropriate Medicare reimbursement for cell and gene therapies is critical to supporting patient access to these therapies, especially for patients in rural and underserved communities.

V. CMMI Must Not Mandate Participation in Phase I Models

CMS proposes to establish, beginning January 2027, a mandatory, five-year model – the Ambulatory Specialty Model (ASM) – to test whether upstream management of chronic disease would lead to reductions in avoidable hospitalizations and unnecessary procedures for Medicare beneficiaries with heart failure or low back pain. As discussed in more detail below, we support efforts to address chronic diseases and to ensure patients have access to the care they need. PhRMA supports CMS collaborations with stakeholders on models that test methods to harness market competition and reinforce the Medicare program's evolution toward value-based payment and service delivery. However, it is vital to ensure that any new payment and service delivery models do not impede patient access, undermine physician practices, or discourage medical progress through top-down governmental price setting, and comply with the statute (Social Security Act 1115A) and U.S. Constitution.[73] For these reasons, ***we strongly object to the manner in which the Center for Medicare and Medicaid Innovation (CMMI) seeks to test this model.*** We have raised similar concerns in the past and reiterate them here given the agency's proposal to make ASM mandatory.

Section 1115A of the Social Security Act (SSA) authorizes CMMI "to test innovative payment and service delivery models."[74] This is a significant testing authority, but as CMS is aware, it is subject to strict statutory requirements regarding what may be tested, how a test is evaluated, and the circumstances in which a model can be expanded. Section 1115A first and foremost requires the Secretary to "select models to be tested."[75] The verb "test" refers to an effort to "try" something—as opposed to implementing it outright—on a limited basis for purposes of evaluating performance, usually through comparing the results of the experimental intervention with the results of a control group. [76] The surrounding text of Section 1115A confirms this ordinary understanding of the word "test," for example by requiring that a model be modified or terminated if certain spending or quality of care improvements are not expected to occur.[77] Next, Section 1115A sets up a two-phase process in which Phase I models may, under appropriate circumstances, be expanded in duration and scope "(including implementation on a nationwide basis)" in Phase II. Before proceeding to Phase II, the statute compels the Secretary to first evaluate "each model tested" in Phase I. Accordingly, the sole objective of Phase I testing is developing the evidence necessary to determine whether an expansion of the model into Phase II would be permitted and otherwise appropriate. Only if that evaluation is positive (as determined by the specified statutory criteria)[78] is the Secretary authorized to implement, through rulemaking, an expanded model under Phase II. Despite this directive, CMS

[73] We also emphasize that in developing and carrying out CMMI models, the agency must follow the U.S. Constitution, including adhering to its well-established principles. We refer the agency to PhRMA's prior comments on the constitutional constraints governing CMMI models, such as the presentment clause, and the non-delegation doctrine, and principles of constitutional avoidance.
[74] SSA § 1115A(a)(1).
[75] SSA § 1115A(a)(1)(b)(2)(A).
[76] See Test, V., Oxford English Dictionary (2d ed. 1989) ("to try, put to the proof; to ascertain the existence, genuineness, or quality of").
[77] SSA § 1115A(b)(3)(B).
[78] Expansion is permitted only if the Secretary determines that expansion (1) is expected either to reduce spending without reducing quality of care or to improve the quality of patient care without increasing spending, and (2) would not deny or limit the coverage or provision of benefits. Additionally, the CMS Chief Actuary must certify that the expansion "would reduce (or would not result in any increase in) net program spending" under Medicare or Medicaid. Section 1115A does not permit the Secretary to waive statutory requirements in Phase II expansion (in contrast to waiver authority afforded in Phase I). SSA § 1115A(c), (d)(1).

essentially proposes ASM as a Phase II mandatory model before proper testing and evaluation has been performed on a limited, voluntary basis under Phase I.

PhRMA would note that historically CMMI has lacked clear and meaningful transparency with the public. Meaningful improvements to increase transparency include providing ample and numerous options for public comment including during model development/implementation/and policy changes, a clear roadmap of all of CMMI's model timelines (including prior to initiating rulemaking or publishing requests for applications (RFAs)), as well as publicly posting savings estimates for each model, and whether the agency has met the criteria to expand the model in the future. Increasing transparency would allow providers, patients, and policymakers to better understand the models' impacts, promote accountability, and foster broader engagement in innovation efforts.

Notably, although Congress created the Physician-Focused Payment Model Technical Advisory Committee (PTAC) to encourage clinician-led innovation, CMMI has never implemented a PTAC-recommended model. Greater transparency into the agency's review and decision-making processes—particularly regarding PTAC submissions—could help clarify how stakeholder input informs model development and selection.

Finally, PhRMA urges CMMI to only implement ASM on a voluntary participation and recommends that the agency consider additional patient protections and continued engagement with interested parties before ASM is implemented. For example, PhRMA strongly encourages CMMI to seek additional comment from the public as the model is further developed and if it is implemented in order to best safeguard Medicare beneficiaries and providers and ensure policies do not cause unintended consequences and harms.

VI. Prevention and Management of Chronic Disease—Request for Information

CMS is seeking stakeholder input on expanding Medicare support for chronic disease prevention and management and how best to address gaps in care and promote healthier behaviors. We appreciate the Administration's focus on addressing the chronic disease epidemic, and we agree that more must be done to address the root causes of chronic disease and to ensure patients have access to the care they need to get and stay healthy. Any effort to mitigate chronic disease must include policies that support access to medicines, which are proven tools for prevention, early intervention and long-term disease management.

Biopharmaceutical companies continue to invest in treatments for conditions that disproportionately affect older populations, including over 400 candidates in development.[79] ***As CMS considers future payment policies, we urge the agency to avoid approaches that could discourage continued innovation, as sustained investment is essential to developing the next generation of treatments that will help patients live longer, healthier lives and ensuring that Medicare remains equipped to meet the growing burden of chronic disease.***

Recognizing the Urgency of Chronic Disease

Chronic disease is the leading driver of healthcare spending in the United States, accounting for over 90 percent of the nation's $4.5 trillion in annual healthcare costs.[80] Although 80 percent of chronic disease is preventable, millions of Americans continue to suffer from conditions that diminish their quality of life and strain our

[79] PhRMA. (July 2023). Medicines in Development 2023 Report: The Leading Chronic Diseases Impacting Older Americans. Available at: https://cdn.aglty.io/phrma/global/blog/import/pdfs/MID-Chronic-Illness-Older-Americans-2023.pdf
[80] Centers for Disease Control and Prevention. (July 2024). Fast Facts: Health and Economic Costs of Chronic Conditions. Available at: https://www.cdc.gov/chronic-disease/data-research/facts-stats/index.html

healthcare system.[81] More than 90 percent of Medicare beneficiaries have at least one chronic disease, and almost 80 percent have two or more.[82]

The economic and human dimensions of the chronic disease epidemic are staggering. Obesity-related chronic illness alone is expected to cost Medicare and Medicaid $4.1 trillion over the next decade, threatening the stability of these programs.[83] The financial pressures are compounded by the human toll: Chronic diseases are among the leading causes of death in the United States, with heart disease and stroke alone claiming over 944,000 lives annually.[84] Tackling this crisis requires a comprehensive strategy that integrates upstream prevention with coordinated care to both confront the underlying causes of chronic disease and mitigate its widespread impact.

Integration of Medicines and Lifestyle Interventions

Most chronic diseases are caused by risk factors including poor nutrition, lack of physical activity, excessive alcohol use, and tobacco use, which are deeply rooted in lifestyle. In addition, the conditions where people are born, live, work, and age can limit the opportunities for people to make healthy choices.[85] Addressing these root causes requires a person-centered approach that empowers individuals to make sustainable changes in their daily lives.

However, lifestyle changes alone are often difficult to establish and maintain[86] [87] and may not be enough for individuals already at risk of or managing chronic diseases. Integrating pharmaceutical interventions with lifestyle support offers a more realistic and effective path forward. Medicines can help prevent disease progression, reduce costly complications and even save lives, giving patients the time and stability they need to pursue meaningful lifestyle changes that target the underlying cause of disease.[88]

For example, in cardiovascular disease, statins and antihypertensives significantly reduce the risk of heart attacks and strokes in at-risk populations, but their effectiveness is maximized when combined with dietary improvements, increased physical activity, and smoking cessation.[89] Similarly, the near-elimination of hepatitis C in the United States through antiviral treatments has only been possible when paired with robust screening, diagnosis, and care coordination efforts.[90] In the case of diabetes and obesity, anti-obesity medications are helping patients manage weight and blood sugar levels, but their full potential is realized when used alongside nutritional counseling, physical activity programs, and behavioral support.[91] Mental health care offers another compelling

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[81] Katz, D. L. et al. (July 2018). Lifestyle as Medicine: The Case for a True Health Initiative. *Am J Health Promot.* Available at: https://pubmed.ncbi.nlm.nih.gov/28523941/

[82] Watson, K. B. et al. (April 2025). Trends in Multiple Chronic Conditions Among US Adults, By Life Stage, Behavioral Risk Factor Surveillance System, 2013–2023. Preventing Chronic Disease. Available at: http://dx.doi.org/10.5888/pcd22.240539

[83] Joint Economic Committee. (2023). The 2023 Joint Economic Report. Available at: https://www.jec.senate.gov/public/_cache/files/c7df7ee3-2562-44f9-bcc0-fb038ff9967c/the-2023-joint-economic-report.pdf

[84] Centers for Disease Control and Prevention. (July 2024). Fast Facts: Health and Economic Costs of Chronic Conditions. Available at: www.cdc.gov/chronic-disease/data-research/facts-stats/index.html

[85] Centers for Disease Control and Prevention. (October 2024). About Chronic Diseases. Available at: https://www.cdc.gov/chronic-disease/about/index.html

[86] Middleton, K. R. et al. (August 2016). Long-Term Adherence to Health Behavior Change. *Am J Lifestyle Med.* Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4988401/

[87] Jepson, R. G. et al. (September 2010). The Effectiveness of Interventions to Change Six Health Behaviours: A Review of Reviews. *BMC Public Health*. Available at: https://pubmed.ncbi.nlm.nih.gov/20825660/

[88] Rodis, J.L. et al. (October 2017). Improving Chronic Disease Outcomes Through Medication Therapy Management in Federally Qualified Health Centers. *Journal of Primary Care & Community Health*. Available at: https://pubmed.ncbi.nlm.nih.gov/28381095/

[89] Korhonen, M. J. et al. (February 2020). Lifestyle Changes in Relation to Initiation of Antihypertensive and Lipid-Lowering Medication: A Cohort Study. *J Am Heart Assoc*. Available at: https://pubmed.ncbi.nlm.nih.gov/32019405/

[90] Gowda, C., & Lo Re, V. (March 2018). Strategies for the Elimination of Hepatitis C Virus Infection as a Public Health Threat in the United States. *Curr Hepatol Rep*. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC6168203/

[91] LeBlanc, E. S., et al. (September 2018). Behavioral and Pharmacotherapy Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. *JAMA.* Available at: https://pubmed.ncbi.nlm.nih.gov/30326501/

example: While the development of effective medicines remains challenging, new therapies for schizophrenia that target mechanisms beyond dopamine are opening the door to more personalized treatment.[92] [93] Yet, these advances must be supported by access to therapy, community-based services, and social supports to truly improve outcomes.[94]

Critically, the benefits of these pharmaceutical interventions depend on consistent and appropriate use. Poor medication adherence remains a significant barrier to achieving better health outcomes and controlling costs. For example, improved adherence among patients with diabetes could prevent over 1 million emergency department visits and hospitalizations annually, resulting in potential savings of $8.3 billion each year.[95] Likewise, every $1 spent on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes, or high cholesterol can yield $3 to $10 in savings from avoided emergency room visits and hospitalizations.[96] These examples underscore that when paired with person-centered care, medicines can significantly improve outcomes, reduce complications, and help bend the cost curve of chronic illness.

Addressing Undercaptured Services in the Physician Fee Schedule

We appreciate CMS' inquiry into how the Medicare Physician Fee Schedule (PFS) can better support chronic disease prevention and management. ***There are several opportunities to strengthen Medicare's approach to chronic disease prevention by aligning coding and payment structures to better support sustained health improvement.***

- *Support for Improved Medication Adherence:* Nearly half of all prescriptions are taken incorrectly[97], which contributes to avoidable complications, hospitalizations, and emergency department visits.[98] Among Medicare beneficiaries, poor adherence to medications for chronic conditions like diabetes, hypertension, and heart failure results in billions of dollars in excess spending annually. For example, improving adherence to high blood pressure medications alone could save Medicare $13.7 billion per year and prevent over 100,000 emergency visits and 7 million inpatient days.[99] Patients often struggle with adherence due to a combination of factors: lack of understanding about their condition or treatment, forgetfulness, side effects, cost barriers, and limited support systems. To address these challenges, CMS could incorporate supportive services, such as motivational interviewing, to assist patients to initiate and maintain adherence to prescribed therapies.[100]

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[92] FDA. (September 2024). FDA Approves Drug with New Mechanism of Action for Treatment of Schizophrenia. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-drug-new-mechanism-action-treatment-schizophrenia
[93] Kantrowitz, J. T., et al. (May 2023). New Developments in the Treatment of Schizophrenia: An Expert Roundtable. *Int J Neuropsychopharmacol*. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC10229849/
[94] Keepers, G. A., et al. (September 2020). The American Psychiatric Association Practice Guideline for the Treatment of Patients with Schizophrenia. *American Journal of Psychiatry.* Available at: https://psychiatryonline.org/doi/10.1176/appi.ajp.2020.177901
[95] Jha, A. K., et al. (August 2012). Greater Adherence to Diabetes Drugs is Linked to Less Hospital Use and Could Save Nearly $5 Billion Annually. *Health Affairs*. Available at: https://pubmed.ncbi.nlm.nih.gov/22869663/
[96] Roebuck, M.C., et al. (January 2011). Medication Adherence Leads to Lower Care Use and Costs Despite Increased Drug Spending. *Health Affairs*. Available at: https://pubmed.ncbi.nlm.nih.gov/21209444/
[97] Neiman, A. B., et al. (November 2017). CDC Grand Rounds: Improving Medication Adherence for Chronic Disease Management — Innovations and Opportunities. *Morbidity and Mortality Weekly Report*. Available at: https://www.cdc.gov/mmwr/volumes/66/wr/mm6645a2.htm
[98] Urick, B. Y., et al. (March 2023). Estimating Medical Cost Offsets from Continuous Adherence Improvement Using Commercially Insured Members' Real-World Data. *Academy of Managed Care Pharmacy Annual Meeting.* Available at: https://www.primetherapeutics.com/documents/d/primetherapeutics/4085-d_-amcp_sp23_healthoutcomes
[99] Lloyd, J. T., et al. (March 2019). How Much Does Medication Nonadherence Cost the Medicare Fee-for-Service Program? *Medical Care*. Available at: https://pubmed.ncbi.nlm.nih.gov/30676355/
[100] Spears, J., et al. (January 2020). A Pharmacist-Led, Patient-Centered Program Incorporating Motivational Interviewing for Behavior Change to Improve Adherence Rates and Star Ratings in a Medicare Plan. *Journal of Managed Care & Specialty Pharmacy*. Available at: https://pubmed.ncbi.nlm.nih.gov/31880222/

- *Empowering Person-Centered Care Through Community Partnerships and Care Coordination:* PhRMA encourages CMS to advance a comprehensive, person-centered approach to chronic disease prevention and management that recognizes the importance of both upstream drivers and care coordination. Community-based organizations, area agencies on aging and other local resources are uniquely positioned to provide essential services, such as meal delivery, transportation, and social support, that empower individuals to follow through on treatment plans, engage in preventive care, and sustain healthier lifestyles. At the same time, providers must be equipped with the infrastructure necessary to support and reward patient-centered care. This includes recognizing and compensating the time and resources required for services like counseling, care coordination, and lifestyle interventions. Together, these efforts help individuals make informed, sustainable choices to improve their health.

- *Advancing High-Quality Care for Chronic Disease Prevention and Management:* PhRMA supports CMS' efforts to align quality metrics with holistic, person-centered care for Medicare beneficiaries, especially those with multiple chronic conditions.[101] Adults 65 and older often have co-morbidities, leading to higher hospital readmission rates and hospitalization costs that may be 20–30 percent higher. [102,103] Outcomes-based metrics can incentivize providers to deliver high-value preventive care that reflects patient priorities and care preferences. These measures ensure care plans are tailored to individual needs and reward providers for improving health outcomes, not just cutting costs. As chronic conditions become more prevalent, CMS' focus on metrics that anticipate care quality across diverse settings is essential to advancing value-driven healthcare.

We appreciate CMS' leadership in seeking input on how to strengthen chronic disease prevention and management through Medicare. As the burden of chronic and mental health conditions continues to grow, it is essential that Medicare policies reflect the full range of tools and services that help patients get and stay healthy. Medicines are a proven and indispensable part of this strategy, especially when paired with lifestyle interventions, community support and personalized care.

VII. Strengthening Medicare's Approach to Mental Health Care for Older Americans

The proposed rule contains a number of provisions aimed at addressing the significant mental health challenges facing America's seniors. In particular, PhRMA commends CMS for its efforts to address these challenges by supporting access to behavioral health care, enhancing care coordination and integration, and modernizing coverage and reimbursement of evidence-based tools to address the complex needs of America's seniors and the range of mental and chronic health conditions they face.

Mental health conditions are both common and consequential among older adults. 12.5 percent of adults age 60 and older were found to have experienced any mental illness.[104] As the nation's population continues to age, the number of older adults living with mental illness is expected to double by 2030.[105] Despite this growing need,

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[101] 90 Fed. Reg. at 32725.
[102] Basu, J., et al. (June 2016). Hospital Readmission Rates in US States: Are Readmissions Higher Where More Patients With Multiple Chronic Conditions Cluster? *Health Services Research*. Available at: https://pubmed.ncbi.nlm.nih.gov/26481190/
[103] Skinner, H. G., et al. (March 2016). The Effects of Multiple Chronic Conditions on Hospitalization Costs and Utilization for Ambulatory Care Sensitive Conditions in the United States: A Nationally Representative Cross-Sectional Study. *BMC Health Serv. Res*. Available at: https://pubmed.ncbi.nlm.nih.gov/26926525/
[104] Substance Abuse and Mental Health Services Administration. (February 2025). Behavioral Health Among Older Adults: Results from the 2021 and 2022 National Surveys on Drug Use and Health. Available at: https://www.samhsa.gov/data/sites/default/files/reports/rpt45341/2022-nsduh-older-adult-info.pdf
[105] Jeste, D. V., et al. (September 1999). Consensus Statement on the Upcoming Crisis in Geriatric Mental Health: Research Agenda for the Next 2 Decades. *Arch Gen Psychiatry*. Available at: https://pubmed.ncbi.nlm.nih.gov/12884891/

mental illness remains seriously under-treated in the Medicare population. In fact, less than half of older adults diagnosed with a mental illness have received treatment of any kind.[106]

Limited access to behavioral health treatment providers, persistent stigma of mental health conditions, and a fragmented, poorly integrated healthcare system often fail to meet the complex needs of those seeking treatment, leaving many patients behind. These gaps reflect a healthcare system that should more adequately value treatment and prevention to support better patient care and outcomes.

PhRMA has long supported holistic treatment approaches to support better patient outcomes. Evidence shows that outcomes improve when medicines and behavioral health interventions are delivered together. For example, one study found combining antidepressant medication and anxiety medication with psychotherapy significantly improved treatment outcomes and these effects remained strong and consistent up to two years after treatment. Additionally, the study concluded "the effects of pharmacotherapy and those of psychotherapy are largely independent from each other, with both contributing equally to the effects of combined treatment."[107] The importance of integrating behavioral health is widely supported in health outcomes literature. For example, a review of 192 randomized controlled trials and 30 additional trials involving over 20,000 patients with schizophrenia found that psychosocial supports, such as cognitive behavioral therapy and family interventions, improved functional outcomes, quality of life and often reduced relapses when added to the pharmacological standard of care.[108] This synergy underscores the importance of holistic care models that address both biological and social dimensions of mental health.

PhRMA appreciates the steps that CMS is taking to prioritize mental health care in the United States and support more comprehensive access to empirically supported treatment approaches. Addressing the growing crisis requires a multifaceted strategy that improves access to evidence-based care and recognizes the importance of individualized treatment approach for all Americans, including for the Medicare population. To this end, policies to support access to mental health care and improve care coordination and integrated delivery across the care continuum are necessary to adequately treat the range of mental health and chronic conditions facing Americans today are essential. CMS' efforts to expand access to psychotherapy via telehealth are a welcome step towards addressing under-treatment of mental illness as telehealth has become an essential modality for delivering mental health care to older adults.[109] However, as telehealth becomes more embedded in the mental health treatment landscape, it is important to ensure that its use is safe, appropriate, and patient-centered. Though telehealth can reduce barriers to care, it is not always appropriate for every doctor and patient interaction. Accordingly, safeguards are needed to ensure that mental health care received through telehealth is of the same quality, if not higher, than that which is received in a clinical setting, including a requirement that patients maintain periodic in-person provider visits. While PhRMA supports CMS' proposed flexibilities for telehealth to address behavioral health gaps, we encourage CMS to put appropriate safeguards in place to ensure that patients receive high-quality, individualized care regardless of setting. While increasing opportunities for patients to receive mental health care via telehealth has the strong potential to improve access to mental health treatment, the lack of qualified mental health providers remains another critical barrier for older adults in receiving sufficient, coordinated care. As of August 2024, more than one-third of the U.S. population, approximately 122 million

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[109] Agarwal, V., et al. (July 2024). The Mental Health Landscape for Older Adults in the US. Center on Health Policy at Brookings. Available at: https://www.brookings.edu/wp-content/uploads/2024/06/20240702_CHP_Frank_OlderAdultsMH.pdf

people, lived in a designated Mental Health Professional Shortage Area, with rural counties disproportionately affected.[110] Additionally, 65 percent of U.S. counties—including 81 percent of rural counties—do not have access to a single psychiatrist.[111] In fact, only 1.6 percent of licensed psychiatrists live in rural areas.[112] For older adults living in these areas, the lack of access to specialized mental health care can result in delayed diagnoses, limited treatment options, and poorer health outcomes. This behavioral health workforce shortage is compounded by limited provider participation in the Medicare with only 55.1 percent of psychiatrists and 63 percent of psychiatric mental health nurse practitioners participating in fee-for-service Medicare.[113] CMS' work to clarify billing pathways for additional types of mental health professionals can help to address this gap and ensure that older adults can receive care from a broader range of qualified professionals.

Moreover, the interplay between physical and mental health in older adults underscores the importance of integrated, coordinated care. This interplay is often bidirectional: physical ailments can contribute to poor mental health while mental illness can worsen physical outcomes.[114] Strengthening behavioral health integration into primary care and care coordination models is a critical step to supporting a shift to mental health and chronic disease treatment and prevention. PhRMA applauds CMS' ongoing efforts to integrate primary and behavioral health care to advance comprehensive, person-centered approaches that reflect the realities of aging.

In addition to improving access and care coordination, continued innovation in treatment options is essential to meeting the behavioral health needs of older adults. Digital Mental Health Technologies (DMHTs) are tools that are designed to support and enhance prescription medicines, and in some cases may also be used in lieu of medications. They can include mobile apps, wearables, and FDA-cleared software platforms requiring a prescription, known as Prescription Digital Therapeutics (PDTs). PhRMA member companies continue to expand research and development into PDTs and we are pleased to see CMS weighing expansion of coverage of these innovative evidence-based behavioral health interventions in Medicare.

PDTs often include personalized features such as live coaching and adaptive learning modules, engaging patients in their care and allowing for tailored patient support between clinical visits. As a result, these tools offer to address gaps in mental treatment that can result from provider shortages and uncoordinated care, while improving treatment outcomes for patients seeking holistic approaches to treat mental illness. Moving forward, PDTs can play a critical role in improving patient access to mental health treatment and providing comprehensive, individualized care to patients. ***PhRMA supports a thoughtful framework to ensure adequate coverage and reimbursement of these innovative products through the development of payment and coding methodologies and applauds CMS' efforts to ensure Medicare beneficiaries have access to the latest therapeutic advances in evidence-based behavioral health interventions.***

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PhRMA appreciates the opportunity to comment on the CY 2026 Medicare Physician Fee Schedule proposed rule. Please do not hesitate to contact Lauren Neves (lneves@phrma.org) or Sylvia Yu (syu@phrma.org) if we can provide additional information or answer any questions related to our comments.

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[110] Health Resources and Services Administration. (November 2024). State of the Behavioral Health Workforce, 2024. Available at: https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/state-of-the-behavioral-health-workforce-report-2024.pdf
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Sincerely,

/s/

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/s/

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