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June 26, 2025

VIA Electronic Filing – *IRARebateandNegotiation@cms.hhs.gov*

Chris Klomp
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016
Attn: PO Box 8016

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028

Dear Deputy Administrator Klomp,

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS, the Agency) *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028* (Guidance or the Guidance), which CMS released on May 12, 2025.[1] 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 $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.[2]

PhRMA has longstanding concerns about the impact of government price setting on patients, and our country's position as a leader in biopharmaceutical innovation. As it stands today, the U.S. leads the world in biopharmaceutical innovation, but middlemen and government intervention create inefficiency and threaten our leadership – risking American jobs, access to critical treatments and cures, and future innovation.

[1] Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028. Available at: https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf
[2] PhRMA. (July 16, 2024). 2024 PhRMA Annual Membership Survey. Available at: https://phrma.org/resources/2024-phrma-annual-membership-survey

- Three out of every four new medicines are approved in the U.S. before anywhere else in the world.[3]
- Prescription drugs represent a small and stable share (14 percent) of total US health care spending[4] because of the U.S.' unique intellectual property framework that balances innovation with robust generic and biosimilar competition.
- Yet, 50 percent of medicine spending goes to someone who did not make the medicines, and people pay more than they should.[5] Growth in patient out-of-pocket costs for medicines has outpaced growth in the prices paid by insurers[6] – price setting does not address these challenges and instead creates significantly *more* bureaucracy.

Not only does the Inflation Reduction Act (IRA) fail to address these issues, but it has been a disaster for patients. Research has shown that nine in 10 Part D plans say they intend to increase access restrictions on – and limit access to – medicines in the coming years because of the IRA.[7] Further, patients may pay *more* out-of-pocket costs as a result of the IRA – 3.5 million patients taking medicines subject to price setting may see higher out-of-pocket (OOP) costs in 2026, with OOP costs climbing 12 percent on average.[8]

This Administration has inherited the unfortunate responsibility of implementing an irreparably flawed price setting program. While it is impossible to fully erase the disruption that has been and will be caused by the IRA's price setting program, this Administration has an opportunity to take steps to mitigate that harm. This is further reinforced in the Executive Order signed by President Trump on April 15, 2025, entitled "Lowering Drug Prices by Once Again Putting Americans First," which instructed the Secretary of Health and Human Services to "propose and seek comment on" guidance implementing the Medicare Drug Price Negotiation Program. The Executive Order also specifically stated that "The guidance shall improve the transparency of the Medicare Drug Price Negotiation Program, prioritize the selection of prescription drugs with high costs to the Medicare program, and minimize any negative impacts of the maximum fair price on pharmaceutical innovation within the United States."

While the Executive Order appeared to signal a willingness to rethink implementation of the Program, the Draft Guidance not only retains the policy framework set forth by the Biden Administration, but *doubles down on certain inefficient, wasteful, and harmful aspects of the Program,* including the last Administration's position that it can create rules with the force and effect of law, solely through

[3] PhRMA analysis of Novel Drug Approvals at FDA. (2023). Available at: https://www.fda.gov/drugs/development-approval-process-drugs/novel-drug-approvals-fda
[4] The Altarum Institute. (July 2022). Projections of the Non-Retail Prescription Drug Share of National Health Expenditures. Available at: https://drugchannelsinstitute.com/files/Projections-of-Non-Retail-Drug-Share-of-NHE-2022.pdf
[5] BRG. (January 2022). The Pharmaceutical Supply Chain, 2013 – 2020. Available at: https://www.thinkbrg.com/insights/publications/pharmaceutical-supply-chain-2013-2020/
[6] Mallatt J., Dunn A., Fernando L. (September 2024). Consumer Out-Of-Pocket Drug Prices Grew Faster Than Prices Faced By Insurers After Accounting for Rebates, 2007 – 2020. *HealthAffairs.* Available at: https://www.healthaffairs.org/doi/10.1377/hlthaff.2023.01344
[7] Magnolia Market Access. (2024). IRA Payer Insights Report Chartbook Summary of Key Findings. Available at: https://www.magnoliamarketaccess.com/wp-content/uploads/MMA_IRA-Payer-Insights-Survey-4.0_Chartbook_2024.07.31.pdf
[8] Milliman. (June 2024). Expected Impact of the IRA Medicare Drug Price Negotiation Program on Medicare Part D Beneficiary Out-of-Pocket Costs. Available at: https://www.milliman.com/en/insight/ira-mdpnp-impact-on-beneficiary-oop

guidance.[9] Rather than dismantling bureaucracy, this Draft Guidance creates additional bureaucracy within the Agency. Rather than streamlining and alleviating burden to stakeholders, this Draft Guidance adds to their burden. And rather than providing relief to Americans who struggle to afford their medicines at the pharmacy counter, the Draft Guidance fails to offer Americans sufficient protection from health insurance plans, who have publicly stated they intend to *worsen* access to drugs selected for price setting. Any meaningful changes exist merely in the margins of this Draft Guidance.

Further, the so-called "negotiation" as defined in the IRA and detailed further in Draft Guidance documents released by both the current and prior Administration is fundamentally misaligned and incompatible with a true negotiation process. Unfortunately, the framework set forth in both the IRA and the Draft Guidance diverge significantly from the principles and practices of genuine negotiation as seen in the private market. Instead, the structure and implementation of the IRA's pricing provisions raise serious concerns about fairness, transparency, and legality.

- **The IRA's "negotiation" process bears no resemblance to private market negotiations.** Under the IRA, CMS wields unilateral authority to set drug prices with minimal input from manufacturers, who face severe penalties—including market exclusion, exorbitant excise taxes, or civil monetary penalties—if they do not comply. Unlike private negotiations, where both parties engage in mutual exchange and can walk away, CMS dictates terms through a rigid, non-negotiable framework. Manufacturers are required to sign contracts before knowing the final price, cannot revise terms, and are denied legal recourse or transparency into CMS' decision-making process. This coercive structure lacks the flexibility, reciprocity, and balance that define genuine negotiation.
- **CMS' methodology for setting prices lacks transparency and objective standards.** Rather than following a consistent, replicable process, CMS relies on a vague "qualitative approach" that allows it to weigh and combine factors arbitrarily. The Agency provides no clarity on how evidence is evaluated, how factors are prioritized, or how final prices are determined. Moreover, CMS seeks input on potential changes to the starting point that would make the process even less transparent and more subjective. This opacity makes it nearly impossible for manufacturers to understand or influence the outcome, and raises concerns about bias, inconsistency, and the potential for flawed or incomplete analysis. Without a transparent framework, CMS can attempt to justify virtually any price below the statutory ceiling, undermining predictability and fairness. Where CMS does provide a measure of clarity, such as CMS' apparent interest in new approaches to establish a starting point for MFPs (e.g., domestic reference pricing and "unit cost of

[9] *See e.g., Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019). *See also* HHS Office of the General Counsel, Advisory Opinion 20-05 on Implementing Allina (December 2020), available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101111604-mh-advisory-opinion-20-05-on-implementing-allina_12.03.2020_signed.pdf. CMS again cites to Congress' direction to implement through program instruction or other forms of guidance, and claims it is authorized to follow "policymaking procedures that differ from the notice-and-comment procedures that would otherwise apply under the APA or the Medicare statute." But such direction does not explicitly supersede section 1871 or APA requirements. The provision requiring program guidance is not prefaced with a "notwithstanding" clause, a phrasing that would have clarified the IRA's preemptive intent. "Repeals by implication are not favored, and are a rarity." Maine Cmty. Health Options v. United States, 140 S. Ct. 1308, 1323 (2020) (cleaned up).

production and distribution"), those approaches are deeply flawed (See Appendix D for additional detail on PhRMA's concerns with these proposals).

- **The IRA unconstitutionally delegates legislative power to CMS.** As interpreted by CMS, the statute grants it broad, unchecked authority to define key terms, impose penalties, and interpret statutory language without oversight. CMS has already expanded its reach by redefining what constitutes a "manufacturer" and by asserting control over entities not directly named in FDA applications. The Biden Administration even went so far as claiming that the IRA authorized it to contradict the plain language of laws written by Congress.[10] This sweeping assertion of legislative power, combined with the continuation of Biden Administration's expansive interpretations and lack of accountability, raises serious constitutional questions about separation of powers and the limits of agency authority.

The impact of the IRA's unilateral price setting is widespread, causing harm to patients, key stakeholders such as pharmacies and providers, as well as innovation and market competition. In this letter, we articulate our core concerns with the IRA, as well as with CMS' Draft Guidance for IPAY 2028, which have been further exacerbated by an implementation strategy crafted by the Biden Administration that repeatedly overreaches and fails to protect patients. We also discuss implementation issues we believe the Administration should take the opportunity to address immediately. Areas for concern addressed in this letter include:

I. Harms to Biopharmaceutical Innovation and Investment in Research & Development

II. Undermines Competitive Market Dynamics

III. Disruptive to Stakeholders

IV. Puts Patient Access at Risk

Aside from outlining our core concerns with the Guidance, we are attaching to this letter several Appendices that provide technical, in-depth input on specific issues. In many instances, the consensus-based recommendations outlined in the Appendices are in addition to feedback that PhRMA has previously provided to CMS in other comment letters or forums. The topics they focus on are of great importance to PhRMA's membership, and we welcome the opportunity to discuss them in more detail with CMS staff.

Appendix A: Drug Selection;

Appendix B: Effectuation of the Maximum Fair Price and MFP Calculation;

[10] *AstraZeneca v. Becerra*, Case No. 1:23-cv-00931, Tr. Oral Argument at 99-100 (D. Del. Jan. 31, 2024) ("THE COURT: Let's say this is. I read the statute. It's clear as a bell . . . So let's just say I agree with AstraZeneca on that. When would a drug company be able to challenge your designation of its blockbuster product? Let's say it only makes one product. When can it do that? MR. NETTER: So it wouldn't be able to, Your Honor. THE COURT: Ever? MR. NETTER: Ever? Well, unless they could try to convince Congress to change the statutory bar. But it's Congress' prerogative. THE COURT: That doesn't bother you, that you could have -- again, imagine it was, again, that there was no other ambiguity in the statute to shed doubt on AstraZeneca's interpretation. So you're saying that an Agency can come along and can issue a regulation that absolutely contradicts the explicit statutory text of Congress? And here -- and you're saying, tough noogies,
there's no review? MR. NETTER: That is the outcome of the standard analysis on judicial bars.").

Appendix C: Access and Coverage;

Appendix D: Information Collection and Negotiation Process; and

Appendix E: Renegotiation

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I. Harm to Biopharmaceutical Innovation and Investment in Research & Development

The IRA and CMS' implementation of the Program fundamentally alter existing R&D incentives and jeopardize the future development of medicines with very real consequences for patients and the broader health care system. Although impacts may vary by company, the IRA and CMS' interpretation of the statute are already discouraging:

- **Post-Approval Innovation.** CMS' broad definition of QSSD, as well as when drugs become eligible for negotiation within their lifecycle, discourages R&D that improves patient outcomes and occurs after a drug or biological is initially FDA approved.
- **Development of Small Molecule Medicines.** By giving small molecule drugs four fewer years than biologics before price negotiations begin, the IRA discourages their development.
- **Development of Orphan Drugs.** Although the IRA exempts certain orphan drugs from negotiation, CMS' overly narrow interpretation of the exemption's eligibility criteria will further harm innovation for these diseases and the companies that are focused on providing treatment options for these populations.
- **Development of Treatments for Chronic Diseases.** CMS' continued selection of chronic disease medicines – which are comparatively low-cost, but widely used – for price setting signals that the IRA makes investing in these medicines uncertain and risky.

CMS' treatment of medicines containing the same active ingredient or moiety as one drug under the Program discourages the post-approval R&D that results in new drugs and biological products.

CMS' interpretation of Qualifying Single Source Drug (QSSD) under the IRA is untethered from the statute and will stifle the development of innovative and lifesaving treatments by treating new dosage forms and formulations with the same active ingredient or moiety as the same drug - even if they are approved under separate applications for different diseases or patient populations. This means that distinct new treatments could face immediate price setting upon approval, eroding the value of critical post-approval innovation and disincentivizing the development of new forms of medicines. A recent study showed that if CMS had applied this approach retroactively to novel drugs approved between 2006 and 2013, 110 unique drugs and biologics products could have been swept into price setting – more than double the intended 50.[11] The consequences are already evident: for IPAY 2026 and 2027, CMS selected

[11] Stratevi. (2025). Combining Apples and Oranges: An Examination of CMS' Methods for Defining a Qualifying Single Source Drug. Available at: https://static1.squarespace.com/static/621e5edfadb9950783f45d9a/t/67cf3ba77613db2190dfb3a6/1741634472366/Multiple+Forms+Policy+Brief.pdf

16 and 26 distinct NDAs and BLAs, respectively, many with different brand names and some approved within three years – far exceeding the statutory limits on the age of the selected drug.

CMS' implementation of the Program will disincentivize post-approval R&D and the development of small molecule medicines, which are critical for driving treatment advances in certain disease areas.

Under the flawed IRA statute, small molecule medicines face price setting four years before biologic medicines. This so-called "pill penalty" discourages the development of treatments that are often the most accessible and critical for conditions like cancer, mental illness, and chronic diseases. Since the IRA was introduced, early-stage investment in small molecules has plummeted by nearly 70 percent among smaller, early-stage biopharma companies.[12] Because post-approval trials can take years to complete and require significant investment, biopharmaceutical companies are also shifting away from pursuing new indications for already FDA-approved treatment in disease areas where post-approval R&D has been indispensable. Since the IRA's enactment, monthly starts of industry-funded post-approval trials for small molecules have dropped 47.3 percent, a much steeper decline than for other drug types.[13] For example, one study found more than 60 percent of small molecule *cancer* drugs approved between 2006 and 2012 received at least one post-approval indication, and nearly half of those occurred seven or more years after initial approval.[14] Similarly, another analysis examining *cardiovascular* medicines approved between 1995 and 2021 found 92 percent were small molecule medicines and among these, nearly half of approved indications were approved seven or more years after initial approval.[15] Unfortunately, many of these indications may be forgone moving forward.

CMS' interpretation of the orphan drug exclusion threatens the development of new medicines to meet unmet needs for patients with rare diseases.

The Orphan Drug Act of 1983 successfully spurred development of treatments for rare diseases by addressing the limited investment incentives caused by small patient populations, high R&D costs, and low success rates – leading to more than 750 orphan drug approvals since its enactment, compared to just 10 in the decade before passage.[16] However, the IRA threatens this progress by narrowly exempting only single-indication orphan drugs from price setting, and CMS' restrictive interpretation of this exemption further undermines incentives for post-approval research that expands access to additional rare disease indications. Historically, 35 percent of orphan drugs have been approved for more than one disease, and 15 percent for more than one rare disease,[17] but under the IRA, additional designations or approvals outside a single orphan designation disqualifies a drug from exemption, discouraging such efforts. Compounding this, broader IRA disincentives compress the time companies have to recoup investments,

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[12] Schulthess, D.G., O'Loughlin, G., Askeland, M. et al. (2025). The Inflation Reduction Act's Impact Upon Early-Stage Venture Capital Investments. *Ther Innov Regul Sci*. Available at: https://doi.org/10.1007/s43441-025-00773-3

[13] Zheng H., Patterson J., Campbell J. (2025). The Inflation Act and Drug Development: Potential Early Signals of Impact on Post-approval Clinical Trials. *Therapeutic Innovation & Regulatory Science*, 1-9.

[14] PhRMA. (July 2023). Emerging Value in Oncology: How Ongoing Research Expands the Benefits of Oncology Medicines. Available at: https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/PhRMA_Emerging-Value-Report/PhRMA_Emerging-Value-Report_FIN-web_July2023_v2.pdf

[15] Grabowski H., Long G. (March 2024). Post-Approval Indications and Clinical Trials for Cardiovascular Drugs: Some Implications of the US Inflation Reduction Act. *Journal of Medical Economics.* Available at: https://www.tandfonline.com/doi/full/10.1080/13696998.2024.2323903

[16] PhRMA analysis of FDA Orphan Drug Product designation database. Available at: https://www.accessdata.fda.gov/scripts/opdlisting/oopd/

[17] Miller, K.L., Lanthier M. (January 2024). Orphan Drug Label Expansions: Analysis Of Subsequent Rare And Common Indication Approvals. *Health Affairs.* Available at: https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2023.00219.

even though more than 80 percent of revenue for orphan-designated products historically came 10 or more years after initial approval. As a result, the IRA creates financial incentives to prioritize larger indications earlier, which could lead to delayed or fewer treatments for rare disease populations,[18] despite the fact that post-approval uses have historically accounted for 30 percent of all new treatment options for patients with rare diseases.[19]

The IRA and CMS' implementation of the Program will jeopardize our ability to treat and prevent chronic disease and bend the cost curve in the years ahead.

Chronic conditions - including mental illness - are the largest drivers of health care costs, accounting for 90 percent of the $4.5 trillion spent on health care annually,[20] and their impact is set to worsen as the number of individuals with three or more chronic conditions is projected to nearly double by 2030. [21,22,23] With eighty percent of chronic disease considered preventable,[24] bending the cost curve will require a comprehensive strategy centered on prevention, early intervention and continued innovation – especially for the Medicare population. Medicines play a critical role in this effort, helping patients prevent and manage disease, avoid complications, and reduce costly health care services as evidenced by Medicare's spending slowdown between 1999 and 2012, where one quarter of the reduction was attributed to greater use of cardiovascular drugs.[25] Yet, implementation of the Program is undermining these gains by discouraging investment in medicines for common illnesses such as heart disease, diabetes, cancer and autoimmune diseases.[26] The Medicare spending that renders medicines eligible for price setting is a factor not of high price, but wide use. By targeting these treatments for price setting, the IRA is weakening one of our most essential tools for combating chronic illness and controlling long-term costs. Economists at the University of Chicago estimate that IRA's price setting policies could raise overall health care spending by $50.8 billion over a 20-year period due to forgone savings from reduced in medical care utilization that medicines would have otherwise delivered.[27]

Key Concerns and Recommendations

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[18] Masia N. (2024). Will Potential IRA Price Limits Delay Drug Launches? *Health Capital Group.* Available at: https://www.ispor.org/docs/default-source/intl2024/ispor24masiapt4poster138000-pdf.pdf?sfvrsn=2450c107_0

[19] IQVIA. (February 2025). Proliferation of Innovation Over Time: Frequency, Timing and Clinical Value of Expansions Post-Initial Approval. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/proliferation-of-innovation-over-time

[20] CDC. (May 2023). Fast Facts: Health and Economic Costs of Chronic Conditions. Available at: https://www.cdc.gov/chronic-disease/data-research/facts-stats/index.html#:~:text=The%20impact%20of%20chronic%20diseases,significant%20health%20and%20economic%20benefits.

[21] Partnership to Fight Chronic Disease. What Is the Impact of Chronic Disease on America? Available at: https://www.fightchronicdisease.org/sites/default/files/pfcd_blocks/PFCD_US.FactSheet_FINAL1%20%282%29.pdf

[22] Buttorff C., Ruder T., Bauman M. (May 26, 2017). Multiple Chronic Conditions in the United States. *Rand Corporation.* Available at: https://www.rand.org/pubs/tools/TL221.html

[23] U.S. Department of Health and Human Services, Office of Minority Health. Heart Disease and African Americans and Hispanic Americans, Diabetes and African Americans and Hispanic Americans, Obesity and African Americans and Hispanic Americans, Asthma and African Americans and Hispanic Americans, Cancer and African Americans and Hispanic Americans.

[24] Katz D.L., Frates E.P., Bonnet J.P., 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/

[25] Cutler D.M., Ghosh K., Messer K.L., et al. (February 2019). Explaining the Slowdown in Medical Spending Growth Among the Elderly. *Health Affairs.* Available at: https://pubmed.ncbi.nlm.nih.gov/30715965/.

[26] 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

[27] Philipson T.J., Di Cera G. Issue Brief: The Impact of Biopharmaceutical Innovation on Health Care Spending. *The University of Chicago.* Available at: https://ecchc.economics.uchicago.edu/2022/08/03/the-impact-of-biopharmaceutical-innovation-on-health-care-spending/

Orphan Drug Exemption. A drug is disqualified from eligibility for the Orphan Drug Exemption (ODE) immediately after a medicine receives a second orphan designation or a new indication outside of its first orphan designation, whether for a different rare disease or another type of disease. Instead of running the 7- or 11-year eligibility clock from when the product loses the exclusion, CMS chose to instead look back to the original FDA approval date to determine eligibility for price setting. Instead, CMS should begin the clock for eligibility for price setting after the product loses its ODE eligibility, not when the product was originally approved. In addition, CMS should evaluate each drug product or biological product individually, such that the approval of a new drug product or biological product could trigger application of the exclusion and a new seven- or 11-year clock to begin upon loss of that exclusion.

Definition of QSSD. A qualifying single source drug (QSSD) is a drug eligible for price setting under the IRA. CMS has interpreted QSSD as all dosage forms and strengths of a drug from the same manufacturer with the same active moiety (for a small molecule) or active ingredient (for a biologic), even if approved under different applications (NDAs or BLAs). For QSSDs that will be selected for price setting in 2028, CMS is proposing to potentially take this misguided approach even further by grouping fixed-dose combinations together with separately approved drugs with just one active ingredient into a single QSSD. Sweeping drugs approved under different applications into one QSSD for price setting is inconsistent with the statute and ignores the significant time and investment manufacturers make in pursuing approval for improved versions of a drug, or fixed dose combinations. Rather, CMS should revise the guidance and treat products approved under different NDAs or BLAs as distinct QSSDs.

For more detailed legal and policy considerations for how CMS can improve the definition of QSSD and the Orphan Drug Exemption, see Appendix A (Drug Selection) to this letter.

II. Undermines Competitive Market Dynamics

The U.S. market-based system is designed to balance innovation, access, and cost containment by promoting robust competition among brand medicines, generics, and biosimilars—driving down prices, and often reducing costs by 60 percent or more.[28] Competition among brand drugs alone has generated billions in savings, with one study showing that launches of new brand medicines between 2013 and 2017 led to over $10 billion in price reductions across 12 therapeutic classes. [29] Over time, this system delivers long-term savings as branded medicines are followed by generics and biosimilars, which now account for 90 percent of prescriptions and have saved $3.1 trillion over the past decade. [30] Despite this success, the IRA and CMS' implementation of its price setting program threaten to dismantle these incentives by allowing the government to impose prices so low that generic and biosimilar manufacturers may no longer find it viable to enter the market. The IRA undermines the statutory framework that rewards first-to-market generics, weakening their ability to compete and recoup investments. For biosimilars, the misalignment between IRA timelines and the 12-year exclusivity period under the Biologics Price Competition and Innovation Act, coupled with CMS' vague and extra-statutory "bona fide marketing" standard, creates profound uncertainty. With biosimilar development already requiring 7 to 8 years and up

[28] Hernandez, I., et al. (2024). Price benchmarks of drugs selected for Medicare price negotiation and their therapeutic alternatives. *Journal of Managed Care & Specialty Pharmacy.* Available at: https://doi.org/10.18553/jmcp.2024.24153
[29] Dickson S., Gabriel N., Hernandez I. (August 2023). Changes in Net Prices and Spending for Pharmaceuticals After The Introduction Of New Therapeutic Competition, 2011–19. *Health Affairs*. Available at: https://www.healthaffairs.org/doi/10.1377/hlthaff.2023.00250
[30] AAM. (2024). The U.S. Generic & Biosimilar Medicines Savings Report, 2024. Available at: https://accessiblemeds.org/resources/reports/2024-savings-report/

to $250 million in investment,[31] this lack of predictability may make future development financially infeasible, leading to fewer products on the market and potential drug shortages while limiting competition. Though the IRA includes a "Special Rule" to potentially delay selection and price setting of eligible biologics facing biosimilar competition, the IRA's statutory language and CMS' interpretation of the law ultimately fail to provide biosimilar manufacturers with the assurances needed to invest resources for biosimilar development. Ultimately, by substituting price setting for competition, the IRA risks unraveling the very system that has delivered both innovation and affordability to patients.

Key Concerns and Recommendations

Biosimilar Pause. The conditions CMS established for qualifying for the pause fail to provide manufacturers with sufficient certainty to invest in biosimilar development. CMS should provide a "pause" if a biosimilar manufacturer can demonstrate that filed agreements do not bar the manufacturer from marketing or the investor disclosures indicate that the product will be ready for marketing before the end of the relevant period. CMS should apply similar approaches when evaluating requests for the second one-year pause and only deny requests with definitive evidence of an inability to come to market.

Bona Fide Marketing. CMS should clarify that "marketing" of a generic drug or biosimilar biological product means its introduction or delivery for introduction into interstate commerce, not the "bona fide marketing" concept invented by CMS.

For more detailed legal and policy considerations for how CMS can improve the biosimilar pause and its interpretation of "marketed," see Appendix A (Drug Selection).

III. Disruptive to Stakeholders

The IRA requires manufacturers to "provide access" to the government-set MFP when a drug is prescribed to a beneficiary (also known as "effectuating the MFP"). However, the IRA is silent on *how* manufacturers should provide access to the MFP. In implementing the Program thus far, CMS has failed to mitigate the potential harm to stakeholders, particularly pharmacies and health care providers, who dispense and administer price-set drugs. A National Community Pharmacists Association (NCPA) survey of its membership revealed that 93.2 percent of independent pharmacists are considering not stocking, or have already decided not to stock, one or more of the first 10 Part D drugs selected for price setting.[32] If pharmacies and health care providers decline to stock or administer selected drugs, it could lead to significant access issues for patients, particularly given that selected drugs are inherently among the most utilized drugs in the Medicare program.

Key Concerns and Recommendations

Part D Effectuation. For IPAY 2027 and beyond, PhRMA continues to believe that the best, most efficient way to ensure prompt pharmacy payment and reduced stakeholder burden would be for, CMS to rely on a model similar to the Part D Coverage Gap Discount Program, where MFP refunds would be paid to pharmacies at or close to the time pharmacies are reimbursed by Part D plans. CMS would provide funds to cover these payments in advance, with manufacturers later invoiced. While we share CMS' goal

[31] Blackstone E.A., Joseph P.F. (2013). The economics of biosimilars. *Am Health Drug Benefits*, 6(8):469-478. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4031732/

[32] NCPA. (January 2025). Report for January 2025 Survey of Independent Pharmacy Owners/Managers. Available at: https://ncpa.org/sites/default/files/2025-01/1.27.2025-FinalExecSummary.NCPA_.MemberSurvey.pdf

of prompt pharmacy payment, we continue to have significant concerns with the requirement to develop mitigation plans for pharmacies self-identifying as having material cashflow concerns.

In addition, to improve program integrity and avoid forcing manufacturers to make an MFP effectuation payment before a drug's 340B status is known, potentially violating the nonduplication provision, CMS must ensure that manufacturers receive timely and accurate information about 340B units in order to deduplicate 340B and MFP discounts. For this reason, CMS should establish a claims repository (along the lines of the one it is exploring to fulfill its obligation to exclude 340B units from Part D inflation rebates) and share this critical data with manufacturers.

CMS should also make clear that the agency will not impose penalties on manufacturers should the MTF DM or PM systems encounter technical issues affecting payment.

Inclusion of MFP in ASP for Selected Drugs. Under the IRA, providers face billions of dollars in cuts in Medicare Part B reimbursement for provider-administered drugs and potentially face similar reductions in the commercial market. PhRMA firmly believes that CMS lacks the legal authority to include MFP in the calculation of Average Sales Price (ASP). Instead, CMS should exercise its existing authority to exclude the MFP from ASP reporting requirements.

Research suggests that including MFP in ASP would further erode reimbursement, with providers projected to face decreases to add-on payments of up to $37 billion for Part B selected drugs.[33] And because ASP serves as a payment benchmark for a wide swath of commercial market health plans and Medicare Advantage (MA) plans,[34] the decrease in provider payments includes an up to 18 percent reduction in add-on payments for provider-administered selected drugs in the commercial and MA markets.[35] Beyond cuts to provider reimbursement, including MFP in ASP for selected medicines will have broadly negative effects on patient access to selected Part B medicines—especially for patients that receive the medicines at rural, community-based, and independent practices—and is likely to distort the competitive marketplace for Part B medicines.

Given the above, PhRMA requests that CMS clearly state that price-set drug units sold at the MFP are excluded from the calculation of ASP and keep providers whole through the definition of the MFP refund amount.

For more detailed legal and policy considerations on this issue, as well as recommendations for how CMS can improve effectuation of the MFP for Part D selected drugs and exclude MFP from the calculation of ASP, see Appendix B (Effectuation) to this letter.

IV. Puts Patient Access at Risk

Price setting in the Part D program undermines the ability of plans to negotiate with manufacturers, which is foundational to the competitive structure and success of Part D. At the same time, it does little to address plan and PBM abuses that harm patient access and increase out-of-pocket costs. In 2025,

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

[34] A recent survey of commercial insurers showed that they reimburse for 72 percent of covered lives in the physician office based on a medicine's ASP. ASP is also the basis of Medicaid reimbursement for provider-administered medicines in many states. *See*, Avalere Health. (September 2024). Commercial Spillover Impact of Part B Negotiations on Physicians. Available at: https://advisory.avalerehealth.com/insights/commercial-spillover-impact-of-part-b-negotiations-on-physicians

[35] Ibid.

beneficiaries in Part D experienced significant reductions in plan choices, higher premiums, and more restrictive plan designs that threaten access to affordable care for more than 50 million seniors and individuals with disabilities. Unless CMS acts, these harms will worsen in 2026 and beyond. As Part B medicines become eligible for price setting beginning in IPAY 2028, we have increased concerns regarding MA plan use of step therapy to limit access to selected Part B drugs or their competitor (a policy PhRMA opposes).

Government price setting and other provisions in the IRA are reshaping formulary dynamics, and plan responses threaten beneficiary access.

Even before government price setting takes effect, various studies have found that plans and PBMs have begun to employ increasingly stringent practices to restrict access to care.[36] One recent analysis found a substantial increase in plans shifting coverage of price-set drugs away from fixed copayments to coinsurance, leading to an increase in beneficiary cost sharing of up to nearly 76 percent.[37] As a result of the IRA, 83 percent of payers expect to increase formulary exclusions in Part D and the vast majority payers expect to increase some type of utilization management.[38] The use of inappropriate utilization management by plans as a blunt instrument to contain costs in response to increases in plan liability will lead to further barriers to patient access by exacerbating already high provider burden, contributing to provider burnout, altering providers' clinical decision-making, and driving patients to treatments that are not aligned with clinical guidelines or not suited for the individual patient when accounting for their unique characteristics.[39,40,41,42]

In addition to worsening access, the IRA is undermining the Part D program, triggering higher premiums and fewer plan choices for beneficiaries.

The number of stand-alone Part D drug plans fell by 26 percent in 2025, to the lowest number of plans available since the program began.[43] At the same time, premiums for beneficiaries who pay monthly premiums for standalone Part D plans rose by an average of 19 percent in 2025 compared to 2023, before the IRA took effect, despite the IRA's premium stabilization program and CMS' additional premium stabilization demonstration.[44] The independent Medicare Payment Advisory Commission also examined these trends in its most recent Report to Congress, describing concerns about the continued availability of

[36] Joyce G., Blaylock B., Chen J., Van Nuys K. (March 2024). Medicare Part D Plans Greatly Increased Utilization Restrictions on Prescription Drugs, 2011-20. Health Affairs. Available at: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.00999
[37] CAHC/Magnolia Market Access. (February 2025). Rotten to the Core: IRA Undermines Medicare Part D. Available at: https://cahc.net/wp-content/uploads/2025/02/CAHC-Part-D-Penalty-Brief-2025.pdf
[38] Magnolia Market Access. (2024). Inflation Reduction Act Payer Insights Report. Available at: www.magnoliamarketaccess.com/wp-content/uploads/MMA_IRA-Payer-Insights-Survey4.0_Chartbook_2024.07.31.pdf
[39] American Medical Association. (2024). 2024 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf
[40] Salzbrenner S.G. et al. (July 2023). Influence of prior authorization requirements on provider clinical decision-making. *Am J Manag Care*. Available at: https://pubmed.ncbi.nlm.nih.gov/37523751/
[41] Gracie J., Jimenez R., Winkfield K.M. (October 2024). The Burden of Insurance Prior Authorization on Cancer Care: A Review of Evidence From Radiation Oncology. *Adv Radiat Oncol*. Available at: https://pubmed.ncbi.nlm.nih.gov/39758976/
[42] Struthers A. et al. (November 2024). Utilization management and physician burnout. *Am J Manag Care*. Available at: https://pubmed.ncbi.nlm.nih.gov/39546758/
[43] Avalere Health. (October 2024). Number of Part D Plan Choices Declines for 2025. Available at: https://avalere.com/insights/number-of-part-d-plan-choices-decline-for-2025
[44] Internal PhRMA analysis of 2023 and 2025 Part D enrollment and premium data.

a sufficient number of plans in the standalone market, and noting that IRA's changes may further amplify trends that contribute to enrollment shifts towards MA-PDs.[45]

Key Concerns and Recommendations

As described above, price setting in Medicare Part D (as well as other IRA provisions) has caused significant harm to patients and consumers through reduced access to medicines, higher premiums and out-of-pocket costs for price-set medicines, and reduced plan options. We appreciate CMS' recent recognition of the importance of monitoring for potential access disruptions for price-set medicines.[46] However, PhRMA is concerned that CMS' existing formulary review and appeals processes are insufficient to protect patient access, not only for MFP-selected medicines but more generally as well. CMS should adopt stronger oversight and safeguards to protect beneficiary access to price-set medicines, including through improving transparency, enhancing patient utilization management and other access safeguards, and strengthening formulary review reporting.

For more detailed legal and policy considerations on this issue, as well as recommendations for how CMS can improve protect patient access to medicines, see Appendix C (Access and Coverage) to this letter.

* * *

PhRMA appreciates your consideration of these comments. Please feel free to contact Elizabeth Carpenter (ecarpenter@phrma.org) and Jim Stansel (jstansel@phrma.org) if there is any further information we can provide or if you have any questions about our comments.

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Elizabeth Carpenter	James C. Stansel
Executive Vice President	Executive Vice President and General Counsel
Policy & Research	PhRMA
PhRMA	

[45] MedPAC. June 2025 Report to Congress: Medicare and the Health Care Delivery System. Available at: https://www.medpac.gov/document/june-2025-report-to-the-congress-medicare-and-the-health-care-delivery-system/
[46] HPMS. (April 2025). CY 2026 Part D Formulary Submission Information. Available at: https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-3-april-14-18

Appendix A: Drug Selection

I. Identification of Qualifying Single Source Drugs for IPAY 2028

PhRMA opposes the overbroad interpretation of a qualifying single source drug (QSSD) that CMS used for initial price applicability year (IPAY) 2026 and 2027 and proposes to maintain for IPAY 2028. Under *Loper Bright Enterprises v. Raimondo*, an agency is required to apply the "single, best meaning" of a statute.[47] The President issued a memorandum on April 9, 2025, prioritizing the review and repeal pursuant to Executive Order 14219 of existing regulations that are unlawful under *Loper Bright.*[48] The definition of QSSD is untethered from the statute and would continue to stifle the development of innovative and life-saving drug and biological products in contravention of *Loper Bright*. Additionally, for IPAY 2028, CMS suggests that it may take a new approach for identifying potential QSSDs for certain fixed-combination products that raises additional legal and policy concerns. For IPAY 2028 and future years, we urge CMS to carefully consider comments on the QSSD definition – and to choose a definition that aligns with the statute and its focus on the Food and Drug Administration's (FDA's) approval under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA) or section 351(a) of the Public Health Service Act (PHSA). We also urge CMS not to adopt its new proposed approach to aggregation of certain fixed-combination products, which is divorced from FDA's definition of a fixed combination and which depends on CMS' own determination of whether the combination results in a clinically meaningful difference.

The IRA defines a QSSD, in relevant part, as follows:

> (A) DRUG PRODUCTS.—A drug—
>
> > (i) that is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and is marketed pursuant to such approval;
> >
> > (ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 7 years will have elapsed since the date of such approval; and
> >
> > (iii) that is not the listed drug for any drug that is approved and marketed under section 505(j) of such Act.
>
> (B) BIOLOGICAL PRODUCTS.—A biological product—
>
> > (i) that is licensed under section 351(a) of the Public Health Service Act and is marketed under section 351 of such Act;
> >
> > (ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 11 years will have elapsed since the date of such licensure;

[47] 603 U.S. 369 (2024).
[48] White House. (April 2025). Presidential Actions, Directing the Repeal of Unlawful Regulations. Available at: https://www.whitehouse.gov/presidential-actions/2025/04/directing-the-repeal-of-unlawful-regulations/.

(iii) that is not the reference product for any biological product that is licensed and marketed under section 351(k) of such Act.[49]

Thus, the statute establishes two key requirements for each QSSD:

(1) **Approval under an NDA or BLA.** A QSSD must be "approved under section 505(c)" of the FDCA or "licensed under section 351(a)" of the PHSA. At least 7 years (for a drug) or 11 years (for a biological) must have elapsed since the date of "such approval," or "such licensure" – both in the singular, referencing a single new drug application (NDA) or biologics license application (BLA). Therefore, each QSSD is limited to drug products or biological products approved under the same NDA or licensed under the same BLA. The terms "drug product" or "biological product" refer to the finished product, including the unique dosage form, strength, and route of administration.[50]

(2) **Age Requirement.** For a drug product, the statute requires "at least 7 years" to have elapsed from the date of approval to the selected drug publication date. For a biological product, the statute requires "at least 11 years" to have elapsed from the date of approval to the selected drug publication date. Because a drug product or biological product cannot be marketed until it is approved or licensed,[51] the 7 or 11 year "age requirement" must be applied to each particular drug product or biological product, whether it was approved under the original NDA/BLA or a supplement to a given NDA or BLA.

Despite these clear Congressional directives, CMS proposes to continue using an overly broad interpretation of a QSSD that impermissibly aggregates drug products and biological products based on their active moiety or active ingredient—neither of which is mentioned in the IRA. The Guidance specifies that "all dosage forms and strengths of the drug with the same active moiety and the same holder of a [NDA], inclusive of products that are marketed pursuant to different NDAs," constitute the same QSSD.[52] For biological products, the Guidance describes a QSSD as "all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a [BLA], inclusive of products that are marketed pursuant to different BLAs."[53] Additionally, CMS misapplies the age requirement. CMS states that "the earliest date of approval" or "the earliest date of licensure" of the initial FDA application number assigned to the respective NDA / BLA holder for the active moiety / active ingredient (or in the case of fixed combination drugs, for the distinct combination of active moieties / active ingredients) would determine whether the respective 7 or 11 year period for QSSD status had elapsed.[54] The statute, however, requires each individual drug product or biological product to meet the age requirement.

PhRMA urges CMS to align its definition of a QSSD with the statutory requirements. ***Specifically, CMS should require that, for a drug or biological product to be included in a QSSD, it must be approved or licensed under the same NDA or BLA, either as part of the original application or under a supplement***

[49] Social Security Act (SSA) § 1192(e)(1) (emphasis added).
[50] *See* e.g., 21 C.F.R. § 314.3, defining "drug product" as "a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients."
[51] *See* FDCA §§ 505(a), 506A(a), (c); PHSA § 351(a)(1); 21 C.F.R. §§ 314.70, 601.12.
[52] IPAY 2028 Draft Guidance, at 11.
[53] *Ibid*.
[54] *Ibid.* at 14 (emphasis added).

to such application. Further, the approval or licensure of any drug product or biological product must have occurred at least 7 or 11 years (as applicable) prior to the selected drug publication date (i.e., ., the relevant supplement must be at least 7 or 11 years old).[55] Any other approach would violate the statute and stifle innovation. These two principles are briefly addressed further below.

A QSSD must be limited to drug products/biological products that are approved/licensed under a single NDA/BLA.

The terms "active moiety" and "active ingredient" appear nowhere in the QSSD statutory definition (or anywhere in the IRA). Rather, as explained above, the statute unambiguously defines the scope of a QSSD based on an individual NDA or BLA.

The statute's anchor to an NDA or BLA aligns with the fact that Congress authorized FDA to "approve" and "license" drug products and biological products, not their active moieties and active ingredients alone.[56] Moreover, both prongs of the QSSD definition refer to finished products: the subparagraph header for drugs is "[d]rug products," not drug substance or active moiety, and the subparagraph header for biological products similarly refers to "[b]iological products," not active ingredients.

Had Congress intended to define QSSD at the active moiety or active ingredient level, it would have said so in the statute.[57] As demonstrated in a recent amendment to the FDCA's new chemical entity exclusivity provisions that replaced the term "active ingredient" with "active moiety," [58] Congress is familiar with both of these terms and knows how to use them when they are intended.

Additionally, CMS' assertion that its "approach to identifying a potential [QSSD] aligns with the requirement in section 1192(d)(3)(B) of the Act,"[59] (the "Use of Data" provision) is incorrect. The Use of Data provision states:

> In determining whether a qualifying single source drug satisfies any of the criteria [related to a negotiation-eligible drug and the small biotech exception] the Secretary shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug.[60]

The reference to "a qualifying single source drug" and "of the drug" – both in the singular – demonstrate that the Use of Data provision directs CMS to aggregate data on certain eligible drug products or

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[55] Under CMS' current position, "a selected drug will no longer be subject to the negotiation process and will cease to be a selected drug . . . if CMS determines (1) the FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference-listed drug a product that is included in the selected drug, or the FDA has licensed a biosimilar biological product under section 351(k) of the PHS Act that identifies as its reference product a product that is included in the selected drug; and, (2) the generic drug or biosimilar biological product, as applicable, is marketed pursuant to such approval or licensure." IPAY 2026 Initial Guidance, at p. 164. Given CMS' current approach to QSSD, PhRMA supports this position.
[56] FDCA § 505(c); PHSA § 351(a).
[57] *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-254 (1992) ("We have stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there. *See, e. g., United States v. Ron Pair Enterprises, Inc.*, 489 U. S. 235, 241–242 (1989); *United States v. Goldenberg*, 168 U. S. 95, 102–103 (1897); *Oneale v. Thornton*, 6 Cranch 53, 68 (1810). When the words of a statute are unambiguous, then, this first canon is also the last: 'judicial inquiry is complete.' *Rubin v. United States*, 449 U. S. 424, 430 (1981); *see also* Ron Pair Enterprises, supra, at 241.").
[58] *See* Ensuring Innovation Act, Pub. L. No.. 117-9, 135 Stat. 255 (2021).
[59] IPAY 2028 Draft Guidance, at 12.
[60] SSA § 1192(d)(3)(B) (emphasis added).

biological products within the same QSSD. Nothing in the Use of Data provision permits or requires CMS to expand the scope of a QSSD to encompass drug products or biological products approved under "different NDAs or BLAs." Rather, the statute is clear that each QSSD constitutes eligible drug products or biological products approved under a single NDA/BLA (including supplements to such application).

Each drug product or biological product in a QSSD must independently meet the age requirement.

PhRMA opposes CMS' proposal to base the age requirement off "the earliest date" of approval or licensure of the initial FDA application number assigned to the NDA / BLA holder for the active moiety / active ingredient (or in the case of fixed combination drugs, for the distinct combination of active moieties / active ingredients).[61] Under this approach, even a new drug product or biological product (e.g., a new dosage form, strength, or route of administration) approved under a supplemental application after an MFP has been set would be part of the existing QSSD and saddled with its pre-existing MFP. This approach directly conflicts with the statute, which requires that each drug product or biological product independently meet the age requirement. CMS lacks the authority to extend MFPs to drugs and biologics that have not been approved or licensed for the statutorily-specified number of years.

As explained above, the statutory QSSD definition refers back to the number of years (i.e., 7 or 11 years) since "such approval" under section 505(c) of the FDCA or section 351(a) of the PHSA. By law, a new drug product or biological product must be approved before it can be marketed.[62] Thus, for each drug product or biological product, the relevant approval date is the date of FDA approval of the original or supplemental NDA/BLA for that drug product or biological product – not the approval date of an older drug product or biological product that happens to have the same active moiety or active ingredient.

Maintaining CMS' current approach will further stifle medical innovation.

Not only is CMS' current QSSD definition inconsistent with the statute, if carried over to future years it would hurt patients by continuing to curb incentives for innovation. Under CMS' approach, once a product containing a novel active ingredient or active moiety has been approved or licensed, incentives for ongoing or new research on drug or biological products with that active ingredient or moiety would sharply decline. No matter how clinically significant the innovation is, the same manufacturer's novel product with a previously approved active moiety or ingredient would be subject to selection for price setting if approved after the seven- or 11-year period for the initial product. Therefore, this approach can broadly cut incentives to invest in a variety of medical advances. For example, the National Pharmaceutical Council has concluded that the price setting program will lead to delays in single-indication drug launches, reduce investments in post-approval research for new indications, and have a negative impact on long-term health outcomes.[63] Another study observed, since passage of the IRA, a "35% decline in clinical trial launches for the Medicare-aged population and a 70% decline in funding for early-stage developments in small molecules [that] indicates significant negative impacts on the population the IRA legislation is allegedly designed to aid."[64] Even if a product with a previously

[61] IPAY 2028 Draft Guidance, at 14 (emphasis added).
[62] *See* FDCA §§ 505(a), 506A(a), (c); PHSA § 351(a)(1); 21 C.F.R. §§ 314.70, 601.12.
[63] O'Brien J.M., Motyka J., Patterson J. (November 2023). How the IRA Could Delay Pharmaceutical Launches, Reduce Indications, and Chill Evidence Generation. *Health Affairs.* Available at: https://www.healthaffairs.org/content/forefront/ira-could-delay-pharmaceutical-launches-reduce-indications-and-chill-evidence.
[64] Schulthess D.G., O'Loughlin G., Askeland M., Gassull D., Bowen H.P. (April 2025). The Inflation Reduction Act's Impact Upon Early-Stage Venture Capital Investments. *Ther Innov Regul Sci.* Available at: https://pubmed.ncbi.nlm.nih.gov/40223014/

approved active moiety or active ingredient were improved in a way that provides a different and meaningful benefit to patients, the improved product would not receive its own seven- or 11-year period (for drugs or biologics, respectively) before potential identification as a QSSD. For example, products with wholly novel delivery systems for previously approved active ingredients that allow much safer, more effective, and more accessible treatment, such as in the home, would be discouraged. As noted earlier, such a product could even have an MFP from day one – which suggests that the research to fuel development of the advanced product may never occur. To avoid these disincentives for pharmaceutical innovation that will harm public health, CMS should revise its aggregation methodology to conform to the statute.

CMS should apply a consistent approach to fixed-combination products for the purposes of identifying QSSDs and should not adopt the proposed new approach.

For IPAY 2028, CMS suggests that it is contemplating a new and different approach to aggregating certain fixed-combination products. CMS describes a general approach consistent with its IPAY 2027 guidance where a distinct combination of active moieties / active ingredients is considered to be one active moiety / active ingredient for the purpose of identifying potential QSSDs.[65] However, CMS indicates that while this approach "is generally appropriate," it might not be appropriate for certain fixed-combination products for which one of the active moieties or active ingredients is not "therapeutically" or "biologically active" against "the disease state(s) the drug is indicated for and thus does not result in a clinically meaningful difference."[66] CMS provides an example where one active moiety or active ingredient in the fixed-combination product "affects the bioavailability" of the other active moiety or active ingredient "but is not therapeutically active" against the indicated disease state, and CMS concludes that the addition of such component "does not result in a clinically meaningful difference."[67] We have a number of concerns with this proposal:

First, there is no statutory basis for CMS' proposed approach. The IRA does not include any language authorizing CMS to parse the internal composition of FDA-approved drug products. The terms "therapeutically active," "biologically active," and "clinically meaningful difference" do not appear in the statute, and Congress did not delegate to CMS the authority to make judgements about the contribution of individual components to a drug's therapeutic or biological effect or clinical meaningfulness for purposes of the QSSD definition. These are scientific determinations that lie squarely within FDA's jurisdiction and expertise. While CMS' recognition that a fixed-combination product may constitute a distinct QSSD aligns with the statute and FDA practice, CMS' attempt to disaggregate such products based on undefined criteria raises significant concerns.

Second, there is no legal or scientific basis for CMS treating different fixed-combination products differently for the purposes of identifying QSSDs. The described approach is inconsistent with FDA's own longstanding regulations. FDA's fixed-combination regulation states that "[t]wo or more drugs may be combined in a single dosage form when *each component makes a contribution to the claimed effects* and the dosage of each component (amount, frequency, duration) is such that the combination is safe and effective for a significant patient population[.]"[68] This regulation explicitly recognizes special cases

[65] IPAY 2028 Draft Guidance, at 13.
[66] *Ibid*.
[67] *Ibid*.
[68] 21 C.F.R. § 300.50(a).

where components are added "to enhance the safety or effectiveness of the principal active component" or "to minimize the potential for abuse of the principal active component."[69] Because each active moiety or active ingredient in a fixed-combination product *must* contribute to the claimed effects in order for FDA to approve a fixed-combination product, all such components necessarily are "therapeutically active" and "biologically active," and "result in a clinically meaningful difference." CMS' proposed requirement that each ingredient be "biologically active against the disease state(s)" directly contradicts this established FDA framework.

Moreover, under FDA regulations, an "active moiety" is defined as the molecule or ion (excluding certain appendages) "*responsible for the physiological or pharmacological action of the drug substance*,"[70] and "active ingredient" to mean "any component that is intended to furnish *pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease*."[71] A component cannot be classified by FDA as an active moiety or active ingredient and simultaneously be considered therapeutically or biologically inactive. FDA's recognition of a component as such confirms that it is therapeutically and biologically active, not an excipient or inactive ingredient.[72] Thus, there is no legal or scientific basis for adopting an approach in which CMS' treatment of a fixed-combination product would depend on CMS' determination of whether a component is therapeutically or biologically active or results in a clinically meaningful difference.

Third, in deciding which fixed-combination products to develop for patients, pharmaceutical manufacturers have relied upon CMS' existing consistent approach to all fixed-combination products. Having established this approach and induced industry reliance upon it, CMS cannot now arbitrarily abandon it without compelling justification, especially not through the scientifically baseless distinctions proposed here. CMS has provided no adequate justification for abandoning its established approach, and any such departure would require CMS to demonstrate both statutory authority and scientific expertise it does not possess to override FDA's determinations regarding active ingredients under 21 C.F.R. § 300.50. Moreover, CMS lacks both statutory authority and scientific expertise to second-guess FDA's determinations regarding active ingredients under 21 C.F.R. § 300.50, and any attempt to do so would create an impermissible conflict between federal agencies with overlapping jurisdiction over the same products.

Fourth, the proposal creates a situation where products approved per FDA regulations could be penalized under federal reimbursement regulations. This regulatory conflict undermines regulatory predictability, as manufacturers have relied on FDA's 21 C.F.R. § 300.50 standard when developing fixed combination products. The CMS proposal retroactively changes this standard, potentially subjecting compliant products to accelerated selection timelines. Furthermore, it creates dual standards where a product could simultaneously meet FDA's standards for an approvable fixed-combination drug while failing CMS' narrower interpretation for QSSD classification purposes. The lack of harmonization between FDA and CMS standards raises serious concerns about federal health care policy coherence.

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[69] 21 C.F.R. § 300.50(a)(1) and (2).
[70] 21 C.F.R. § 314.3(b).
[71] 21 C.F.R. § 210.3(b)(7).
[72] *See, e.g.,* FDA Final Guidance, *Using the Inactive Ingredient Database* at 1 n. 2 (July 2019) (defining "excipients" to mean any *inactive ingredients* that are added intentionally to therapeutic and diagnostic products, *but that are not intended to exert therapeutic effects at the intended dosage, although they may act to improve product delivery* (e.g., enhance absorption or control release of the drug substance).").

Fifth, PhRMA is concerned that the draft guidance does not provide a clear definition, criteria, or standards for determining what constitutes being "biologically active against the disease state(s)." This ambiguity leads to numerous unanswered questions regarding the scope of activity required, as well as whether components must have a direct therapeutic effect on the primary pathophysiology or if indirect effects such as improving drug delivery or enhancing bioavailability would qualify. The level of evidence CMS would require to demonstrate biological activity remains undefined, as does how broadly or narrowly "the disease state(s)" would be defined. As an example, for cancer drugs, it is unclear whether "biologically active against the disease state(s)" means activity specifically against tumor cells or if enhancing immune function or reducing treatment toxicity would qualify. The term "clinically meaningful difference" is equally problematic due to its vagueness. Will this be assessed based on primary clinical endpoints from pivotal trials, secondary endpoints or exploratory analyses, real-world evidence of improved adherence or quality of life, health care resource utilization metrics, or patient-reported outcomes? What constitutes "meaningful" remains unclear—is a 20 percent improvement in bioavailability meaningful? A 50 percent reduction in infusion time? A change from IV to subcutaneous administration? The stakeholder perspective for determining meaningfulness—whether patients, providers, payers, or CMS specifically—is never clarified. Patients should play a large role in dictating what types of innovation would bring value and fulfill unmet needs, not CMS. Introducing terms like "clinically meaningful difference" at this QSSD determination stage risks conflating identification with a premature value assessment.

Sixth, PhRMA has concerns that the proposed policy would breed uncertainty about when and whether a particular product can be selected for price setting, as determination of whether a component is therapeutically or biologically active or results in a clinically meaningful difference may be difficult to predict, particularly in the absence of clear definitions of these terms. The resulting uncertainty would disincentivize future investment in novel fixed combination products for diseases such as cancer to the detriment of patients.

II. Biosimilars "Pause"

PhRMA urges CMS to implement the biosimilars "pause" provision in section 1192(f) in a way that promotes predictability for biologic and biosimilar manufacturers in the marketplace. Congress has enacted a "Special Rule"[73] enabling certain biosimilar manufacturers to obtain a "pause" before the reference product is selected for MFP price setting to allow time for the biosimilar product to secure approval and begin marketing.[74] The statute provides for an initial 1-year "pause" if CMS determines there is a "high likelihood" that a biosimilar will be "licensed and marketed" before the date that is two years after the selected drug publication date with respect to the IPAY.[75] Further, the statute requires CMS to "delay the inclusion of" a reference product on the list of selected drugs for a second 1-year period if the biosimilar product has not been licensed and marketed during the initial 1-year period and, in response to a request timely made by a biosimilar manufacturer, CMS determines that:

> (1) there remains a "high likelihood . . . that such biosimilar biological product . . . will be licensed and marketed . . . before the date that is

[73] Pub. L. 117-169 § 1102, 136 Stat. 1818, 1854. (August 2022). Available at: https://www.congress.gov/117/plaws/publ169/PLAW-117publ169.pdf.
[74] SSA § 1192(f)(1)(A).
[75] SSA § 1192(f)(2)(A).

> two years after the selected drug publication date for which such biological product" would have been a selected drug, and
>
> (2) "on the basis of clear and convincing evidence," the biosimilar manufacturer "has made a significant amount of progress. . . towards both such licensure and the marketing of such biosimilar biological product . . . since the receipt by the Secretary" of the request for an initial 1-year pause.[76]

Predictable and flexible implementation of the "pause" is required to maintain a robust and competitive U.S. market through biosimilar competition. Congress created a carefully balanced system through the Biologics Price Competition and Innovation Act (BPCIA) to encourage competition in the marketplace between reference biologics and biosimilars, while maintaining incentives for continued innovation. Since the introduction of the first biosimilar in 2015, a total of 44 biosimilars have launched to compete against 13 brand biologic products leading to a total of $36 billion in savings.[77] [78] The introduction of biosimilar competition into the biologics market has led to dramatically lower prices not only for biosimilars, but also for reference products.[79] One recent study examining average sales prices in Medicare since 2015 found brand biologic prices dropped 10-13 percent for *each* additional biosimilar competitor, with some brand biologic competing with as many as six biosimilars.[80] [81] Annualized savings from biosimilars reached $12.4 billion in 2023.[82] The success of the biosimilars market is largely due to the regulatory predictability and efficiencies that have been provided by the FDA's successful implementation of the abbreviated approval pathway for biosimilars and the resources provided through the Biosimilar User Fee Act.

The IRA jeopardizes this carefully constructed balance that has significantly benefited patients and reduced health care spending. The timeframes for MFP price setting are in many cases well before it is feasible for a biosimilar to come to market, creating a significant disincentive for manufacturers to invest in these cost-saving alternatives. The processes necessary to market a biosimilar product can be complex, and there are many steps that are not solely in control of the biosimilar sponsor, including FDA review or timelines for patent litigation under the BPCIA's "patent dance" framework. Despite this complexity, the statutory "pause" provisions set rigid time requirements for completion of these activities. The fact that reference biologics may be selected for MFP price setting before the biosimilar may even be eligible for

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[76] SSA § 1192(f)(2)(B).
[77] Amerisource Bergen. (January 2025). U.S. Biosimilars Landscape. Available at: https://www.amerisourcebergen.com/-/media/assets/corporate/global/resource-pages/cencora-biosimilars-usmarketlandscape-jan25.pdf
[78] Association for Accessible Medicines. (September 2024). 2024 U.S. Generic & Biosimilar Medicines Savings Report. Available at: https://accessiblemeds.org/resources/reports/2024-savings-report/#:~:text=Savings%20from%20biosimilar%20medicines%20alone,of%20these%20lower%2Dcost%20medicines.
[79] Xcenda. (July 2022). Biosimilars are Lowering Costs in the Medicare Part B and Across the Healthcare System Overall. Available at: https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_biosimilar_trends_issue_one_july2022.pdf.
[80] Jofre-Bonet M. et al. (May 2025) The Price Effects of Biosimilars in the United States. *Value in Health*. Available at: https://www.valueinhealthjournal.com/article/S1098-3015(25)00086-5/abstract?_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS1098301525000865%3Fshowall%3Dtrue
[81] PhRMA. (October 2021). The U.S. Market for Biosimilars and Biologics Medicines. Available at: https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/PhRMA---Biosimilars-Market-Multi-Pager_v11.pdf.
[82] IQVIA. (January 2023). Biosimilars in the United States 2023-2027 Competition, Savings, and Sustainability. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027.

licensure only exacerbates the timing issues. Even though biosimilars may not be approved until 12 years after the first licensure of a reference product,[83] the IRA would allow selection of the reference product for MFP-setting after only 11 years.

In this context, it is critical that CMS implements the "pause" provision in as predictable and flexible a manner as possible. In this regard, we are concerned by the brief and inflexible 30-day window CMS anticipates for submission on initial delay requests. We also urge CMS to revise its approach to determining whether there is a "high likelihood" that a biosimilar product will be licensed and marketed during the relevant time period by adhering more closely to the statute and providing additional clarity and flexibility. While we acknowledge that for IPAY 2028, CMS has described in more detail what information it proposes to consider as "clear and convincing evidence" of a "significant amount of progress" in support of an additional delay request,[84] we urge CMS to provide greater clarity on such information. We provide factors that should guide CMS' determination that there is "clear and convincing evidence" of a "significant amount of progress" towards licensure and marketing of the biosimilar product.

CMS should provide a longer window of time for submitting initial delay requests.

For IPAY 2028, CMS explains that it intends to provide the opening date for submissions of initial delay requests after approval of the Drug Selection Information Collection Request (ICR) by the Office of Management and Budget (OMB).[85] Consistent with IPAY 2027, CMS explains that it anticipates a 30-day window for submission of initial delay requests.[86] We are concerned that biosimilar manufacturers cannot predict when OMB may approve the ICR and that 30 days is an inadequate time period to prepare and submit such requests. The lack of notice and brevity of the submission window offer neither the predictability nor flexibility needed to implement the biosimilar pause effectively.

CMS' interpretation of the "high likelihood" requirement is untethered from the statute, unworkably vague, and overly rigid.

The statute directs CMS to determine that there is a "high likelihood" the biosimilar product will be licensed and marketed if it finds that FDA has accepted for review or has approved a biosimilar application, and information submitted by the biosimilar manufacturer "provides clear and convincing evidence that such biosimilar biological product will," within the specified time period, "be marketed."[87] Specifically, the statute provides that CMS will consider the following information in determining whether there is such a "high likelihood":

> All agreements related to the biosimilar product filed with the Federal Trade Commission (FTC) or Assistant Attorney General (DOJ) pursuant to section 1112(a) and (c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA);
>
> To the extent available, the manufacturing schedule for the biosimilar product submitted to FDA during its review of the BLA; and

[83] PHSA § 351(k)(7)(A).
[84] IPAY 2028 Draft Guidance, at 38-39. See also IPAY 2027 Final Guidance, at 177, fn. 84.
[85] IPAY 2028 Draft Guidance, at 28, fn 38.
[86] *Ibid*. at 28-29.
[87] SSA § 1192(f)(3).

To the extent available, certain disclosures by the biosimilar manufacturer that pertain to the marketing of the biosimilar product and that are made in certain filings with the Securities and Exchange Commission (SEC) or in comparable documentation distributed to the shareholders of privately held companies.[88]

As explained above, under *Loper Bright Enterprises v. Raimondo*, an agency is required to apply the "single, best meaning" of a statute.[89] Also as noted above, the President issued a memorandum on April 9, 2025, prioritizing the review and repeal pursuant to Executive Order 14219 of existing regulations that are unlawful under *Loper Bright.*[90] CMS has not implemented the statutory provisions governing the information to be used to make a "high likelihood" determination in a manner that represents the single, best meaning of the statute. The approach described in the draft guidance is inconsistent with the statute and is burdensome.

First, CMS maintains that for CMS to determine that there is a "high likelihood" for purposes of qualifying for a "pause" with respect to IPAY 2028, the biosimilar's application for licensure must be approved or accepted for review by the FDA no later than January 15, 2026.[91] Given the rigid timelines associated with the statutory "pause" and the fact that biologics may be selected for MFP price setting before the biosimilar may even be eligible for licensure, PhRMA urges CMS to allow the biosimilar manufacturer to submit information indicating that its application for licensure will be accepted for review or approved by FDA by the date of selection, i.e., February 1, 2026. CMS could also consider providing at least one quarter of advance notice to manufacturers of drugs anticipated for selection and providing biosimilar manufacturers the opportunity to inquire if a particular reference biologic is among the drugs anticipated for selection.

Second, with respect to CMS' evaluation of the "high likelihood" of marketing, PhRMA has significant concerns with CMS expectations that the above information submitted by the biosimilar manufacturer "demonstrates both (1) that patents *related to* the Reference Drug are unlikely to prevent the Biosimilar from being marketed; and (2) that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar."[92] CMS proposes that it will consider the first requirement met if (A) "there are no unexpired patents relating to the reference product . . . that are applicable to the Biosimilar"; (B) "one or more court decisions or decisions by the United States Patent and Trademark Office (USPTO)'s Patent Trial and Appeal Board (PTAB) establish the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patent relating to the reference product included in the Reference Drug that the patent holder asserted was applicable to the Biosimilar"; or (C) "the Biosimilar Manufacturer has a signed legal agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar before the High Likelihood Deadline, without imposing improper constraints on the Biosimilar Manufacturer."[93,94]

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[88] SSA § 1192(f)(3)(B).
[89] 144 S. Ct. 2244, 2266 (2024).
[90] White House. (April 2025). Presidential Actions, Directing the Repeal of Unlawful Regulations. Available at: https://www.whitehouse.gov/presidential-actions/2025/04/directing-the-repeal-of-unlawful-regulations/.
[91] IPAY 2028 Draft Guidance, at 30.
[92] *Ibid*. at 36 (emphasis added).
[93] *Ibid*. at 36-37.
[94] CMS should clarify that "improper constraints" in this context is meant to refer to the agreements described in section 1192(f)(2)(D)(iv)(II)(aa) or (bb).

With respect to the first requirement (i.e., "that patents *related to* the Reference Drug are unlikely to prevent the Biosimilar from being marketed"), it is unclear which patents CMS considers to be "related to" the reference product. For IPAY 2028, CMS is soliciting comments "regarding whether there is additional or alternative evidence that may demonstrate that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed before the High Likelihood Deadline."[95] We urge CMS to clarify or eliminate the first requirement, as it unnecessarily limits the availability of the "pause." If this factor is retained for IPAY 2028, we support CMS' consideration of additional or alternative evidence in determining whether patents related to the reference product are unlikely to prevent the biosimilar from being marketed before the "High Likelihood" deadline and suggest that this should be at the discretion of the biosimilar manufacturer on a case-by-case basis.

Second, we agree that "CMS should consider public-facing statements in which the Biosimilar Manufacturer asserts that ongoing patent disputes will be resolved within the relevant time period for the High Likelihood Deadline."[96] We urge CMS to consider such public-facing statements, including publicly disclosed biosimilar entry dates, as doing so would represent a less onerous and more efficient way of making such a determination.

Third, CMS is soliciting "comments on whether investments in operationalization efforts, or other Biosimilar Manufacturer activity, may be evidence that demonstrates a patent dispute will be resolved or not prevent marketing of the Biosimilar by the High Likelihood Deadline."[97] Below, PhRMA identifies the types of Biosimilar Manufacturer activities that should be considered in high likelihood determinations.

Related to this issue, PhRMA also requests that CMS clarify that if a Biosimilar Manufacturer has carved out a patent-protected indication or method of use from the Biosimilar's labeling, then such patents would not be considered "applicable to the Biosimilar," and, therefore, will not be considered in this analysis consistent with the approach set forth in the summary of public comments in the Revised IPAY 2026 Guidance. There, CMS noted that "if a Biosimilar Manufacturer has carved out a patent-protected indication or method of use from the Biosimilar's labeling, then such patents would not be considered to be 'applicable to the Biosimilar.'"[98]

With respect to the second requirement (i.e., "that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar"), the term "operationally ready" is vague, and we are concerned that CMS will implement this language narrowly, to the detriment of biosimilar development. CMS rigid requirement that the biosimilar demonstrate both showings also undermines the flexibility necessary to avoid undermining the delicate balance Congress established through the BPCIA.

To give the statute its single, best meaning and to implement an approach that is least burdensome, PhRMA urges CMS to permit submission of additional information and documents by any person or obtained by CMS from any other source for CMS to consider in making a "high likelihood" determination. This approach enables CMS to base its determination on the most comprehensive body of evidence and thus give the statute its single, best meaning. CMS should also acknowledge that public

[95] IPAY 2028 Draft Guidance, at 40.
[96] *Ibid.*
[97] *Ibid.*
[98] *See* Revised IPAY 2026 Guidance, at 26.

disclosures such as press releases or other communications may suffice as evidence that the biosimilar was accepted for review or approved by FDA, of the status of the biosimilar's clinical studies, and of the expected time to market. Much of the information necessary to make a "high likelihood" determination is available in readily accessible public sources and should not necessitate a burdensome submission by the biosimilar manufacturer.

In addition, we recommend that CMS find a "high likelihood" of marketing if, absent definitive evidence of an inability to come to market based on the manufacturing schedule, the biosimilar manufacturer meets either of the following criteria:

1. Agreements filed with the FTC/DOJ do not bar the biosimilar manufacturer from marketing the biosimilar product before the end of the relevant period; or

2. The investor disclosures indicate plans to market, or the manufacturing schedule submitted to FDA for the biosimilar product indicates that commercial lots of the biosimilar product are expected to be produced, before the end of the relevant period.

These criteria are directly tied to the information that the biosimilar manufacturer is required to submit under section 1192(f)(1)(B)(ii). Moreover, allowing the biosimilar manufacturer to satisfy *either* showing provides necessary flexibility to prevent the IRA from jeopardizing biosimilar development.

If CMS has remaining questions about the likelihood of marketing, CMS could also consider the following additional criteria:

- The biosimilar manufacturer has not stated in its disclosures to investors or in filings to the SEC, such as Forms 10-K or 10-Q, that it will not market the biosimilar product before the end of the relevant period;

- The biosimilar manufacturer has not withdrawn its BLA;

- The biosimilar manufacturer is not in arrears for any user fees due under section 744H of the FDCA for the biosimilar application;

- No manufacturing facility where the biosimilar is made, processed, etc., has a classification of Official Action Indicated;

- No clinical trial protocol amendments have been filed that would delay enrollment completion dates and subsequent biosimilar marketing beyond the pause period.

CMS should undertake a predictable and flexible approach toward evaluating requests for the second 1-year pause.

If an initial "pause" is granted, then for purposes of assessing whether the requirements for a second 1-year pause have been met, the statute requires CMS to determine, on the basis of "clear and convincing evidence," whether a biosimilar manufacturer has made a "significant amount of progress" toward "licensure" and "marketing." This re-evaluation is to be based on the following sources of information:

All agreements related to the biosimilar product filed with the FTC/DOJ pursuant to section 1112(a) and (c) of the MMA; and

Any additional information and documents submitted by the biosimilar manufacturer in response to a request from CMS.[99]

PhRMA appreciates that for IPAY 2027, CMS solicited comment regarding the types of documentation and information that may constitute "clear and convincing evidence" of a "significant amount of progress." For IPAY 2028, CMS describes procedures for submission of additional delay requests and the requirements for granting them in its draft guidance that largely mirror those described for an initial delay request. CMS has provided a high-level description of the information it will use to determine whether a "significant amount of progress has been made" based on a "holistic review."[100] CMS explains that it will "consider if the Biosimilar Manufacturer can demonstrate affirmative progress towards being operationally ready to market the Biosimilar" and will "consider the Biosimilar Manufacturer's progress on the actions, activities, and milestones that are typical of the normal course of business leading up to the marketing of a drug since the successful Initial Delay Request submission for the Biosimilar evidenced in both any updates or supplements to the documents" specified above.[101] These general descriptions lack specificity and thus do not provide sufficient notice of the types of evidence CMS may consider in making a "significant amount of progress" determination.[102] It is not clear what CMS considers to be "operationally ready" or "actions, activities, and milestones that are typical of the normal course of business leading up to the marketing of a drug."[103] These vagueness of these evidentiary standards will not lead to predictable implementation of the biosimilar pause. We recommend clarifying these points.

We maintain that CMS' analysis of an additional delay request should be both predictable and flexible. To that end, CMS should simply seek attestation by the biosimilar manufacturer that it has made progress toward marketing in order to determine whether to grant a second-year pause. To the extent CMS makes a further inquiry, it should be limited to definitive evidence of an inability to come to market and absent such definitive evidence of an inability to come to market, CMS should find a "significant amount of progress" if any of the criteria below are met:

1. If the biosimilar application was pending upon review during the first year of the pause:
    a. FDA has since approved the application;
    b. The first cycle of review remains ongoing, i.e., FDA's user fee goal date for action on the application has not yet occurred; or
    c. FDA has issued a complete response letter to the biosimilar manufacturer for the BLA and, as of the time that CMS is assessing eligibility for the second 1-year pause, the biosimilar manufacturer has resubmitted the BLA; or
2. The biosimilar manufacturer's investor disclosures indicate plans to market before the end of the relevant period;

[99] SSA § 1192(f)(2)(B)(i)(II).
[100] IPAY 2028 Draft Guidance, at 38.
[101] IPAY 2028 Draft Guidance, 38-39.
[102] *Ibid*. at 38-39.
[103] "Rule of law principles require that parties have fair notice and an opportunity to conform their behavior to legal rules." *Circus Circus Casinos, Inc. v. NLRB*, 961 F.3d 469, 476 (D.C. Cir. 2020). *See also supra* note **Error! Bookmark not defined.**.

3. The manufacturing schedule submitted to FDA for the biosimilar product indicates that commercial lots of the biosimilar product are expected to be produced before the end of the relevant period; or

4. Agreements filed with the FTC/DOJ do not bar the biosimilar manufacturer from marketing the biosimilar product before the end of the relevant period.

If CMS has remaining questions about the likelihood of marketing, CMS could also consider the following additional criteria:

- The biosimilar manufacturer has not stated in its disclosures to investors that it will not market the biosimilar product before the end of the relevant period;
- The biosimilar manufacturer has not withdrawn its BLA;
- The biosimilar manufacturer is not in arrears for any user fees due under section 744H of the FDCA for the biosimilar application; and
- No manufacturing facility where the biosimilar is made, processed, etc., has a classification of Official Action Indicated.

III. "Bona Fide Marketing"

PhRMA opposes CMS' extra-statutory concept of "bona fide marketing." In relevant part, section 1192(e)(1) of the SSA defines a qualifying single source drug (QSSD) as a drug product "that is not the listed drug for any [generic] drug that is approved and marketed under section 505(j)" of the FDCA and a biological product "that is not the reference product for any [biosimilar] biological product that is licensed and marketed under section 351(k)" of the PHSA.[104] Similarly, section 1192(c) provides that a product ceases to be a "selected drug" beginning before the first year that begins at least nine months after the date on which the Secretary determines at least one generic drug or biosimilar biological product "is approved or licensed (as applicable)" and "is marketed pursuant to such approval or licensure."[105]

Nonetheless, the Draft Guidance refers to "bona fide marketing," stating that CMS "will consider a generic drug or biosimilar to be marketed when the totality of the circumstances, including the data specified below, reveals that the manufacturer of that approved generic drug or licensed biosimilar is engaging in bona fide marketing of that drug or biosimilar."[106] The Draft Guidance also states that "[t]he determination whether a selected drug should not be subject to the negotiation process and ultimately removed from the selected drug list" will depend upon evidence that "reveals that the manufacturer of the generic drug or biosimilar is engaging in bona fide marketing of that drug or product."[107] Furthermore, even after CMS determines that a potential QSSD will not be considered a QSSD or that a selected drug has ceased to be a selected drug, CMS "will monitor . . . whether meaningful competition continues to exist in the market by ongoing assessments of whether the manufacturer of the generic drug or biosimilar is engaging in bona fide marketing."[108]

[104] SSA § 1192(e)(1)(A)(iii) & (B)(iii).
[105] SSA § 1192(c)(1).
[106] IPAY 2028 Draft Guidance, at 14.
[107] IPAY 2028 Draft Guidance, at 156 (emphasis added).
[108] IPAY 2028 Draft Guidance, at 176.

The addition of the term "bona fide" adds an extra-statutory limitation and is at odds with the ordinary meaning of "marketed." CMS' approach also is inconsistent with other provisions of the IRA, where Congress expressly imposed volume-based requirements for marketing purposes. Finally, the statute does not permit CMS to monitor for "bona fide marketing" after it determines that a product is not a QSSD or has ceased to be a selected drug or even vaguely contemplate such a monitoring program.

The statute does not allow for imposition of CMS' "bona fide" qualifier.

As noted, CMS is obligated under *Loper Bright*[109] and the President's April 9, 2025 memorandum[110] to adopt the single, best meaning of the IRA and withdraw any interpretation that conflicts with that single, best meaning. PhRMA urges CMS to withdraw the bona fide qualifier because it is inconsistent with the single, best meaning of the statute.

The ordinary meaning of "marketing," which is also the way "marketing" is used in the pharmaceutical sector specifically, does not support CMS' narrowly-focused approach that departs from the best meaning of the relevant statutory text. For example, Merriam-Webster's dictionary defines marketing as "to expose for sale in a market."[111] In a Supreme Court case interpreting the meaning of "marketing" when the term was undefined in a statute, the Court looked to the "ordinary meaning" of the term and concluded that "[m]arketing ordinarily refers to the act of holding forth property for sale, together with the activities preparatory thereto … The word does not require that the promotional or merchandising activities connected with the selling be extensive."[112] Thus, when "marketing" is undefined, the Court simply requires the product to be "for sale."[113]

These definitions also reflect the generally accepted, ordinary meaning of "marketed" in the context of a pharmaceutical product, and, consequently, the meaning of "marketed" that Congress intended in the context of the IRA. For instance, the ordinary meaning of "marketing" is consistent with FDA's conception of marketing under section 505(j) of the FDCA, which is relevant given that the IRA's statutory QSSD and selected drug definitions reference a generic drug "marketed under section 505(j)."[114] In the context of 180-day exclusivity for first generic applicants, the FDCA provides that FDA shall not make effective a subsequent generic application until "180 days after the date of the first commercial marketing of the drug . . . by any first applicant."[115] In regulations, FDA defines the term "commercial marketing" (a term that is narrower than "marketing") as "the introduction or delivery for introduction into interstate commerce of a drug product described in an ANDA, outside the control of the ANDA applicant, except . . . for investigational use . . . or transfer of the drug product to parties identified in the ANDA for reasons other than sale."[116] Similarly, for purposes of implementing section 506I of the

[109] *Loper Bright*, 144 S. Ct. 2244, 2266 (2024).
[110] White House. (April 2025). Presidential Actions, Directing the Repeal of Unlawful Regulations. Available at: https://www.whitehouse.gov/presidential-actions/2025/04/directing-the-repeal-of-unlawful-regulations/.
[111] Merriam-Webster.com. "Market." Available at: https://www.merriam-webster.com.
[112] *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187 (1995)
[113] *Ibid.* ("One can market apples by simply displaying them on a cart with a price tag; or market a stock by simply listing it on a stock exchange; or market a house (we would normally say 'place it on the market') by simply setting a 'for sale' sign on the front lawn. Indeed, some dictionaries give as one meaning of 'market' simply 'to sell. ' See, *e.g.,* Oxford Universal Dictionary 1208 (3d ed. 1955); Webster's New International Dictionary 1504 (2d ed. 1950).").
[114] SSA § 1192(e)(1)(A)(iii); *see also id.* SSA § 1192(c)(1)(A)(i).
[115] FDCA § 505(j)(5)(B)(iv)(I).
[116] 21 C.F.R. § 314.3.

FDCA concerning required notifications to FDA about the marketing status of a product,[117] FDA considers a product's marketing status to depend on whether a product is distributed by the application holder, i.e., whether the product is available for sale.[118]

In contrast, the Draft Guidance imposes an extra-statutory limitation on what qualifies as marketing of a generic or biosimilar biological product for purposes of the QSSD definition and for determining whether a product ceases to be a selected drug or otherwise is no longer subject to the price setting process or to an MFP. Indeed, in the IPAY 2026 Initial Guidance's "Appendix C: Definitions for Purposes of Collecting Manufacturer-Specific Data," CMS defined "marketing" as "the introduction or delivery for introduction into interstate commerce of a drug product."[119] Perhaps recognizing the tension between this definition and its extra-statutory "bona fide marketing" concept, CMS deleted this definition from the IPAY 2026 and 2027 Guidances, both of which instead refer to "[m]arketing costs" as "expenditures incurred in the introduction or delivery for introduction into interstate commerce of a drug product, specifically including media advertisements, direct-to-consumer promotional incentives including patient assistance programs, promotion of the drug to health professionals, and other paid promotion."[120] For IPAY 2028, CMS has maintained this definition but has proposed to add after "health professionals" "including providing free products to health professionals or patients."[121] While these expenditures may not be relevant to either generics or biosimilars, the introduction into interstate commerce of a drug product applies equally to define marketing in the generic and biosimilar context.

In this Draft Guidance for IPAY 2028, CMS has provided three examples to illustrate its analysis of "bona fide" marketing:

1. If a potential QSSD has at least one approved generic drug or licensed biosimilar that has "high and consistent PDE utilization, AMP sales, and/or ASP sales," then CMS indicates that it will consider the generic(s) or biosimilar(s) of the potential QSSD "bona fide" marketed.
2. If a potential QSSD might "have a newly or recently approved generic or licensed biosimilar and the product has relatively low PDE utilization, AMP sales, and/or ASP sales,"[122] CMS explains that where it finds "in additional review of public information that the generic or biosimilar manufacturer has successfully launched their product, and there is no evidence of agreements limiting distribution of the generic or biosimilar product," then CMS will consider the generic or biosimilar product of the potential QSSD as "bona fide" marketed.[123]

3. If a potential QSSD might have an approved generic or licensed biosimilar product "with no PDE utilization, AMP sales, and/or ASP sales," if CMS finds "in additional review of public information that there are ongoing patent disputes and no generic or biosimilar manufacturer has

[117] Section 506I requires NDA and ANDA holders to provide written notification prior to withdrawing an approved product from sale and if the drug will not be available for sale within 180 days of the date of approval.
[118] FDA. (August 2020). Guidance for Industry: Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format. Available at: https://www.fda.gov/media/120095/download
[119] IPAY 2027 Draft Guidance, at 82.
[120] Revised IPAY 2026 Guidance, at 194; Draft IPAY 2027 Guidance, at 131.
[121] Draft IPAY 2028 Guidance, at 209.
[122] *Ibid*.
[123] *Ibid.*

successfully launched their product," then CMS will consider the generic or biosimilar product of the potential QSSD as not "bona fide" marketed.[124]

We appreciate that CMS has provided these examples and has clarified certain types of data sources that it intends to consult for determining if "bona fide" marketing exists. These examples, however, do not resolve the unlawful and extra-statutory nature of the "bona fide" qualifier. Moreover, the third example should be deleted, as it would result in a determination that the generic drug or biosimilar is not "marketed" even where it is. For instance, this example would result in the wrong outcome where a particular biosimilar has recently launched, e.g., at risk or based on a settlement without any patent litigation proceedings as to its biosimilar (notwithstanding the existence of other patent disputes as to biosimilars of the same reference product), but PDE, AMP, and ASP sales do not yet reflect the launch.

CMS' approach conflicts with other provisions of the IRA.

CMS' imposition of the "bona fide" qualifier conflicts with other provisions of the IRA addressing the biosimilar "pause" and the treatment of authorized generics. Although Congress made no reference to "bona fide" marketing or any similar gloss in the QSSD or selected drug definitions, in other provisions of the same section of the statute, CMS expressly imposes limitations on what qualifies as marketing. When "Congress includes particular language in one section of a statute but omits it in another section of the same Act," it is "generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."[125] Congress's decision not to qualify the term "marketed" in the QSSD or selected drug definitions demonstrates that CMS' additional "bona fide" limitation conflicts with the statute.

The IRA expressly prohibits manufacturers from receiving the biosimilars-based selection "pause" based on volume-limited arrangements. Specifically, section 1192(f)(2)(D)(iv) states that "[i]n no case shall the Secretary delay the inclusion of a biological product as a selected drug" if "the manufacturer of the biosimilar . . . entered into any agreement . . . with the manufacturer of the reference product . . . that . . . restricts the quantity (either directly or indirectly) of the biosimilar biological product that may be sold in the United States over a specified period of time."[126] Volume-limited arrangements were also known in the industry at the time Congress enacted the IRA. Clearly, then, Congress knew how to impose volume-based requirements or limitations and did so in the very same section of the statute but elected not to do so in the definitions of QSSD and selected drug.

The statute does not permit CMS to continually evaluate "bona fide marketing".

Furthermore, there is no statutory mechanism that permits CMS to monitor "whether the manufacturer of the generic drug or biosimilar is engaging in bona fide marketing" *after* it determines that a potential QSSD will not be considered a QSSD or that a selected drug should be removed from the Program.[127] Nonetheless, CMS states that it "will monitor, after such . . . determination is made, whether meaningful competition continues to exist in the market by ongoing assessments of whether the manufacturer of the generic drug or biosimilar is engaging in bona fide marketing."[128] CMS seems to imply that it can *revisit*

[124] *Ibid.*
[125] *Russello v. United States,* 464 U.S. 16, 23 (1983) (citations omitted).
[126] SSA § 1192(f)(2)(D)(iv) (emphasis added).
[127] IPAY 2028 Draft Guidance, at 176.
[128] IPAY 2028 Draft Guidance, at 176.

such determinations and potentially restore a product to "selected drug" status, even though this is not contemplated by the statute. The statute is clear that once a product is determined not to meet the definition of a QSSD or ceases to be a selected drug, it is no longer eligible for price setting. Instead, the statute provides explicitly that once a selected drug ceases to be a selected drug, CMS' agreement with the manufacturer "shall no longer be effective" and the drug "is no longer considered a selected drug."[129]

There is no statutory basis for CMS to restore selected drug status to a product that is no longer a selected drug or to enter into a new section 1193 agreement with a manufacturer after the parties' section 1193 agreement has terminated due to the approval and marketing of a generic or biosimilar. Further, the product's MFP and the manufacturer's agreement to provide access to that MFP to entities that dispense or administer the drug to Medicare beneficiaries are set forth in the agreement—which would have terminated.[130] Accordingly, a whole new process of price setting procedures and setting an MFP for the drug would be needed for the Program to apply, but the statute never mentions or even hints at this extended series of events or any of its parts. Congress would not have authorized this approach of CMS ending a product's selected drug status, terminating the CMS-manufacturer agreement, and then reinstating the drug's selected drug status and requiring the manufacturer to enter into a new agreement, without saying so expressly. Nor would Congress have silently delegated to CMS the unilateral authority to develop and carry out this far-fetched re-selected drug process. CMS' approach has no statutory foundation and conflicts with the statute's express terms. Moreover, to the extent CMS is suggesting it has jurisdiction to police competition, and the expertise necessary to do so, that suggestion is incorrect.[131] Instead, that authority rests with the agencies charged with enforcement of the antitrust laws.

IV. Orphan Drug Exclusion from Qualifying Single Source Drugs

CMS' interpretation of the orphan drug exclusion is overly narrow. Section 1192(e)(3)(A) provides for a wholesale exclusion from the IRA for "a drug that is designated as a drug for only one rare disease or condition under section 526 of the [FDCA] and for which the only approved indication (or indications) is for such disease or condition."[132] CMS' careless implementation of the exclusion itself as laid out in the IPAY 2028 Draft Guidance also represents serious flaws. In fact, the process that CMS notes it will follow to determine whether a drug will qualify for the orphan drug exclusion relies on databases that may not accurately reflect whether a drug's indication falls within the scope of the orphan drug designation.

Like the Guidance for IPAY 2026 and 2027, the proposed Guidance for IPAY 2028 continues to constrain the exclusion in ways that are not supported by the statute and that would undermine research and development in the rare disease space. As addressed further below, the Guidance has this effect in two ways. First, for orphan drugs that lose eligibility for the exclusion, CMS proposes to apply the seven- or 11-year age requirement *retroactively* from the date of initial approval or licensure. Second, per CMS'

[129] SSA § 1193(b) (emphasis added).
[130] SSA § 1193(a)(3); CMS, Medicare Drug Price Negotiation Program Template Agreement, Addendum 1 (Negotiated Maximum Fair Price).
[131] Courts are unlikely to find that Congress implicitly granted an agency certain important powers (and instead will require an express grant of authority) where the agency "has no expertise in crafting …policy [in the area in question]." *King v. Burwell*, 135 S. Ct. 2480, 2489 (2015). *See also, e.g.*, *Gonzales v. Oregon*, 546 U.S. 243, 266–67 (2006) (Congress would not be presumed to delegate interpretive authority to the Attorney General on an issue where he lacked expertise); *City & Cnty. of San Francisco v. Trump*, 897 F.3d 1225, 1242 (9th Cir. 2018) (an agency interpretation of an important economic and political question may not be entitled to deference and "[t]his is particularly true where the agency lacks expertise").
[132] SSA § 1192(e)(3)(A).

overly broad interpretation of a QSSD, CMS proposes to evaluate applicability of the orphan drug exclusion on an active moiety or active ingredient basis, rather than for each individual drug product or biological product.

In each case, the best reading of the statute compels the opposite result. The fact that the IRA provides for an exclusion from the definition of a QSSD for eligible orphan drugs indicates that the seven- or 11-year clock should only begin running once a product loses eligibility for the exclusion. It also supports evaluating each drug product or biological product individually, such that the approval of a new drug product or biological product could trigger application of the exclusion and a new seven- or 11-year clock to begin upon loss of that exclusion.

Our proposed interpretation also preserves incentives for orphan drug research and development, consistent with Congress's mandate. More than forty years ago, Congress incentivized the development and approval of drugs to treat rare diseases and conditions by enacting the Orphan Drug Act, and FDA has approved hundreds of drugs under that framework. The orphan drug exclusion in the IRA reflects Congress's intent to promote continued orphan drug development to meet the needs of patients with rare diseases. PhRMA urges CMS to interpret the exclusion with this policy goal in mind, i.e., to encourage continued drug development for patients with rare diseases or conditions.

The seven- or 11-year clock should begin upon loss of eligibility for the orphan drug exclusion.

When a product initially qualifies for the orphan drug exclusion but subsequently loses its eligibility, CMS should interpret the statute in a manner that initiates the drug's selection timeline from the date on when the exclusion was lost. In other words, the seven- or 11-year clock should begin when the previously excluded drug receives a designation for a second orphan disease or gains approval for a use outside a single orphan designation—not from the date of the earliest approval or licensure of the active moiety or active ingredient, as CMS proposes.[133]

CMS' contrary interpretation fails to give the orphan drug exclusion the full and meaningful effect intended by Congress. Under CMS' proposed approach, the clock would be considered to have run *retroactively* from an approval that initially qualified for the exclusion. This reading is inconsistent with the scope and purpose of the exclusion, which exempts orphan drugs from the definition of a QSSD altogether if conditions are met. By disregarding the exclusion's intent and applying the timeline retroactively, CMS' interpretation undermines the very protection that the orphan drug exclusion aims to provide.

Policy reasons also compel CMS to interpret the law in this manner: If selection timing is retrospectively linked to an orphan drug's previously-exempt approvals once the exemption is lost, then companies may be incentivized to delay or altogether forgo seeking orphan approval. Instead, manufacturers may be driven to prioritize initial approval for indications with a larger potential patient population in order to maximize the potential value of the product before it becomes subject to price setting. CMS' interpretation therefore undermines Congress' steadfast commitment to encouraging the development of orphan drugs, a policy that has been in place for over four decades and was explicitly extended to the IRA through the orphan drug exclusion in section 1192(e)(3)(A). CMS must recognize the far-reaching

[133] IPAY 2028 Draft Guidance, at 16-17.

implications of its interpretation and align its approach with the long-standing legislative intent to promote the development of orphan drugs to meet the significant unmet need of patients.

CMS' approach disincentivizes companies from following the science and effectively undermines the existing incentives in the Orphan Drug Act designed to bring new treatments for rare and orphan diseases as quickly as possible. Consider, for instance, a company researching a new drug for an orphan indication that could be brought to market as its initial FDA approval, potentially offering a curative therapy to a small population of patients with limited or no other treatment options. Consider as well that this drug may have other promising applications that will take significantly more time and resources to bring to market but would serve a much larger patient population. Under CMS' current interpretation the company is incentivized to prioritize seeking the first approval for the larger population to allow it to have the full seven- or 11-year period to earn sufficient revenues to earn a return on its investment and continue investing in post-approval R&D. By contrast, if the company chooses to launch the orphan indication first, the manufacturer could face a much shorter—or even nonexistent—period to market the larger indication before price setting. If, for example, five years after the initial approval, FDA approves a new, non-orphan indication, the product would have as few as two years to be marketed for the non-orphan indication before potential selection for price setting. The consequences are even more perverse if a company obtains a second orphan designation. In such a scenario, the drug might never receive marketing approval for a second orphan use, but any subsequent uses would be subject to a retroactively truncated timeline before selection.

The above scenarios clearly illustrate how CMS' interpretation unjustly penalizes drugs that were initially subject to the orphan drug exclusion compared to other, non-orphan products. By contrast, if CMS interprets the statute to link eligibility for price setting to the date of the approval for an indication outside the first orphan designation or receipt of a new designation, CMS would preserve the incentives for a manufacturer to seek an orphan indication early and make the medicine available quickly to an underserved group of patients, as well as incentives for seeking orphan drug designation. By aligning its interpretation with the legislative intent and the needs of rare disease patients, CMS can foster an environment that encourages innovation, accelerates access to orphan drugs, and upholds the spirit of the Orphan Drug Act.

The orphan drug exclusion should be applied to the drug or biological products approved in a single NDA/BLA.

PhRMA maintains that CMS should determine the applicability of the orphan drug exclusion based on the specific drug or biological products approved in a single NDA or BLA, consistent with our proposed interpretation of the QSSD definition described above. Currently, the Draft Guidance states that "[t]o determine whether a potential qualifying single source drug qualifies for the Orphan Drug Exclusion, CMS will consider *all* dosage forms and strengths of the potential qualifying single source drug, as described in section 30.1 of this draft guidance."[134] This interpretation indicates that CMS will aggregate multiple drug or biological products based on their active moiety or active ingredient and then subsequently evaluate each aggregated grouping to determine whether it meets the conditions of the orphan drug exclusion. Further, if any single drug product or biological product loses the exclusion, other products with the same active moiety or active ingredient would also lose the exclusion regardless of their

[134] IPAY 2028 Draft Guidance, at 16 (emphasis added).

individual orphan drug status. This blanket application of the exclusion criteria extends the problems with the QSSD definition, potentially penalizing drugs that have successfully met the requirements for orphan drug designation.

The shared active moiety and ingredient approach suffers from the same inherent flaws as CMS' proposed definition of a QSSD.

PhRMA believes a QSSD must be strictly limited to those drug or biological products approved by FDA in a single NDA or BLA. Since the orphan drug exclusion is explicitly defined as an exception from the definition of a QSSD, it logically follows that it should be applied on an NDA/BLA basis as well. Furthermore, each drug or biological product approved under an individual NDA or BLA must independently meet the age requirement, which should be calculated from the date the exclusion is lost, as discussed above.

In addition to aligning with the statute, this approach better preserves incentives for orphan drug research and development. Under CMS' interpretation, once the orphan drug exclusion is lost for a single drug product or biological product (e.g., due to its approval for a non-rare disease), there would be severely diminished incentives to pursue new orphan drug approvals for the same active moiety or active ingredient. This would have a chilling effect on the development of new therapies for rare diseases, as manufacturers would be discouraged from investing in additional orphan indications once the exclusion is lost for any product sharing the same active moiety or ingredient. By adopting a product-specific approach, CMS can ensure that the incentives for orphan drug development remain robust, encouraging manufacturers to continue pursuing new treatments for rare diseases even if the exclusion is lost for a particular product.

V. Interpretation of Section 1192(c)(1) Regarding Timing of Generic or Biosimilar Entry

PhRMA disagrees with CMS' interpretation of section 1192(c)(1) to require that a generic drug or biosimilar is approved and marketed by November 1, 2026—over a year before IPAY 2028 begins—in order for a drug selected by February 2026 not to be subject to an MFP in IPAY 2028. So long as CMS makes a determination of generic or biosimilar approval and marketing by March 31, 2027 (i.e., at least nine months prior to January 1, 2028), the selected drug should not be subject to an MFP for IPAY 2028.

Consider a drug selected in February 2026 for IPAY 2028 for which CMS determines on March 1, 2027, that a generic drug has been approved and marketed. Section 1192(c)(1) states that "each negotiation-eligible drug included on the list published . . . *with respect to an initial price applicability year* . . . shall be *referred to* as a 'selected drug' with respect to *such year* and *each subsequent year* beginning before the first year that begins at least 9 months after the date on which the Secretary determines at least one drug or biological product" has been approved or licensed and marketed pursuant to such approval or licensure.[135]

The provision should be read such that if the generic or biosimilar launches by March 31, 2027, the drug would no longer be "referred to" as a selected drug with respect to the year beginning on January 1, 2028, either because "such year" begins at least nine months after CMS' determination of generic approval and marketing; or because such year is a subsequent year that begins at least nine months after CMS'

[135] SSA § 1192(c)(1) (emphasis added).

determination. Accordingly, the MFP would not go into effect in IPAY 2028. Before CMS made its determination of generic approval and marketing, the drug was "referred to as a 'selected drug' with respect [to IPAY 2028]"—consistent with the statutory language—as the manufacturer was required to submit data to CMS, engage in the price setting process, sign an MFP agreement, and have its MFP published.

The above approach helps promote competition by incentivizing market entry of generics and biosimilars, while also giving CMS a nine-month lead time to terminate selection of a branded drug after generic or biosimilar entry. By contrast, if CMS continues with its proposed interpretation, a generic or biosimilar launched more than a year before the IPAY begins (e.g., on November 2, 2026) would still have to compete against a price-set brand name drug beginning on January 1, 2028.

Appendix B: Effectuation of the Maximum Fair Price and MFP Calculation

PhRMA appreciates the opportunity to provide technical comments on the portions of the *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028* (Draft Guidance) governing effectuation of the Maximum Fair Price (MFP) in Part B and Part D (sections 40.4 and 90), the determination of a single MFP and ceiling price as part of the negotiation and renegotiation process (section 60), and the imposition of civil monetary penalties for manufacturers that fail to ensure access to the MFP (section 100).

In general, PhRMA notes that the Draft Guidance will likely be finalized after manufacturer MFP effectuation plans for Initial Price Applicability Year (IPAY) 2026 are due on September 1, 2025. Because of this, we urge the Centers for Medicare & Medicaid Services (CMS, the Agency) to:

- Clearly denote that any significant changes made between the draft and final versions of the guidance are not in effect for IPAY 2026; and
- Publicly report metrics on pharmacy enrollment and other aspects of the MTF DM and PM roll-out as we approach the start of IPAY 2026, as well as to publish more detailed information on the MTF testing scope and timeline process. Specifically, we request that CMS publish a detailed test plan covering scenarios, file formats, and timelines as soon as possible. Early visibility will allow manufacturers to prepare data, workflows, and staffing for a robust pilot cycle.

In the sections below, PhRMA provides more specific recommendations that CMS should make in final guidance. A selection of key recommendations and requests include:

- **MFP Effectuation in Part B.** CMS needs to take steps in future rulemaking or guidance to require Medicare Advantage (MA) plans to report claims data on a more frequent basis for selected provider-administered medicines and to require MA plans to mandate 340B covered entities to identify 340B-eligible claims through the use of mandatory modifiers.
- **MFP Effectuation in Part D.** CMS should clarify that manufacturers using the standard default refund amount (SDRA) may use it as a true default (i.e., are presumed to have provided access to the MFP). CMS should also broaden the approach to claims edits related to MFP eligibility to include claims identified as outliers by the Drug Data Processing System (DDPS) with regards to fields listed in Appendix B of the Draft Guidance
- **Establishing a Single Ceiling Price and MFP.** Starting with Part B and Part D drugs selected for IPAY 2028, we urge CMS to work with Primary Manufacturers at the start of the negotiation process to align on the best analytical approach to calculating a single ceiling price and MFP for each selected drug, along with therapeutic alternatives. If CMS continues with a 30-day equivalent supply approach (or for drugs where CMS and the Primary Manufacturer agree that a 30-day equivalent supply approach is best), we urge CMS to make a number of changes to its current methodology. And regardless of the approach, CMS should ensure that it provides needed detail on its calculation of MFPs to allow for understanding and replication.
- **Civil Monetary Penalties.** CMS should affirmatively commit to not imposing civil monetary penalties (CMPs) on manufacturers that do not provide access to the MFP as a result of technical

issues with the Medicare Transaction Facilitator Data Module (MTF DM) or Payment Module (MTF PM), or for any other issue that is outside the manufacturer's control. CMS should also ensure that CMPs are not imposed based on new technical requirements imposed close to the start of (or during) the IPAY.

I. Sections 40.4 and 90 – Effectuation and Compliance Oversight for Drugs Covered under Medicare Part B

PhRMA appreciates the Agency's solicitation of recommendations on a variety of topics related to how manufacturers can provide access to the MFP for selected drugs covered under Medicare Part B. We agree with CMS' proposed intention to align, as much as possible, the MFP effectuation approach for Part B and Part D selected drugs, including by continuing to offer Primary Manufacturers the ability to provide access to the MFP through a retrospective approach facilitated by the MTF Data Module (DM) and Payment Module (PM) that is data driven and transparent. However, there are some unique considerations for selected drugs covered under Part B, including a much greater number of providers and a current lack of timely receipt of claims data for beneficiaries enrolled in MA plans.

Excluding MFP from the Calculation of ASP

PhRMA firmly believes that CMS lacks the legal authority to include MFP in the calculation of Average Sales Price (ASP) but has the legal authority to exclude the MFP from ASP reporting requirements. Given the significant policy and legal rationales detailed below, ***we urge CMS to explicitly confirm MFP's exclusion from ASP in order to provide critical certainty for manufacturer reporting and stability to provider payments and to protect patient access.***

Beginning in IPAY 2028 for selected Part B drugs, the IRA requires provider reimbursement for such drugs to be based on the MFP as opposed to the ASP, which serves as the basis of reimbursement for the majority of separately payable Part B drugs today. This will drastically reduce Medicare reimbursement for provider-administered selected medicines even while costs necessary to administer products in-office remain the same. Indeed, research suggests that if CMS were to include MFP in ASP it would further erode reimbursement, with providers projected to face decreases to add-on payments of up to $37 billion for Part B selected drugs.[136] And because ASP serves as a payment benchmark for a wide swath of commercial market health plans and MA plans,[137] the decrease in provider payments includes an up to 18 percent reduction in add-on payments for provider-administered selected drugs in the commercial market and MA.[138] The inclusion of MFP in the calculation of ASP would most significantly impact oncology practices.[139] Equally concerning, 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. As a result, more practices could close or consolidate with hospital systems, reducing patient access to community providers and increasing Medicare program costs.

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[136] Avalere Health. (September 2024). Commercial Spillover Impact of Part B Negotiations on Physicians. Available at: https://advisory.avalerehealth.com/insights/commercial-spillover-impact-of-part-b-negotiations-on-physicians.
[137] A recent survey of commercial insurers showed that they reimburse for 72 percent of covered lives in the physician office based on a medicine's ASP. ASP is also the basis of Medicaid reimbursement for provider-administered medicines in many states. *See*, Avalere Health. (September 2024). Commercial Spillover Impact of Part B Negotiations on Physicians. Available at: https://advisory.avalerehealth.com/insights/commercial-spillover-impact-of-part-b-negotiations-on-physicians.
[138] *Ibid.*
[139] *Ibid.*

Given the significant negative impact expected, and the fact that CMS lacks the legal authority to include MFP in the calculation of ASP, selected drug sales at MFP should be excluded from ASP reporting. Below, we outline the numerous policy and legal arguments for this critical exclusion:

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

The IRA explicitly includes MFP in Best Price and excludes MFP from Average Manufacturer Price (AMP),[140] 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.[141] In *West Virginia v. EPA,* a seminal case on the major questions doctrine, the Court held that the EPA could not lawfully regulate certain emissions because it lacked "clear congressional authorization" to do so.[142] Specifically, the Court said that "[t]his view of EPA's authority [advocated by EPA] was not only unprecedented; it also effected a 'fundamental revision of the statute, changing it from [one sort of] scheme of . . . regulation' into an entirely different kind."[143] Hence, the Court doubted that Congress would grant EPA the discretion to regulate in this manner without a clear delegation.[144]

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, thanks to President Biden's [IRA] – the historic law lowering health care costs – Medicare is able to negotiate the prices of prescription drugs."[145] And any CMS decision to require that manufacturers include MFP pricing in their ASP calculations would change ASP from a market-based metric—what Congress intentionally created in the 2003 Medicare Modernization Act—to a metric largely dominated by a single CMS-set price, which is likely to cause major repercussions for providers and patients who rely on physician-administered drugs. In addition, the IRA excludes Part B drugs for the Program's first two years—inclusion of MFP in ASP for selected IPAY 2026 and IPAY 2027 drugs with Part B utilization would eliminate this two-year timeline by injecting MFP into ASP before IPAY 2028.

As discussed above, including MFP in ASP could have dramatic and sustained adverse effects on health care providers and patients. Such a policy could sharply reduce payments to providers for physician-administered drugs – across the Medicare Fee-for-Service (FFS), MA, and commercial markets, and over a long period of time – thus jeopardizing the ability of physicians and other

[140] SSA §1927(c)(1)(C)(ii)(V), (k)(1)(B)(i)(VI).
[141] *Util. Air Regul. Group v. EPA,* 573 U.S. 302, 324 (2014) (internal quotations omitted).
[142] *West Virginia v. Env't Prot. Agency*, 597 U.S 697, 732, 734 (2022).
[143] *Ibid.* at 728.
[144] *Ibid*. at 729. See also, *e.g.*, *ibid.* at 723 (Even where an agency's regulatory assertion "had a colorable textual basis, . . . [e]xtraordinary grants of regulatory authority are rarely accomplished through modest words, vague terms, or subtle device[s]. Nor does Congress typically use oblique or elliptical language to empower an agency to make a "radical or fundamental change" to a statutory scheme.") (internal quotations and citations omitted).
[145] 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.

providers to furnish these important medicines to their patients. Including MFP in ASP would substantially reduce ASP, which would likely erode (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.

Moreover, selected and deselected drugs may seem like a rarity today, but their number will quickly mount, as CMS will choose 20 new selected drugs every year from 2029 forward.[146] Eventually, selected and deselected drugs could account for the vast majority of 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 medicines, and with implications for clinical decision making. Accordingly, CMS lacks authority to require that manufacturers include MFP in their ASP calculations.

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, 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 Medicare Part B drug reimbursement, it also provided a mechanism for monitoring market prices and adjusting ASP-based payments in certain situations. Specifically, 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, AMP 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,[147] as well as once they are deselected.

CMS Has Existing Authority to Exclude MFP from ASP

[146] SSA § 1192(a).
[147] SSA §1847A(i)(3)(A)(ii).

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.[148] 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.

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."[149]

CMS could thus 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.

Defining a Standard Default Refund Amount for Medicare Part B Drugs

PhRMA appreciates CMS' solicitation of comments in section 40 regarding whether the MTF DM should include a standard default refund amount (SDRA) among the claim-level data elements shared with manufacturers and how such SDRA could be calculated.

As PhRMA has previously discussed with CMS, we continue to believe that deciding on a formula to define the SDRA is more complicated for Part B covered drugs than under Part D. In Part D, Wholesale Acquisition Cost (WAC) provides a natural anchor that ensures sufficient access to the MFP for the vast majority of pharmacies and other dispensers.[150] By contrast, there is not as clear of a pricing metric that would work for the vast majority of providers for Part B drugs. From our conversations with members, we believe that provider acquisition cost can be significantly further below WAC than pharmacy acquisition cost, making WAC a poor choice for a Part B SDRA.

PhRMA continues to discuss with our membership a number of options for how to define a Part B SDRA and we will provide separate, additional comments on this topic to CMS as soon as possible.

Claim-level Data Elements Needed for Medicare Part B Effectuation

PhRMA appreciates CMS' solicitation of comments regarding considerations for claim-level data elements pertaining to selected drugs payable under Medicare Part B.

We believe that the claim-level data fields that will already be provided from the MTF DM for selected drugs covered under Part D should also be provided for selected drugs covered under Part B (including NDC codes, as we discuss in more detail later in this appendix). However, given differences in claims

[148] 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."
[149] 70 Fed. Reg. 70,478, 70,481 (Nov. 21, 2005) (amending 42 C.F.R. § 414.802).
[150] Based on NADAC surveys, on average, pharmacies purchase brand single-source drugs for about 4 percent below WAC. *See* https://www.medicaid.gov/medicaid/prescription-drugs/downloads/retail-price-survey/nadac-equiv-metrics.pdf.

and reimbursement between the two programs, some additional data fields will be required for Part B drugs. Specifically, at a minimum, ***PhRMA strongly encourages CMS to provide the following additional fields to manufacturers on a detailed claim-level basis for provider-administered drugs covered under both the Part B FFS program and MA:***

- Medicare Advantage Plan ID (for MA only);
- HCPCS Code (J-Code/Q-Code) and the NDC-11;
- Claim Number (would replace the Prescription/Service Reference Number field);
- Unit of Measure;
- Date of Administration (would replace Date of Service);
- 340B Covered Entity ID/NPI;
- Place of Service code;
- 340B Claims Modifier Field ("TB" modifier);
- Vial Wastage Modifier Field ("JW" and "JZ" modifiers); and
- "UD" Modifier Field.

One distinction for drugs payable under Part B is that CMS already requires the use of the "TB" modifier to identify 340B eligible units in the Part B FFS program. Given the statutory prohibition in the Act for duplicate 340B and MFP discounts, the "TB" modifier field should be provided to manufacturers to assist in deduplication. PhRMA continues to have significant concerns, however, that all prescriptions subject to a 340B agreement may not be appropriately captured. As noted in prior comments to the Agency, PhRMA requests that CMS also add a non-340B modifier (similar to the addition of the "JZ" modifier to indicate no discarded units), such that Part B claims cannot be silent on whether a 340B determination was made. CMS also should require the use of the "TB" modifier and a non-340B modifier by providers seeking reimbursement under MA, which we discuss in more detail below.

Finally, ***we continue to urge CMS to establish a claims-data repository or clearinghouse to identify 340B prescriptions dispensed or administrated to beneficiaries*** and to share this critical identification data with Primary Manufacturers. This is particularly crucial for Part D given the lack of a mandatory claims modifier but would also be useful for Part B drugs.

Providing Access to the MFP in Medicare Advantage for Provider-Administered Selected Drugs

Effectuating the MFP for provider-administered selected drugs furnished to MA enrollees will present some unique considerations that CMS will need to address. First, a critical component of MFP effectuation in both Part B and Part D is the provision of claims data to verify a selected drug has been administered or dispensed to a Medicare beneficiary. Under Part D, claims data are already being reported to CMS by Part D plan sponsors in the form of Prescription Drug Event (PDE) data, and under Part B FFS, the Medicare Administrative Contractors (MACs) likewise already receive claims data from providers and could provide these data to the MTF DM. However, CMS currently has limited visibility into MA claims. CMS does receive MA Encounter Data, but these data can be reported with a significant timing lag (over a year).[151] This significant lag would prevent prompt payment of MFP refunds to providers serving MA patients. ***We thus strongly recommend that CMS require MA plans to submit***

[151] See 42 CFR 422.310(g) and CMS. Encounter Data Submission and Processing Guide. (May 2025). Version 5.2. Available at: https://www.csscoperations.com/internet/csscw3_files.nsf/F2/ED_Submission_Processing_Guide_20221130_v5.2.0.pdf/$FILE/ED_Submission_Processing_Guide_20221130_v5.2.0.pdf.

claims data to the MTF DM on a more frequent basis for purposes of MFP effectuation, and PhRMA believes CMS can rely on various authorities to do so.[152]

Second, CMS must address how it will identify and handle claims for 340B drugs administered to Part B MA beneficiaries. The "TB" 340B claims modifier is not currently required on provider claims to MA plans. ***PhRMA strongly encourages CMS through future guidance or rulemaking to require MA plans to require 340B covered entities participating in their networks to utilize the "TB" modifier,*** and we believe CMS has the authority to do so effective for IPAY 2028.[153] As we have noted to CMS previously (and discuss in more detail below in the Part D effectuation section of this technical appendix), under the existing 340B replenishment model, chargeback requests are made at the package level, not at the individual claim level. As such, manufacturers have, at best, very limited insight into whether 340B replenishment requests contain underlying Medicare administrations. Thus, in the absence of a claims modifier or other method for identifying individual 340B claims (such as a claims repository), manufacturers will be unable to avoid 340B/MFP duplicate discounts in MA. ***CMS should also require the use of a non-340B modifier, as well, such that a clear 340B determination is made for each MA and FFS claim.***

Other Part B Effectuation Recommendations

Timing of Manufacturer MFP Refund Payments

PhRMA recommends that manufacturers have 30 days from the receipt of claims data to make the MFP available to providers for selected Part B drugs. This would align with the current timing required for CMS to reimburse providers under Part B and would thus mirror CMS' determination of the reimbursement timeline in Part D (Part D plans have 14 days to pay pharmacies from the receipt of a clean claim, which CMS pointed to in establishing the 14-day prompt MFP payment window for manufacturers).

Manufacturer Compliance and Oversight

PhRMA appreciates CMS' solicitation of comments in section 90 of the Draft Guidance on the types of information that should be included in the MFP Effectuation Plans for drugs payable under Part B, and how the requirements may need to differ from what is outlined for selected Part D drugs. PhRMA generally recommends that the MFP Effectuation Plan process remain highly similar across Part B and Part D selected drugs. However, PhRMA will require more detailed information about the effectuation process for drugs payable under Part B in order to provide meaningful comment.

Moreover, PhRMA would note a similar response to the comment solicitation regarding the complaints and dispute process for Part B selected drugs and how it may (or may not) need to differ from the process for Part D selected drugs. Again, while we generally believe that the process should be as similar as possible for Part B drugs as Part D drugs, PhRMA reiterates that we will require more information regarding the effectuation process for drugs payable under Part B in order to provide meaningful comment on this issue.

[152] *See, e.g.,* SSA §§ 1853(a)(3)(B), 1857(e); 42 C.F.R. §422.310.
[153] *Ibid.*

II. Sections 40.4 and 90 – Effectuation for Drugs Covered under Part D

Potential Private Market Solutions

PhRMA appreciates CMS' solicitation of comments on potential private market solutions that could offer an alternative to the MTF. However, ***we continue to believe that the best, least burdensome, and most efficient way to effectuate the MFP would be for CMS to utilize an approach similar to the Part D Coverage Gap Discount Program (CGDP), including pass-through of CMS pre-funded MFP refund amounts to dispensers on behalf of Primary Manufacturers at the time of claim adjudication with manufacturers invoiced at a later date.*** We urge CMS to consider this approach for IPAY 2027 and subsequent years. Because of the risk of 340B/MFP duplicate discounts under any approach to effectuation***, we continue to note that effectuation models must include a solution on identifying 340B claims to be consistent with the statute***.

While we are aware of several entities that are working to develop private market solutions, our understanding is that none of these solutions will be able to transmit MFP refund payments from manufacturers to dispensers before mid-2026 at the earliest and none currently offer an "end-to-end" solution that could replace the capabilities of the MTF DM and PM. In addition, with the start of IPAY 2026 still six months away, neither CMS nor any supply chain stakeholders have any experience to draw upon with regards to MFP effectuation or the functioning of the MTF DM or PM, let alone how the MTF DM and PM will work for Part B covered selected drugs for IPAY 2028. Thus, we believe the Agency's solicitation on private market solutions is premature. We would recommend that the Agency wait until at least after IPAY 2028 concludes before seeking feedback on whether private market alternatives could provide a meaningful option for MFP effectuation.

More broadly, PhRMA again stresses that CMS should also build in substantial lead-time if it intends to impose significant new requirements or expectations on manufacturers with respect to MFP effectuation.

PhRMA also remains concerned with the Agency's continued interpretation of the IRA as placing "sole responsibility" to provide access to the MFP on manufacturers, yet at the same time, placing strict requirements on manufacturers if they choose to use an approach outside the MTF PM. For example, CMS is maintaining the requirement for manufacturers to transmit payment to dispensers within 14 days from receipt of MTF DM claim data even if a pharmacy and manufacturer have agreed to a different timeline under an alternative arrangement. Given the Agency's repeated statements that it is "sole responsibility" of manufacturers to provide access, then for arrangements outside of the MTF PM, CMS should defer to terms governing pharmacy and manufacturer agreements.

Section 40.4.1 – Retrospective Refund Amount to Effectuate the MFP and the Standard Default Refund Amount

Making the SDRA a True Default

PhRMA appreciates the Agency's continued support on defining an SDRA for Part D covered drugs as the difference between the wholesale acquisition cost (WAC) and the MFP for a selected drug. We believe the ability to utilize an SDRA will bring significant efficiencies to both Primary Manufacturers and dispensers in effectuating the MFP.

However, ***we continue to urge CMS to further solidify use of the SDRA by making it a true default.*** While CMS notes that the Agency believes "using WAC to calculate an SDRA generally *best approximates* the acquisition costs of dispensing entities and offers a *reliable refund amount* for both manufacturers and dispensing entities,"[154] (emphasis added) the Agency in the very same sentence indicates that the SDRA is for manufacturers and dispensing entities that "agree to use such standardized pricing."

A key goal of establishing an SDRA is to reduce stakeholder burden by allowing the MFP refund to be easily defined by a method that results in a sufficient MFP refund and that does not require entity-by-entity negotiation or agreement. Otherwise, the SDRA (which has "default" in its name) is hardly a default under either the dictionary definition or common understanding of the word. ***CMS should explicitly allow Primary Manufacturers to assume the SDRA is sufficient to provide the dispenser access to the MFP for the selected drug.*** This would reduce burden on both Primary Manufacturers and dispensers by lessening the situations where dispensers would need to engage in the process of coming to an agreement with Primary Manufacturers. Further, because CMS acknowledges that the SDRA best approximates acquisition costs, dispensing entities claiming acquisition costs beyond the SDRA could be required to provide documentation and explanation for such claims.

Dispenser Acquisition Costs that Exceed WAC

PhRMA continues to have significant concerns with the Agency's implication that the SDRA may not be sufficient to provide access to the MFP. We note that the Draft Guidance includes new language specifying that when CMS is determining whether a manufacturer has provided access to the MFP, the Agency "will undertake a fact-specific assessment that will consider…. whether the retrospective refund amount… is sufficient to account for commercially reasonable costs the dispensing entity is likely to encounter in the supply chain…."[155] While we recognize the Agency's concern that not all dispensers are able to acquire drugs at or below WAC, we continue to believe this is a small minority of dispensers. Further, the Draft Guidance could undermine the integrity of the program by creating adverse incentives for dispensers and others in the pharmaceutical supply chain to improperly increase profits through arrangements that artificially increase MFP refund amounts.[156]

Concerns with potential manipulation of prices and profits are not hypothetical, as instances of stakeholders artificially increasing costs to others in the supply chain are abundant. For example, until CMS prohibited the practice beginning in January 2024, Part D plan sponsors could enter into arrangements with pharmacies that resulted in the Part D negotiated price being higher than the final

[154] Draft Guidance at 58.
[155] Draft Guidance at 165.
[156] For example, consider an illustrative selected drug with a WAC of $100 and an MFP of $40. Wholesaler A typically purchases the selected drug from the Primary Manufacturer at a price of $96, and Dispenser B typically purchases the selected drug from Wholesaler A at a price of $98. Utilizing the SDRA, the Primary Manufacturer would owe an MFP refund of $60, giving Dispenser B a margin of $2 on the transaction (excluding dispensing fees) and Wholesaler A likewise a margin of $2. However, consider that Dispenser B could enter into an arrangement with Wholesaler A to acquire the selected drug at a cost of $120. The Primary Manufacturer would then owe an MFP refund of $80. If Wholesaler A agrees to retrospectively refund $10 of the acquisition price to Dispenser B, Wholesaler A would earn a margin of $14 and Dispenser B could earn a margin of $10 (excluding dispensing fees), substantially higher than before.

payment from the Part D plan sponsor to the pharmacy.[157] The resulting inflated negotiated price increased costs to the federal government in the form of higher low-income subsidies, to manufacturers in the form of higher Part D coverage gap discounts, and to beneficiaries with coinsurance in the form of higher cost sharing, as all of these figures are calculated based on the Part D "negotiated price."

Thus, PhRMA remains concerned, based on past precedent, about exposing Primary Manufacturers to significant risk of having to pay artificially inflated MFP refund amounts (and of the program integrity spillover effects for CMS if the Program becomes a vehicle for inflating revenues in the supply chain). We therefore recommend that CMS take the following actions in final guidance:

- ***Specify the type of documentation that a dispenser must provide to a Primary Manufacturer if the dispenser is seeking an MFP refund calculated on a basis other than the SDRA.*** Specifically, this documentation should cover not only the acquisition cost to the dispenser (net of all price concessions) but should also disclose any business arrangements or ownership arrangements between the dispenser and the entity they are purchasing the selected drug from.
- ***Track which dispensers or types of dispensers are claiming acquisition costs above WAC.*** If CMS notices an increasing trend in these arrangements, the Agency should publicly report it to increase awareness among policymakers and stakeholders and engage in dispenser audits to ensure dispensers or other supply chain entities are not inappropriately profiting by inflating MFP refund amounts.

Section 40.4.2.1 – Primary Manufacturer Participation in the MTF DM

Treatment of Claims with DDPS Edits

PhRMA supports the Agency's proposed approach to handling claims with DDPS edits and agrees with the proposed listing of DDPS edits impacting MFP eligibility included in Appendix B of the Draft Guidance. We believe CMS' proposed approach fairly balances the interests of both dispensers and manufacturers.

However, PhRMA is concerned that the definition of "Invalid" for certain fields listed in Appendix B of the Draft Guidance may be too narrow for the purposes of appropriately calculating the correct MFP refund payment amount. For example, a quantity of 1,200 tablets for one prescription of a selected drug that is more commonly dispensed as a quantity of 120 is clearly an error. But, the quantity of 1,200 tablets is greater than 0.001, which means it would seem to be considered valid for the purposes of the DDPS transmitting the claim to the MTF DM under CMS' proposed approach. In this situation, the manufacturer would be responsible for a very large MFP refund outlay and would then have to wait for the error to be resolved by the Part D plan and pharmacy before receiving an adjustment. ***Given this, we ask that CMS broaden the interpretation of edits related to MFP eligibility to also include outliers identified by DDPS that impact payment by the Part D plan.*** In other words, claims identified as having an outlier value for a field listed in Appendix B would also not be transmitted to the MTF DM until the outlier value is resolved.

[157] CMS. Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency. Final Rule. May 9, 2022. Available at: https://public-inspection.federalregister.gov/2022-09375.pdf.

We also encourage CMS, through coordination between the DDPS and MTF DM, to allow dispensing entities to track when claims have been transmitted from the DDPS to the MTF DM and to Primary Manufacturers. Until a Primary Manufacturer receives claims data from the MTF DM, they will be unable to respond to any dispensing entity inquiries on a given claim. By sharing the status of claims transmission, CMS can improve transparency, reduce premature inquiries, and reduce stakeholder burden.

Clarification on Timing for MFP Refund Payments

PhRMA strongly urges CMS to modify its current technical guidance that the 14-day prompt MFP payment deadline remains unchanged even if the due date falls on a weekend or holiday.[158] Specifically, we ask that CMS instead specify that if the 14-day prompt MFP payment window deadline falls on a Saturday, Sunday, or holiday, the payment deadline is extended to the first business day thereafter. This would align with manufacturer payment requirements under the Part D Manufacturer Discount Program,[159] as well as with other federal standards governing prompt pay terms.[160] Wire transfers for electronic payments cannot be processed on weekends or holidays given that the US Automated Clearing House (ACH) Network only operates on business days,[161] creating the need for CMS to establish appropriate deadlines.

Section 40.4.2.2 – Dispensing Entity Enrollment in the MTF DM

Dispensing Entities with Material Cashflow Concerns

While PhRMA shares the Agency's goal of ensuring dispensers are paid promptly, we continue to believe that the best way to alleviate pharmacy cashflow concerns would be for CMS to utilize an approach similar to the Part D CGDP, including pass-through of CMS pre-funded MFP refund amounts to dispensers on behalf of Primary Manufacturers at the time of claim adjudication with manufacturers invoiced at a later date. As noted above, we continue to urge CMS to consider this approach for IPAY 2027 and subsequent years.

PhRMA continues to have concerns with the requirement to develop mitigation plans for pharmacies self-identifying as having material cashflow concerns. Again, while we share the Agency's goal of prompt pharmacy payment, there is no statutory basis for the requirement, and the lack of quantifiable standards for which pharmacies can self-identify creates significant difficulty for manufacturers in making determinations about which dispensers are most in need of assistance.

To allow manufacturers to better target mitigation plans, CMS should affirmatively acknowledge that Primary Manufacturers are permitted to require that any pharmacies claiming material cashflow concerns provide documentation to Primary Manufacturers to support such claims.

Section 40.4.3.1 – Required Primary Manufacturer Reporting of Claim-Level Payment Elements for MFP Refund Payments When a Primary Manufacturer Passes Payment through the MTF PM

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[158] CMS. (May 2025). Medicare Transaction Facilitator: Manufacturer Frequently Asked Questions. Available at: https://www.cms.gov/files/document/manufacturer-technical-faqs.pdf.
[159] CMS. (December 2024). Revised Medicare Part D Manufacturer Discount Program Final Guidance. Available at: https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf.
[160] *See e.g.* Code of Federal Regulations. Title 5, Chapter III, Subchapter B, Part 1315. Available at: https://www.ecfr.gov/current/title-5/chapter-III/subchapter-B/part-1315.
[161] Nacha. The ABCs of ACH. Available at: https://www.nacha.org/content/abcs-ach.

Transaction Codes for Manufacturer Claim-level Payment Elements

In the Draft Guidance, CMS notes that a manufacturer should use Payment Code "4" to indicate that no MFP refund is being transmitted on a given claim because the claim is 340B-eligible and the 340B ceiling price is below the MFP. However, a drug's 340B ceiling price can also be equal to the MFP or, under certain circumstances, higher than the MFP. PhRMA is concerned that the Draft Guidance fails to account for the combined requirements across section 1193(d)(1) *and* section 1193(d)(2) of the Act. Thus, we strongly urge CMS to:

- Expand Payment Code "4" to include the scenario where the 340B ceiling price is equal to the MFP; and
- Add an additional Payment Code to address the scenario where the 340B ceiling price is higher than the MFP to indicate that a manufacturer is transmitting less than a full MFP refund amount. Specifically, the manufacturer's MFP refund amount in this scenario should be the difference between the 340B ceiling price and the MFP.

More detail is provided on these recommendations below.

PhRMA also remains highly concerned about CMS' refusal to play a role in identifying and deduplicating 340B claims, with CMS stating in the Draft Guidance that the Agency "will not, at this time, assume responsibility for deduplicating discounts between the 340B ceiling price and MFP."[162] Under the current 340B replenishment model used by the majority of covered entities, manufacturers have, at best, very limited insight into whether 340B replenishment requests contain underlying Medicare dispenses, which creates a significant risk of duplicate 340B and MFP discounts despite the IRA's statutory prohibition.[163]

Under the 340B replenishment model, the pharmacy or provider will track, typically with a computerized system, units of medicines dispensed or administered to individuals who the covered entity or its third-party administrator classifies as 340B-eligible patients. When a certain threshold of units is reached, the pharmacy or provider places an order to replenish that stock at the discounted price.[164] A manufacturer will provide access to the 340B price on the replenishment order through a wholesaler chargeback. However, requests for chargebacks are at the package level, and typically do not contain information about the individual prescriptions underlying the replenishment request. As an example, a 340B covered entity could seek to replenish a 900-tablet bottle of a selected drug at the 340B price. Underlying that request are prescriptions filled for 340B patients with a variety of insurance coverage, but the manufacturer will not know which, if any, of those prescriptions were filled by Part D beneficiaries. Indeed, laws in at least eight states[165] include express provisions prohibiting manufacturers from requiring claims data from 340B covered entities as a condition of providing access to the 340B price. This makes it extremely difficult, if not impossible, for manufacturers to avoid the risk of 340B/MFP duplicate discounts.

[162] Draft Guidance at 96.
[163] By discussing the replenishment model used by covered entities, we do not mean to imply that that the model is consistent with the 340B statute.
[164] For an overview of the replenishment model, as utilized by contract pharmacies in the 340B program, please see: OIG. (February 2014). Memorandum Report: Contract Pharmacy Arrangements in the 340B Program. Available at: https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.
[165] Colorado, Nebraska, New Mexico, North Dakota, South Dakota, Tennessee, Utah, and West Virginia.

While we continue to urge CMS to facilitate deduplication of statutorily prohibited 340B/MFP claims, such as through a claims repository with mandatory reporting or through HHS not blocking manufacturers from offering the 340B price as a rebate, in the interim, we recommend CMS adopt a clear way for manufacturers to address the 340B/MFP duplicate discounts they can identify, such as by expanding the Payment Codes to cover situations where the 340B ceiling price is equal to or higher than the MFP.

Specifically, as noted above, we ask that CMS expand Payment Code "4" to include the scenario where the 340B ceiling price is equal to the MFP. If a manufacturer can utilize Code "4" both where the 340B ceiling price is equal to or lower than the MFP refund, the manufacturer can continue to provide access to the 340B price while avoiding a duplicate 340B/MFP discount. We believe the expansion of Code "4" to include the scenario of the 340B ceiling price equaling the MFP is consistent with the requirements of sections 1193(d)(1) and 1193(d)(2) of the Act.

PhRMA also recommends that CMS expand the existing list of Payment Codes to address the scenario where the 340B ceiling price is higher than the MFP. The new code would recognize that manufacturers have calculated the MFP refund as the difference between the higher 340B ceiling price and the MFP.[166] Section 1193(d)(2) of the Act states that a manufacturer of a selected drug "shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals… at such [340B] ceiling price in a *nonduplicated amount to the [340B] ceiling price* if such maximum fair price is below the ceiling price for such selected drug" (emphasis added). But the existing Payment Element Codes established by CMS do not seem to contemplate this scenario. And again, because manufacturers typically lack the information necessary to exclude individual prescriptions from a replenishment chargeback request, there is a high likelihood that, without further due diligence by CMS in designing the MTF system, a manufacturer will pay both an MFP refund and provide access to the 340B ceiling price on the same claim. If manufacturers can provide access to the MFP in this scenario by paying the difference between the higher 340B ceiling price and a lower MFP, while still providing the 340B covered entity with access to the 340B price, this could assist in preventing a duplicate discount.

MTF DM Receipt File

In the Draft Guidance, CMS notes that, for informational purposes, the MTF DM will issue a receipt file to Primary Manufacturers that elect to participate in the MTF PM. We appreciate CMS' solicitation of comments on content for the receipt file that would be informative for Primary Manufacturers.

PhRMA believes the following data elements would be crucial to include in such a receipt file:

- Record ID;
- Whether payment was made via ERA or remittance (paper check);
- Method for determining MFP refund amount;
- Amount of payment sent as the MFP refund:
    - Amount exclusive of any credits;
    - Amount of any credits applied; and
    - Net amount of payment sent as the MFP refund.
- Transaction code;

[166] This could also be addressed by amending the existing Payment Code "2".

- Date of service (date prescription was dispensed); and
- Date and timestamp of MFP refund payment initiation by the MTF PM.

Section 40.4.3.2 – Primary Manufacturer and MTF PM MFP Refund Payment Adjustments due to Claim Amendments Through the MTF PM

Claim Adjustments and Reversals

PhRMA requests that the MTF not automatically apply credits and debits, as this could create difficulties with manufacturers' ability to reconcile to MFP refund payments. Instead, notification of credits and debits should first be shared with Primary Manufacturers, as manufacturers must have the opportunity to validate pricing and payment values prior to credit/debit application. Or at a minimum, if the MTF is automatically applying credits and debits, Primary Manufacturers must have full transparency into the underlying original MFP refund claim. This approach will improve data integrity and reduce reconciliation discrepancies between CMS and manufacturers.

Credit/Debit Ledger and Manufacturer Termination of Participation in the MTF PM

Given the potentially long run-out period on claims, PhRMA recommends that manufacturers terminating participation in the MTF PM maintain access to the credit/debit ledger, including to accruals of credits and debits, during the run-out period for claims initiated while the manufacturer was still participating in the MTF PM.

In addition, PhRMA urges CMS to develop a process for manufacturer reimbursement in situations where there are insufficient MFP refund claims against which to apply accrued credits. This scenario may occur, for example, when a generic or biosimilar competitor has come to market, but due to timing, the brand is still a selected drug. We would be happy to engage with CMS on how best to address this issue.

Finally, PhRMA again encourages CMS to provide access to the credit/debit ledger system to manufacturers that choose to utilize alternative arrangements outside the MTF PM to provide access to the MFP. Because manufacturers using alternative arrangements will still be reporting claims-level payment information to the MTF DM, this information can be used to populate a simple, non-dynamic credit/debit record system. While we understand the credit/debit ledger system could not be used to alter the actual payments from manufacturers utilizing alternative arrangements, it will still be useful to manufacturers in having a central record of payments within the MTF system.

Section 40.4.5 – Nonduplication with 340B Ceiling Price

As discussed above, PhRMA has significant concerns with the Agency's current intention not to play a role in deduplicating MFP and 340B discounts. Duplicate MFP and 340B discounts are clearly prohibited under the IRA, yet under the current 340B replenishment model used by the majority of covered entities, manufacturers have, at best, very limited insight into whether 340B replenishment requests contain underlying Medicare dispenses. To improve program integrity and avoid forcing manufacturers to make an MFP effectuation payment prior to knowing a drug's 340B status, potentially violating the IRA's nonduplication provision, CMS must ensure that manufacturers receive timely and accurate information about 340B units in order to deduplicate 340B and MFP discounts. For this reason, CMS should establish a claims repository and utilize mandatory and enforceable claim modifiers for 340B covered entities (CEs). Or alternatively, we continue to maintain that HHS should not block manufacturers from offering

the 340B price as a rebate, which would ensure manufacturers have crucial claims data to prevent duplication of MFP/340B discounts in the absence of HHS action. If CMS fails to prevent prohibited duplicate 340B/MFP discounts, this could create an unsustainable burden on manufacturers, as well as undermine program integrity and add to the already ongoing waste, fraud, and abuse that has plagued the 340B program.

Requiring 340B CEs (or entities acting on their behalf, such as third-party administrators, or TPAs) to submit claim-level data[167] to a neutral claims repository could provide CMS with the information necessary to efficiently identify duplicate 340B and MFP discount requests. CMS could also utilize this data to remove identified 340B-eligible units from the Part D inflation rebate, which the IRA also requires, effective January 1, 2026.

Mandatory 340B claim modifiers, appended at or soon after drug dispense or administration, could also be an effective methodology for identifying 340B-eligible units in Part D if CMS enforces compliance with such a requirement. However, PhRMA maintains significant concern that modifiers, even when mandatory, do not identify all 340B-eligible units, because available evidence suggests CEs may fail to comply with existing 340B modifier requirements under Medicare Part B and manufacturers are ill-equipped to police this type of CE non-compliance. For example, a 2023 report by IQVIA found that only 61 percent of administrations of Part B separately payable drugs originating at rural referral centers and sole community hospitals used a relevant 340B modifier,[168] a highly concerning result given that CMS required these entities at the time of the study to use the "JG" and "TB" modifiers[169] on claims seeking Medicare Part B payment for a 340B-acquired drug. While there are situations where it is appropriate for CEs not to use the relevant 340B claims modifiers,[170] a finding of 61 percent modifier usage seems outside the bounds of expected utilization when by comparison, IQVIA found that 89 percent of administrations of Part B separately payable drugs originating at 340B disproportionate share hospitals used a relevant modifier.[171] Since the requirement to use either the "JG" or "TB" modifiers applies equally to disproportionate share hospitals, rural referral centers, and sole community hospitals, PhRMA would have expected more similar modifier utilization.

Department of Health and Human Services (HHS) Enforcement

In recognition of CMS' position that it "will not, at this time, assume responsibility for deduplicating discounts between the 340B ceiling price and MFP"[172] and will not require dispensers to indicate to Primary Manufacturers which selected drug claims are for 340B-eligible units,[173] ***PhRMA urges HHS to exercise enforcement discretion with respect to Primary Manufacturers' deduplication efforts.***

[167] For example, claim-level data could include the prescription reference number or claim number, prescribed date, date of service, NDC, quantity dispensed, the BIN/PCN of the beneficiary' prescription drug insurance, National Provider Identifier (NPI) of the dispensing pharmacy, 340B number and name of the CE, wholesaler invoice number, and any utilized 340B claim modifier.
[168] IQVIA. (February 2023). Can 340B Modifiers Avoid Duplicate Discounts in the IRA? Available at: https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2023/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.pdf.
[169] Per the CY 2024 OPPS/ASC final rule, effective January 1, 2025, CMS will require all 340B CEs to use the "TB" modifier.
[170] For example, if the CE is able to purchase the drug at a lower price than the 340B price, or if the state is claiming a Medicaid rebate on the drug, the CE would not claim the 340B discount and not utilize the relevant modifier on the Part B claim.
[171] IQVIA. (February 2023). Can 340B Modifiers Avoid Duplicate Discounts in the IRA? Available at: https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2023/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.pdf.
[172] Draft Guidance at 96.
[173] Draft Guidance at 66.

Specifically, HHS should not pursue enforcement against a Primary Manufacturer under the agencies' respective IRA and section 340B authorities if the Primary Manufacturer can demonstrate it has engaged in reasonable, good faith efforts with a covered entity to fulfill the manufacturer's obligations under section 1193 of the SSA and section 340B(a)(1) of the PHS Act, as applicable. As noted above, the prevailing 340B replenishment model presents significant challenges to appropriately identifying individual prescription claims that are the basis for CE replenishment requests at the applicable 340B price. If 340B CEs and other prescription drug supply chain stakeholders do not work in good faith with a Primary Manufacturer to identify which selected drug claims are for 340B-eligible units, then a Primary Manufacturer should not be subject to an HHS enforcement action if the manufacturer, despite its reasonable, good faith efforts, is unable to provide access to the 340B ceiling price or MFP.

In addition, PhRMA strongly recommends that ***HHS promote program integrity by taking steps to ensure 340B CEs do not claim duplicate 340B and MFP discounts.***

Finally, we continue to urge that CMS should consider whether the claim is subject to the 340B de-duplication exception under Section 1193(d)(1) of the Act, which could appropriately exempt it from an MFP refund obligation, when assessing whether the MFP was made available.

III. Section 60 – Establishment of a Single MFP and Ceiling Price under the Negotiation and Renegotiation Process

Calculating a Single Ceiling Price and MFP

PhRMA appreciates the Agency's solicitation for comment in section 60 of the Draft Guidance regarding the calculation of a single MFP and ceiling price.

PhRMA has numerous significant concerns with CMS' current approach to the calculation of a single ceiling price and MFP based on a 30-day equivalent supply for drugs covered under Part D and the Agency's proposed approach for drugs covered under Part B. As detailed below, the reliance on claims data to establish the 30-day equivalent supply can lead to undervaluing of drugs, particularly those with more frequent recurring administrations. The 30-day equivalent supply approach is also ill-suited to drugs with variable dosing, for example with dosing that varies based on a patient's body weight or with dosing that varies based on the treatment phase of the condition. Given this, PhRMA strongly recommends that for both Part B and Part D drugs selected for IPAY 2028 and beyond CMS should:

- ***Maintain flexibility and work with Primary Manufacturers at the start of the negotiation process to align on the best analytical approach to calculating a single ceiling price and MFP for each selected drug, along with therapeutic alternatives.***
- ***Consider a per unit approach as a default methodology.*** A per unit approach could be the best method for many drugs, although does present challenges in certain circumstances.

If CMS continues with a 30-day equivalent supply approach (or for drugs where CMS and the Primary Manufacturer agree that a 30-day equivalent supply approach is best), we urge CMS to make a number of changes to its current methodology, including ***utilizing labeled dosing regimens as opposed to claims data, dividing all days supplied and days-in-between values by 30, and to work with Primary Manufacturers to appropriately adjust the MFP for drugs with non-linear pricing per unit.***

A number of PhRMA's concerns with the Agency's current 30-day equivalent supply approach could be well addressed by the Agency moving to a per unit approach for drugs selected for IPAY 2028 and beyond, where a single ceiling price and MFP would be calculated per unit of a drug.[174] For example, we believe a per unit approach could be the best methodology for drugs with variable dosing, as a price per unit easily accommodates dosing that needs to change in strength or frequency. However, a per unit approach can also be inappropriate in certain scenarios. For example, a per unit approach may not be well-suited to Part B covered drugs reimbursed under multiple HCPCS codes where pricing per unit varies across codes. A per unit approach may also present challenges in comparing pricing for a selected drug with a therapeutic alternative if the therapeutic alternative is delivered as a different formulation, has different billable units, or requires different strengths. In these situations, using a 30-day equivalent supply approach to compare pricing between a selected drugs and its therapeutic alternative may be superior.[175]

Given the relative strengths and weaknesses of both approaches, as noted above, ***we urge CMS to be flexible and work with Primary Manufacturers to agree on the best approach to calculating a single ceiling price and single MFP for each selected drug starting with Part B and Part D covered drugs selected for IPAY 2028***. However, we believe that a per unit approach is likely the best method for many of the drugs the Agency will consider under the Program, and as such, could be established as a default.

More detail on our reasoning and recommendations is provided below.

There are several reasons why we believe a single ceiling price and single MFP per unit would be superior to calculating a single MFP per 30-day equivalent supply in most circumstances, and as such, should be the default methodology used by CMS. First, because CMS has relied on quantities dispensed (and proposes to rely on a similar approach for provider-administered drugs by calculating the average days between administrations) as opposed to FDA-approved dosing regimens, it is difficult for stakeholders to understand how CMS arrived at the publicly reported single MFP values. The majority of stakeholders lack access to the claim-level data necessary to replicate CMS' estimate of a 30-day equivalent supply, creating a lack of transparency for stakeholders and raising questions about program integrity.

Second, variations in quantities dispensed (such as starter packs, prescriptions filled at less than a typical supply due to unique patient treatment considerations, breaks in medication treatment due to surgical care, etc.) result in CMS establishing 30-day equivalent supplies that no patients actually take. For example, a selected drug meant to be taken as one tablet per day on an ongoing basis would typically be considered to have a 30-day equivalent supply of 30 tablets. But dispenses of lesser quantities of this same drug could lead to CMS estimating an average 30-day equivalent supply of, for hypothetical example, 28.3 tablets. No patient is actually prescribed 28.3 tablets, and as such, the single MFP reported by CMS

[174] We believe the unit could vary across selected drugs. For example, for a selected drug solely available as an oral solid, a single MFP per tablet/capsule could work well. By contrast, for a selected drug available as both an oral solid and oral liquid, a single MFP per milligram would be more appropriate. For drugs administered as reconstituted powders, a per unit of active ingredient approach may be best. But in varying the unit across drugs, it would then be crucial for CMS to include the definition of a unit for each selected drug in the publicly released MFP files to ensure program transparency.

[175] For selected drugs with therapeutic alternatives administered in the same form, a per unit approach can still be appropriate. However, CMS would need to be sure to then appropriately compare the therapeutic alternative to the selected drug, as dosages needed for clinical effectiveness can differ across therapies. For example, if a selected drug is administered as 5ml per week and its therapeutic alternative is administered as 10 ml per week, CMS would need to compare the price per ml for the selected drug against the price per 2ml of the therapeutic alternative to ensure an appropriate comparison.

carries very little value for patients or other stakeholders. If CMS believes that reporting a single MFP at the per unit level will not be meaningful for patients or other public stakeholders, the Agency could highlight the MFP for the most commonly dispensed package size or administered amount as part of its release of public MFP files.

Third, because the dosing and package size of medicines varies, CMS is already calculating a per unit MFP in addition to the single MFP per 30-day equivalent supply. This creates extra work for CMS staff that could be avoided by going straight to a per unit MFP calculation.

Fourth, the 30-day equivalent supply approach presents unique challenges for medicines with dosages that change based on body weight, indication, or the progression of treatment. For example, patients with different body weights will require different amounts of insulin over a period of 30 days for the treatment of Type I diabetes. Insulin dosing also varies depending on if a patient is using insulin to treat either Type I or Type II diabetes. And many cancer medicines and treatments for autoimmune diseases require more frequent administrations early on in the course of treatment versus less frequent administrations once a condition has been stabilized or reached a maintenance phase. Using a 30-day equivalent approach like CMS has been using for covered Part D selected drugs, and is proposing for covered Part B selected drugs, obscures these important differences in dosing and can lead to the undervaluing of medicines. By contrast, establishing a single ceiling price and MFP per unit preserves this variation in dosing much more accurately.

Fifth, the 30-day equivalent supply approach is particularly ill-suited to medications taken on an as-needed basis (such as rescue inhalers) or taken on an infrequent basis (such as long-acting injectables). Utilization of medicines taken on an as-needed basis can vary substantially between patients, and long-acting injectable administration can occur bi-annually or on an alternative frequency per year. Both of these situations lead to logically suspect results of 30-day equivalent supplies established based on average dispenses or the average of time in between administrations.

Given all of the reasons above, we believe CMS calculating a single ceiling price and MFP per unit would be a superior approach, and as such, should be the default methodology. However, we again note that because a per unit approach can present challenges in certain situations, CMS should maintain flexibility and should work with Primary Manufacturers to assess whether a per unit approach or 30-day equivalent supply approach would be best for a particular selected drug.

For selected Part B and Part D covered drugs where the Agency and Primary Manufacturer agree that a 30-day equivalent supply approach is more appropriate (or if CMS continues with a 30-day equivalent supply approach across all selected drugs), we strongly recommend the following changes for both Part D and Part B covered drugs:

- ***CMS should use FDA-approved dosage regimens to set 30-day equivalent supplies for Part B and Part D covered drugs.*** If CMS does not use approved dosage regimens, then CMS should ensure that the Agency's calculations of 30-day equivalent supplies do not exceed FDA-approved dosage regimens for selected drugs.
- ***CMS should always divide the days supplied (or days-between-service for Part B covered drugs) by 30 to establish a 30-day equivalent supply.*** Treating all drugs with a days supplied of less than or equal to 34 as one 30-day supply, as CMS does currently for Part D covered drugs

and is proposing for Part B covered drugs, can result in significantly undervaluing drugs with more frequent administrations. For example, consider an oncology drug that is infused once every 14 days. CMS is proposing to treat each administration of this drug as one 30-day supply, when in reality, a patient taking this drug will receive on average 2.14 administrations each 30 days. If CMS instead were to divide the 14 days by 30, it would give CMS the much more accurate result that each administration of this drug represents 0.467 30-day equivalent supplies. This approach would also align with CMS' existing methodology for drugs with a days supplied that exceeds 34.[176]

- ***Prior to the start of the negotiation process for a given selected drug, CMS should speak with the Primary Manufacturer and other stakeholders about existing approaches to calculating 30-day equivalent supplies.*** Manufacturers have significant experience with calculating 30-day equivalent supplies under certain state drug price transparency reporting requirements, and there are certain vendors that assist manufacturers with these calculations. We suggest that CMS speak with manufacturers and these vendors to better understand how 30-day equivalent supplies are calculated for medicines, particularly medicines falling into one of the more complicated situations described above, such as medicines with dosages that vary by indication or during the course of treatment. For example, for drugs with dosages that vary by the patient's weight, manufacturers today can calculate 30-day equivalent supplies by relying on the average weight of patients.

- ***CMS should provide greater transparency into how it calculates the single MFP for each selected drug and how it calculates the starting point for negotiation.*** This is particularly the case if CMS utilizes different approaches for different selected drugs. But even if CMS maintains the 30-day equivalent supply approach, CMS should report the estimated 30-day equivalent supply as part of the publicly released MFP files, along with the underlying calculation inputs to show how the MFP per package (and per HCPCS code for Part B covered drugs) was calculated.

Requiring Reporting of NDC Codes for Part B Covered Drugs

PhRMA strongly encourages CMS to require the submission of NDC codes for reimbursement for selected drugs under Part B FFS and on MA claims effective for IPAY 2028.

Currently under Part B FFS, reimbursement of Part B covered drugs is handled at the HCPCS code level. For reimbursement, CMS publishes an ASP-based payment rate per HCPCS-code unit representing a potentially blended price across different strengths and package sizes. A provider then indicates on the claim the HCPCS code and number of billing units administered. A drug's NDC is not a required field for Medicare reimbursement for most covered Part B drugs.

However, MFP effectuation based on HCPCS codes may not produce a refund that provides reasonably accurate access to the MFP to the provider. For example, in some cases, a HCPCS code may include multiple single-source drugs (e.g. J9217, or all insulins which are grouped together under J1817). Only one of these drugs may be a selected drug, or the drugs may be separate selected drugs. In this situation,

[176] *See* 42 C.F.R. § 423.104(d)(2)(iv)(A)(2*)*; CMS. (June 2023). Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026. Available at: https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf; Draft Guidance at 113.

the specific drug administered to the MFP-eligible individual could not be identified by the HCPCS code alone, so it would not be possible to determine if the individual received a selected drug (or which selected drug the individual received). To address this problem and establish the MFP refund amount, and indeed to ensure appropriate provider reimbursement, it will be crucial for CMS and manufacturers to know the underlying NDC of the medicine administered to the MFP-eligible beneficiary.

In addition, if CMS proceeds with calculating an MFP per 30-day equivalent supply, requiring reporting of NDCs would then avoid the agency having to estimate allocation of the HCPCS code 30-days supply to underlying NDCs.

Providers are already required to report the NDC for reimbursement under Medicare in certain circumstances (see the Medicare Claims Processing Manual, Chapter 26) and for other federal programs, such as Medicaid. As such, requiring providers to report the NDC more broadly on Medicare claims would not be a unique or unprecedented burden.

For these reasons, CMS should require the submission of NDC codes for reimbursement under Part B FFS and on MA claims through guidance and rulemaking effective for IPAY 2028.

IV. Section 100 – Civil Monetary Penalties and Failure of Manufacturer to Ensure Access to a Price Less than or Equal to the MFP in 2026, 2027, and 2028

PhRMA notes that CMS appears to have added a new example for "Violations of the Agreement" in Table 10, specifically the "[f]ailure to submit data requested by CMS in accordance with its oversight responsibilities under section 1196(b) of the Act." This open-ended language creates considerable uncertainty for primary manufacturers and should be struck or specified further so that manufacturers can anticipate the information that might lead to CMPs.

We also continue to urge CMS to ensure that no civil money penalties will accrue on manufacturers should CMS delays or technical difficulties cause the MTF DM or PM systems to encounter technical issues at the outset of IPAY 2026. As CMS acknowledges in section 40.4.3.2 of the draft guidance: "The precise process of authorization surrounding payment transfer continues to be developed." Given the uncertainty regarding payment transfer, CMS should affirmatively commit to hold harmless policies where payments are not transmitted, received, or logged due to events outside the control of the Primary Manufacturer. This would include delays in CMS notifying manufacturers of key systems requirements that must be met without sufficient time for manufacturers to build systems capabilities for those requirements. CMS could ensure that manufacturers are held harmless through specifying that the "additional context, evidence refuting the violation, proof of mitigation of noncompliance, and/or other factors for CMS' consideration," as specified in section 90.2 of the draft guidance will automatically include evidence, such as of MTF PM or MTF DM malfunction/delay and/or CMS introduction of new technical or substantive requirements.[177]

[177] In section 40.4.3.1 of the Draft Guidance, CMS recognizes that technical errors may cause delay, stating: "If the Primary Manufacturer is unable to transmit the claim-level payment elements, for example, if there is a technical breakdown in the transmission process, the Primary Manufacturer must continue to attempt to transmit the claim-level payment elements in good faith until successful transmission of the claim-level payment elements and must maintain documentation of the Primary Manufacturer's good faith effort in case there is a related complaint or dispute."

Appendix C: Access and Coverage

The Inflation Reduction Act (IRA) threatens the success of the Medicare Part D program's market-based prescription drug benefit through its introduction of government price setting. Along with broader IRA provisions, price setting is expected to erode the incentive structure that enables private sector negotiation, while doing little to address plan and pharmacy benefit manager (PBM) abuses that hinder patient access and raise out of pocket costs.[178,179] Thought leaders, clinicians, patients, and other stakeholders have raised serious concerns about increasingly restrictive trends in Medicare Part D formulary design and utilization management (UM)[180,181,182], and these concerns materialized in 2025 plan designs, from copayments to coinsurance trends,[183] combined with significant reductions in plan choices and higher premiums,[184] threaten affordable access to care for millions of beneficiaries.

This summer, CMS will review 2026 plan bids that reflect government price setting for the first time. As the Part D program approaches its 20-year anniversary, CMS must ensure it continues delivering affordable access to innovative, life-saving treatments for more than 50 million seniors and individuals with disabilities.

Although CMS has expressed concerns that Part D sponsors "may be incentivized in certain circumstances to disadvantage selected drugs" we remain concerned that CMS' existing formulary review process may not be sufficient to protect patient access.[185] As initial price applicability year (IPAY) 2028 will also see Part B drugs eligible for selection for the first time, PhRMA also has concerns about access for patients covered by Medicare Advantage, where plans are using step therapy to limit access to physician-administered therapies. Patients shouldn't pay more or face more difficult barriers to accessing their medicines than they did before CMS set prices for those medicines. We recommend CMS adopt stronger oversight and safeguards to protect beneficiary access in three key areas:

- **Improving transparency and data collection**. CMS should require Part D sponsors to report data that will provide critical transparency into the true impact of coverage denials on Part D beneficiaries, and develop meaningful, patient-centered measures of medication access in the Star Ratings program.
- **Enhancing patient access safeguards.** CMS should ensure all prior authorization (PA) requirements are accessible to all stakeholders, require plan sponsors to allow utilization

[178] Council for Affordable Health Coverage. (February 2025). Rotten to the Core: The Inflation Reduction Act Pill Penalty. Available at: https://cahc.net/rotten-to-the-core-the-inflation-reduction-act-pill-penalty/
[179] Pioneer Institute. The Inflation Reduction Act (IRA): Impact on Medication Pricing, Spending, Affordability, and Access. Available at: https://pioneerinstitute.org/the-inflation-reduction-act-ira-overview/
[180] Westrich K., Buelt L., Motyka J., Campbell J.D. (June 2025). Tracing the Arc of Medication Utilization Management Over Time. *Health Affairs Forefront.* Available at: https://www.healthaffairs.org/content/forefront/tracing-arc-medication-utilization-management-over-time
[181] Fendrick A.M., Axelsen K. (January 2025). Medicare Reforms Necessitate More Formulary Oversight. *Health Affairs Forefront.* Available at: https://www.healthaffairs.org/content/forefront/medicare-reforms-necessitate-more-formulary-oversight
[182] Fendrick, A.M. (August 2024). CMS Should Do More to Fulfill the IRA's Promise to Lower Drug Costs for Patients. *Health Affairs Forefront.* Available at: https://www.healthaffairs.org/content/forefront/cms-should-do-more-fulfill-ira-s-promise-lower-drug-costs-patients
[183] Avalere Health. (October 2024). 2025 Part D Formularies Shift to More Coinsurance and UM. Available at: https://advisory.avalerehealth.com/insights/2025-part-d-formularies-shift-to-more-coinsurance-and-um
[184] Avalere Health. (October 2023). Part D Premiums Increasing Despite Stabilization Program. Available at: https://advisory.avalerehealth.com/insights/part-d-premiums-increasing-despite-stabilization-program
[185] Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028", §110.

management (UM) to "follow" the patient, update Medicare Plan Finder (MPF) to require plans to clearly display specific UM requirements, and require plans to allow beneficiaries to obtain initial coverage determinations directly at the pharmacy counter. Further, CMS should ensure appropriate oversight of MA plans' use of step therapy for Part B drugs, given the inclusion of Part B drugs in IPAY 2028.

- **Strengthening formulary review reporting.** CMS should monitor and publicly report on formulary trends across all Part D plans and ensure the average number of medicines covered per class does not decrease.

The recommendations below represent key improvements CMS should consider.

I. Improve Transparency and Data Collection

Government price setting and other Part D provisions in the IRA are reshaping formulary dynamics, leading to increased risk of access disruptions due to plan financial pressure. While Part D plan dynamics are facing unprecedented changes, the ultimate impact of Part D sponsors' implementation of formulary UM and the appeals processes are opaque and currently are not available to either CMS or the public for review.

Moreover, recent analysis suggests that these processes are not adequate to prevent Part D beneficiaries from facing excessive barriers to timely access. For example, a recent IQVIA white paper that followed patients from 2020 to 2024 across five chronic therapeutic areas found that:

- Over 70 percent of Medicare Part D patients were initially denied coverage when trying to fill a new prescription for pulmonary arterial hypertension (PAH), multiple sclerosis (MS), immunology, and migraine medications.
- 10 to 19 percent of patients faced delays of five weeks or longer.
- On average, patients encountered two to three rejections before receiving approval, though some had to go through eleven or more.[186]

A survey of Medicare beneficiaries by the organization No Patient Left Behind (NPLB) revealed a similar concerning trend, finding that, among beneficiaries reporting their Part D plan initially rejected a medicine prescribed by their doctor, 40 percent had to use a medication that was not their physician's first choice, and 17 percent were unable to access any prescribed treatment at all.[187]

These findings underscore the importance of CMS collecting, and making transparent, additional data on the real-world effects of formulary design and plan UM policies, including the Part D appeals process.

CMS has traditionally depended on the appeals process to ensure access to medically necessary treatments. However, this approach places the burden on beneficiaries, often during urgent health situations, and offers little transparency into downstream impacts, patient outcomes, or broader system patterns. These data gaps hinder CMS' ability to evaluate beneficiary access to medications and to assess the fairness and consistency of plan decision-making processes and formulary design.

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[186] IQVIA. (June 2025). The Impact of Formulary Controls on Medicare Patients in Five Chronic Therapeutic Areas. Available at: https://www.iqvia.com/locations/united-states/library/white-papers/the-impact-of-formulary-controls-on-medicare-patients-in-five-chronic-therapeutic-areas

[187] No Patient Left Behind (March 2024). Price Controls Hinder Treatment Access in Medicare Part D. Available at: https://www.nopatientleftbehind.org/resource-materials/price-controls-hinder-treatment-access-in-medicare-part-d

These findings highlight the significant time, effort, and administrative burden Medicare patients face when starting a new prescribed therapy after an initial denial from their Part D plan. For patients with chronic conditions or those newly diagnosed and just beginning treatment, these barriers can be overwhelming, delaying care at a critical moment. These problems could be further exacerbated by the IRA's disruption to Medicare Part D. To safeguard patient access, CMS should take the steps outlined below.

CMS should require Part D sponsors to report data that will provide critical transparency into the true impact of coverage denials on Part D beneficiaries who rely on Medicare Part D. While UM may sometimes be an appropriate tool for Part D sponsors, it is essential that CMS, and the public, understand the real-world effects of these tools on beneficiary access to needed medications to ensure that UM is used in ways that are clinically appropriate and not as a cost-driven procedural barrier.

To ensure meaningful oversight, CMS should collect and publicly report both plan and beneficiary-level data that capture the true patient experience enabling CMS, researchers, advocates, and the public to assess the efficacy and impact of current coverage policies. These measures could include efforts to understand the experience when beneficiaries are denied coverage for their medicine at a pharmacy, such as:

- How often are beneficiaries denied coverage at the point of sale?
- Of those denied coverage, how many pursue an appeal? How many abandon therapy entirely?
- How long does it take between the first point of sale rejection until a beneficiary ultimately receives the medicine they were prescribed or a therapeutic alternative?

Furthermore, when beneficiaries attempt to appeal their plan's denial, CMS should collect more granular, contract level data on how often beneficiaries are successful in reversing plans' rejections.

These measures will provide CMS with critical insight to strengthen Part D plan oversight and review.

CMS should develop meaningful, beneficiary-centered measures of real-world beneficiary access to Part D medicines, reflective of plan UM practices, within the Star Ratings Program. Currently, the only Star measure that holds plans accountable for their coverage decisions evaluates how quickly a Medicare Advantage (MA) plan sends information for an independent review, and the rate at which an independent review (the "IRE") upholds the plans' appeals.[188] To more accurately measure beneficiary access, CMS should consider developing measures for the Star Ratings program that track the overall or therapeutic-area specific denial rate relative to an acceptable standard or average, or the rate at which plan sponsors fully or partially overturn coverage denials upon initial beneficiary appeal. This would serve as a proxy for potentially inappropriate rejections or insufficient plan transparency to prescribers. This enhanced data will provide CMS with critical insights into beneficiary experiences, enabling more effective oversight and targeted reforms to protect patient access and improve health outcomes.

II. Improve Patient Access Safeguards

The IRA introduced unprecedented changes to the structure of the Medicare Part D – disruption which builds on nearly a decade of increased UM restrictions in Part D.[189] Recent data show that plans are

[188] CMS. Medicare 2025 Part C & D Star Ratings Technical Notes. Available at: https://www.cms.gov/files/document/2025-star-ratings-technical-notes.pdf

[189] Joyce G., Blaylock B., Chen J., Van Nuys K. (March 2024). Medicare Part D Plans Greatly Increased Utilization Restrictions on Prescription Drugs, 2011-20. *Health Affairs*. Available at: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.00999

employing even more stringent practices to restrict access. For example, a recent analysis of 2023 coverage found that:

- Five out of ten standalone prescription drug plan (PDP) beneficiaries and six out of ten Medicare Advantage prescription drug plan (MA-PD) beneficiaries are in plans where they may face step therapy requirements embedded within prior authorization for psoriatic arthritis medicines. [190]
- In PDPs, psoriatic arthritis medicines are subject to step therapy 93 percent of the time and multiple sclerosis medicines are subject to step therapy 51 percent of the time.[191]

While UM strategies can play a useful role in ensuring that patients receive clinically appropriate medicines at lower costs, research shows that excessive UM restrictions may also harm Medicare beneficiaries by delaying treatment, substituting less effective medicines, and decreasing medication adherence, potentially leading to avoidable progression of diseases and harmful health effects. Without strong oversight and guardrails, the very tools intended to manage costs may ultimately undermine the goals of the Part D program. The following recommendations outline targeted actions to protect beneficiary access, improve transparency, and ensure clinically appropriate care.

CMS should ensure that all prior authorization requirements, including prerequisite therapy protocols, are fully transparent, accessible, and understandable to both patients and providers. We commend CMS for its recent step in requiring plans to include a new field – *'Prerequisite Therapy Required'*– as part of prior authorization criteria,[192] and urge CMS to take further action to promote transparency and accessibility.

CMS should make use of the full extent of its authority to ensure patient access is not disrupted, including ensuring that patients who are stable on an MFP-selected drug or a treatment alternative in the same class are not inappropriately switched to a different medicine or face other barriers to continued access.

CMS should update the Medicare Plan Finder to include specific types of UM requirements for covered medicines, and this information should be more prominently displayed. Currently, MPF indicates that a medicine is subject to prior authorization or step therapy restrictions, but it does not include information on exactly what medicines must be tried prior to receiving the originally prescribed medication. After using MPF, a beneficiary today would have to call the plan or find the information on the plan's website. Making this information easily accessible and understandable on MPF, particularly for medicines selected for price setting, will ensure beneficiaries can make well-informed decisions when selecting a plan that best meets their health care needs. Without clear visibility into these restrictions, beneficiaries may enroll in plans without fully understanding what will be required to access necessary medications. This additional transparency may be particularly helpful for beneficiaries taking selected medicines, given the risk of additional access challenges for those medicines.

CMS should require Part D plan sponsors to honor previously satisfied UM requirements when beneficiaries switch plans within the same parent organization. CMS should aim to create a seamless system where UM "follows the patient" during any plan changes – that is, once a beneficiary has met a

[190] "Embedded" step therapy refers to instances when the formulary lists the drug as having PA and does not note ST, but the PA criteria require a patient to step through at least one drug
[191] Avalere Health. (March 2025). Part D Prior Authorization Policies May Include Step Therapy. Available at: https://advisory.avalerehealth.com/insights/part-d-prior-authorization-policies-may-include-step-therapy
[192] HPMS. (April 2025). CY 2026 Part D Formulary Submission Information. Available at: https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-3-april-14-18

UM requirement for a specific medication, that approval should be transferable across plans. As a first step, CMS should require Part D sponsors to honor existing UM approvals and not impose new or repeated UM requirements on beneficiaries undergoing ongoing treatment who switch plans within the same parent organization. For patients with chronic or complex conditions, having to repeatedly "re-prove" delays care, burdens providers, and puts patients at risk. This is especially important given a recent analysis showing a sharp rise in insurer exits in 2024 after the IRA (relative to the prior six years), leading to 7.5 percent of beneficiaries (nearly three million people) losing their Part D plans and raising serious concerns about continuity of care.[193]

CMS should require plans to allow patients to initiate coverage determinations directly at the pharmacy counter to protect timely access to medically necessary medications. A well-functioning appeals and exceptions process is a vital safeguard for Medicare Part D beneficiaries, particularly as changes under the IRA may increase coverage restrictions. The current process is often complex and burdensome, discouraging patients from pursuing needed care. To reduce the administrative burden that prevents patients from accessing their medication, CMS should ensure that processes that are developed that allow patients to begin the coverage determination process at the point of sale, while minimizing any additional burdens on pharmacists. This will help reduce delays, minimize administrative barriers, and support faster access to prescribed therapies.

CMS should ensure appropriate oversight and guardrails over Medicare Advantage plans to ensure that enrollees do not face undue barriers to Part B selected drugs and their competitors beginning in IPAY 2028.

Beyond the access concerns that PhRMA has conveyed regarding Part D medicines subject to price setting, our concerns extend to potential barriers that Medicare Advantage enrollees could face when attempting to access selected Part B medicines and/or their competitors beginning in IPAY 2028.

Unlike in fee-for-service Medicare, MA plans are allowed to impose step therapy (ST) requirements on Part B medicines. Step therapy is a form of utilization management that requires patients to try and fail on one or more plan-selected medicines before gaining access to a clinician-preferred medicine. CMS issued guidance in 2018 giving MA plans the ability to use ST for Part B medicines for the first time starting in 2019, and codified this policy in regulations issued in 2019 and implemented in 2020.[194] As mentioned in numerous previous comment opportunities, PhRMA is categorically opposed to the use of ST in MA for Part B medicines, and believes that the guidance and regulation allowing MA plans to use ST for Part B medicines violate Social Security Act § 1852(a) because they permit MA plans to impose restrictions that do not exist in Original Medicare.[195]

In the years since MA plans were first allowed to impose ST restrictions, their use of ST for Part B drugs has risen significantly, concurrent with a sustained increase in the share of eligible Medicare beneficiaries electing to enroll in MA plans over traditional fee-for-service Medicare. By 2023, more than half of MA enrollees (54 percent) were enrolled in plans that apply ST to 10 of the most commonly-used medicines for the treatment of rheumatoid arthritis.[196] The increased prevalence of ST requirements for Part B medicines in MA is linked to significant burdens for physicians attempting to prescribe, and patients

[193] Cai C.L., et al. (May 2025). Insurer Exits After the Inflation Reduction Act Part D Redesign. *JAMA.* Available at: https://pubmed.ncbi.nlm.nih.gov/40367936/
[194] 84 Fed. Reg. 23,832 (May 23, 2019).
[195] See PhRMA comments on (CMS-4180-P) Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (January 2019).
[196] Avalere Health. (May 2024). MA Plans Increase Use of Step Therapy for Part B Drugs. Available at: https://advisory.avalerehealth.com/insights/ma-plans-increase-use-of-step-therapy-for-part-b-drugs

attempting to access, clinically appropriate treatments. In a recent survey of 300 providers across specialties, 94 percent of respondents reported that ST limits access to clinically-preferred Part B treatments—and over 60 percent of providers described the burden of ST for Part B medicines on patient access as "high" or "extremely high."[197]

CMS should take a lesson from the significant cost and access barriers that Part D enrollees are already facing and take proactive and decisive action to ensure that MA enrollees who rely on Part B medicines to treat chronic and complex conditions like cancer are not negatively impacted by plan behavior. Consistent with our recommendations on Part D access safeguards, we believe that CMS should adopt strong oversight and transparency safeguards to ensure that MA enrollee access to Part B selected drugs and their competitors are not disrupted by burdensome ST requirements.

III. Strengthen Formulary Review Standards and Engage Stakeholders

CMS conducts annual reviews to ensure Part D formularies comply with coverage requirements and do not discriminate against specific beneficiary groups. In the IPAY 2028 draft guidance, CMS acknowledges concerns that Part D plan sponsors might broadly restrict access to medicines selected for negotiation after those drugs have been announced, specifically, in the contract year prior to the drug's MFP taking effect, but notes that CMS did not observe such behavior in contract year 2025 for drugs with initial price applicability in 2026.[198] However, an analysis evaluating changes in formulary coverage for the 25 medicines that have been selected for federal price setting found that fewer medicines are available on formulary in 2025 relative to 2024. Payers are increasingly combining administrative forms of UM, exclusions, and tiered patient cost sharing; interactions with collective implications for patient access. For instance, in addition to the decrease in coverage, another analysis found that the average OOP cost for 9 of 10 MFP medicines increased by 32 percent. CMS should undertake comprehensive analysis of the aggregate impact of these mechanisms to assess the overall effects on patient access.

Exacerbating this, the heightened risk of plans further restricting access will increase as government price setting increasingly influences coverage incentives. These access restrictions could take the form of placing more medicines on non-preferred tiers, increasing coinsurance, or excluding certain medications altogether, actions that could significantly undermine patient access to critical treatments.

CMS should monitor and publicly report on formulary trends across all Part D plans, including by therapeutic area and plan type to ensure beneficiaries are not losing access to needed treatment options under IRA. CMS should also monitor and ensure that the average number of medicines covered in each class does not decrease. This monitoring will be particularly important over time and should begin with drug classes with one or more selected drugs. In addition, it is crucial for CMS to clearly articulate the specific steps it will take to prevent further limitations on access to medications, ensuring that beneficiaries are not worse off than they were prior to IRA implementation.

CMS should build a robust and ongoing public engagement structure to strengthen its oversight framework. As noted above, CMS' Part D formulary oversight standards are not transparent and currently do not include a formal, accessible mechanism for systematically collecting and incorporating feedback from patients, caregivers, clinicians, and other stakeholders. CMS could draw on lessons learned from patient-focused listening sessions conducted for selected drugs, using that experience to help start developing a consistent, meaningful, and transparent process for integrating stakeholder perspectives

[197] Avalere Health. (June 2025). White Paper: Provider Survey on Part B Step Therapy in Medicare Advantage. Available at: https://advisory.avalerehealth.com/insights/white-paper-provider-survey-on-part-b-step-therapy-in-medicare-advantage
[198] IPAY 2028 Draft Guidance at § 110.

into formulary review standards and UM policies in Medicare Part D. This approach would help ensure that coverage decisions are grounded in the real-world needs of beneficiaries and do not inadvertently limit access to critical treatments.

Appendix D: Information Collection and Negotiation Process

As in prior years, the Centers for Medicare & Medicaid Services' (CMS, the Agency) draft Initial Price Applicability Year (IPAY) 2028 Guidance fails to establish a clear, consistent methodology for arriving at maximum fair prices (MFPs). Meeting this basic standard is not only required by the statute[199] but is also essential for ensuring accountability of government decision-making. The lack of consistent methodology – reflected in the Guidance and Appendix A of the Draft Guidance (relating to definitions for purposes of collecting data) – creates unpredictability and adds unnecessary burden, exacerbating the MFP program's harmful effects.

To date, CMS has declined to provide any meaningful insight into how it uses manufacturer- or stakeholder-submitted data as part of the "clear and consistent" methodology required by statute. The draft 2028 Guidance unfortunately continues to leave this problem unaddressed. This results in manufacturers facing an opaque process with unclear decision-making standards, exceptionally burdensome data submission requirements, and little recourse but to adhere to the agency's arbitrary demands, even when these demands violate the spirit and letter of the Paperwork Reduction Act (PRA). The lack of transparency throughout the entirety of the price setting process underscores this approach as it remains uncertain whether the Agency even knows what information it needs, which could be a contributing factor for why the Agency continues requesting lengthy and at times irrelevant data from key stakeholders.

Further, some of the potential changes for which CMS seeks input would worsen, rather than mitigating, the harmful effects of the Inflation Reduction Act's (IRA) drug price controls. We are particularly concerned about the Agency soliciting comments on potential new starting points for the initial offer in the IPAY 2028 draft guidance, including "the unit cost of production and distribution of the selected drug" and "other domestic reference prices." These factors – which would further devalue and discourage research and development of new medicines and risk introducing further uncertainty into a process that is already unpredictable – should be rejected by CMS. Additionally, as discussed in detail later in the appendix, PhRMA continues to advocate that CMS should place greater emphasis on the 1194(e)(2) factors relative to 1194(e)(1) factors as manufacturer-specific factors are less relevant for determining MFPs.

CMS' lack of transparency may also discourage participation from patients, caregivers, clinicians, and other key stakeholders. With no transparency into how – or if – CMS is using data or the stories from these stakeholders, there is a risk that key stakeholders will stop replying to the Agency, as they may not feel that the significant investment required to submit data 28 days post selection or forfeit an afternoon for a roundtable or town hall is worth the time or effort. To address this, CMS should clarify how it uses submitted data in the MFP explanations, enabling stakeholders to tailor future submissions to what matters most in the Agency's decision-making.

Consistent with prior comments, PhRMA urges CMS to make basic improvements in the Guidance document's provisions on methodology and process and streamline and modify the upcoming Information Collection Request (ICR) in order to establish a consistent process and methodology,

[199] SSA § 1194(b)(1) ("The Secretary shall develop and use a consistent methodology and process.")

encourage more meaningful stakeholder participation, improve predictability, and reduce unnecessary data submission burdens. Specifically, we recommend the following changes:

- **Information Collection Request / Appendix A of the Draft Guidance:**
  - Streamline and simplify data submission requirements to reduce unnecessary burden and improve CMS decision-making; and
  - Clarify timing of ICR data certification.

- **Manufacturer-Specific Data Elements [1194(e)(1)]:**
  - Eliminate unnecessary regulatory burden and correct methodological inaccuracies;
  - Align data submission requirements with current business practices;
  - Limit submission of R&D costs to a single amount related to a selected drug;
  - Allow manufacturers the option to stipulate that they have recouped research and development (R&D) costs through a simple yes/no checkbox;
  - Do not place greater emphasis on the 1194(e)(1) factors when adjusting the preliminary price;
  - Clarify how data on pending and approved patents will be used to adjust MFP; and
  - Do not collect "forward-looking" forecasts during the data collection process.

- **Evidence About Alternative Treatments [1194(e)(2)]:**
  - Place greater emphasis on the 1194(e)(2) factors vis a vis 1194(e)(1) factors. Within such (e)(2) factors, focus on those directly related to patient benefit and how the selected drug performs in the real world compared to clinically appropriate therapeutic alternatives;
  - Clarify how CMS will weigh different data elements in MFP price-setting;
  - Improve process and standards on selection of therapeutic alternatives;
  - Reject alternative starting points such as the unit cost of production and distribution or domestic reference pricing as a starting point for the initial offer;
  - Support meaningful stakeholder engagement; and
  - Strengthen safeguards against use of quality-adjusted life years (QALYs) and related metrics.

I. Information Collection Request Data Burden and Noncompliance with Paperwork Reduction Act

In advance of IPAY 2026, PhRMA articulated concrete and actionable recommendations focused on key considerations under the Paperwork Reduction Act (PRA) for the implementation and application of the price setting process. Unfortunately, as it did with most comments, the Agency disregarded our recommendations and continued with its burdensome and inefficient process. For IPAY 2027, PhRMA again reiterated our concerns with how CMS' ICR forms are overly burdensome and, as a result, continue to fall far short of the three-prong regulatory test established by the PRA.[200] Yet, the previous administration made only minor changes – along with a modest and underestimated increase in burden estimates - while failing to address the ICR's inefficiencies and PRA noncompliance.

[200] 5 C.F.R. § 1320.5(d)(1)(i)-(iii)

The PRA was enacted in 1995 due to the "enormous growth of our federal bureaucracy" and "its seemingly insatiable appetite for data."[201] However, the previous administration ignored PRA requirements to "minimize and control burdens and maximize the practical utility"[202] of information collections and instead imposed an overly burdensome and complicated process to collect data. This is not only a waste of pharmaceutical manufacturer resources but also is an inefficient use of CMS staff time. There is no evidence[203] that CMS even considered the majority of information provided to the agency to determine the MFPs for IPAY 2026, yet – instead of complying with the PRA and reducing the burden on all data submitters – the previous administration allowed the ICR to balloon from a 47-page form in IPAY 2026 to 73 pages in IPAY 2027.

Further, the 28-day timeline to submit information to the Agency after drug selection is unreasonable and, in many cases, infeasible absent significant preparation in advance of selection. The information requested by CMS is not only vast and far-reaching, but it often requires a lookback of one or more decades along with complex coordination across many business functions under compliance pressure. The intensive process of then quality- and fact-checking the compiled data in order to certify this submission (which can be nearly impossible if possessed solely by a "Secondary Manufacturer") is extremely burdensome and can require substantial time compiling and analyzing data in advance of this compressed 28-day period. The Agency adds to this burden as it is unclear if respondents must continually update their ICR submissions or if they must only modify their submission(s) if it later becomes clear that the information submitted was incorrect based on the information available at the time of submission or if the data changes (e.g., due Medicaid Best Price restatement window). This resubmission process is burdensome and, given the lack of transparency into the MFP setting-process, it remains unclear why CMS requires continued data submission or how the Agency evaluates this data. The renegotiation process makes this even more opaque as CMS states that while manufacturers may voluntarily submit data to be considered for renegotiation, this submission is separate from the "ongoing obligation to update . . . original data submissions."[204] ***PhRMA recommends CMS clarify the certification requirements so that manufacturers must only update submissions if the submitter becomes aware that information was incorrect as of the time of submission.***

Furthermore, there is little evidence to validate why CMS needs the requested information as the Agency has provided no transparency into how, or even if, it used the vast amounts of data collected during the IPAY 2026 and IPAY 2027 price setting process. The IPAY 2026 "explanations" mostly repeated information available in Guidance instead of providing any assurance that CMS truly needed all the information collected. Nor has CMS articulated a data destruction schedule for the vast amounts of proprietary information it has collected or will collect. Not only do these flaws raise questions as to the goals behind the process, but it underscores a lack of consideration for the burden the request imposes or CMS' duties under the PRA.

PhRMA appreciates that CMS is soliciting feedback on the forthcoming ICR for IPAY 2028, and that the Administration is considering streamlining the MFP price-setting factors to reduce burden and improve efficiency. To this end, ***we again urge CMS to consider the requirements and intent of the PRA and,***

[201] *Dole v. United Steelworkers of Am*., 494 U.S. 26, 32 (1990)
[202] 5 C.F.R. § 1320.1
[203] CMS. (December 2024). MFP Explanations. Available at: https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices
[204] IPAY 2028 Guidance at § 50.1.

consistent with our prior comments to the Agency[205] along with the comments included in this Appendix, streamline and simplify the data submission requirements of the ICR – particularly but not limited to the manufacturer-specific data elements.

II. Manufacturer-Specific Data Elements [(e)(1) Factors]

Section 1194(e)(1) (hereinafter referred to as the (e)(1) or manufacturer-specific factors) of the IRA describes the following manufacturer-specific data that CMS shall consider for purposes of negotiating the MFP of a selected drug: "(A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs;" "(B) Current unit costs of production and distribution of the drug;" "(C) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug;" "(D) Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act for the drug;" and "(E) Market data and revenue and sales volume data for the drug in the United States."

For IPAY 2026 and IPAY 2027, the previous Administration interpreted the statute in a manner that led them to require Manufacturer-Specific Data Elements that were flawed and incongruent with current business practices. As stated above, many of the elements requested for collection violated the PRA in terms of both utility and necessity. For example, CMS continues to divide R&D costs into several categories—an approach that goes far beyond how manufacturers typically track or report this data and may conflict with standard document retention practices.[206]

While CMS' effort to streamline R&D data is a small step in the right direction, collapsing multiple subdivisions of R&D costs into two categories while still requiring manufacturers to include basic pre-clinical research for indications of the selected drug and post-IND costs among other costs does not adequately alleviate manufacturer burden associated with data submissions or make submitted data more relevant to determining MFP. CMS has significant opportunities to align data submission requirements with the PRA and current business practices to improve the utility and accuracy of submitted data and reduce the burden that manufacturers face in adhering to the current requirements.

In addition, CMS continues to ask questions that fall far short of capturing the full context surrounding the requested data. We support CMS' goal of prioritizing patient perspectives in its decision-making, and as such, continue to ask CMS to ensure that its data collection seeks to fully understand the market and any unintended consequences from price setting. The ICR offers no way for manufacturers to fully explain the complex and non-linear path of pharmaceutical innovation, which often involves costly setbacks, restarts, and dead ends.

Research and Development Costs

PhRMA appreciates that CMS is soliciting comments on opportunities to streamline the definitions research and development costs and hopes this signals some recognition that the current data requirements

[205] PhRMA. (September 2024). PhRMA Comments on IPAY 2027 Negotiation Data Elements and Negotiation Process ICRs. Available at: https://www.regulations.gov/comment/CMS-2024-0198-0018
[206] Draft IPAY 2028 Guidance at p. 206 (Appendix A)

are unworkable for manufacturers. However, we remain concerned about the subdivision of R&D reporting requirements into more than one category and believe the changes do not go far enough to reduce the burden on manufacturers. Additionally, PhRMA opposes CMS removal of acquisition costs as part of the overall calculation of R&D costs for a particular drug. An acquiring company pays for the value of the R&D already carried out by the selling company. The acquiring company also must weigh whether its money is better spent on the acquisition or investing internally in R&D. Furthermore, if a manufacturer has acquired the selected drug, CMS' position appears to be that the manufacturer may have *no* R&D costs to report. Yet, reporting an R&D cost of zero or minimal amounts would not be representative of the actual costs that went into developing and bringing the product to market. While PhRMA supports consolidating reporting and greater transparency, ***we strongly urge the new Administration to address the burden and methodological inaccuracies that resulted from the past Administration's approach to implementation of the (e)(1) factors.***

In its 2026 and 2027 IPAY Guidance, CMS' reporting requirements for R&D costs have been misaligned with how manufacturers actually track, allocate, and publicly report costs, creating significant compliance challenges under compressed timelines. While CMS' proposed streamlining of reporting requirements for IPAY 2028 is a modest improvement, it does not go far enough to reduce the overall burden of data collection. Manufacturers cannot easily reconstruct highly detailed R&D costs for drugs developed over a decade or more ago, especially given CMS' overly broad definition of QSSD to include products approved under different applications.

Additionally, costs for "abandoned and failed" products with the same "mechanism of action" may be difficult if not impossible for companies to attribute to a drug development program in the ways CMS has specified. This is because of the nature of investment decisions in biopharmaceutical R&D, which include factors that extend well beyond the mechanism of action of the drug candidate. These difficulties are compounded when drug products are developed through the efforts of multiple companies, through early-stage R&D licensing arrangements, or other partnerships. Preclinical investments in platform technologies or tools like artificial intelligence (AI) are shared across programs, making product-level cost allocation, especially for pre-clinical development activities, nearly impossible. CMS' approach demands a level of precision that is impractical, burdensome, and disconnected from how R&D is conducted and documented in practice.

As noted below, CMS should amend the Guidance to allow manufacturers to stipulate, without more, that they have recouped R&D costs through a simple yes/no checkbox. In the alternative, CMS should limit required submission of R&D costs to a single, total amount related to the selected drug, while allowing companies to voluntarily provide supplemental data. In addition, manufacturers should be given the opportunity to provide a supporting narrative.

Research and Development Cost Recoupment

PhRMA continues to be concerned about the validity of CMS' approach to capturing "R&D recoupment" - which does not account for all distribution and supply chain costs required to get products to market, among other concerns - and urges the Agency to acknowledge the concept's flaws and the difficulty of accurately quantifying and complying with it. As PhRMA and others have continually noted, very few

drug candidates that enter clinical trials are ultimately FDA-approved – in fact, just 12 percent.[207] Companies plan R&D across entire portfolios, expecting that only a few successful drugs will generate enough revenue to offset the many costly failures.[208] As a result, CMS' interpretation of the IRA requirement to consider R&D costs at the product level and the extent to which they have been recouped is not only impractical—given how investments are tracked—but also unnecessary under the statutory language. CMS' fundamental misunderstanding of the economics of the biopharmaceutical marketplace exacerbates this flawed provision by continuing to require companies to report in a manner not required by the IRA, such as providing detailed R&D costs and the extent to which they have been recouped, as well as by subdividing such costs into more than one subcategory.

While we appreciate CMS' willingness to consolidate some categories of R&D costs, rather than continuing this highly flawed approach, PhRMA strongly recommends that CMS allow a single global response for all the manufacturer's R&D costs across all development programs, similar to a Form 10K for Securities and Exchange Commission (SEC) filing, and a single attestation (YES/NO) for recoupment with the option to provide a supporting narrative. In addition, CMS should place minimal weight on recoupment and specify that it will not be used to reduce an MFP determined on the basis of a drug's therapeutic and clinical attributes. If a respondent stipulates "YES" that they have recouped research costs, then CMS need not gather any additional information. If a manufacturer checks "NO," then the manufacturer should be allowed the flexibility to provide an explanation, free of word limits, as to how the costs weren't recouped . This approach would also accord with section 1194(e)(1)(A), which merely requires that CMS consider R&D costs and the extent to which they have been recouped. CMS could reason that in cases where a manufacturer stipulates it has recouped R&D costs, the agency would have no need to further include R&D costs in the price-setting analysis (as the costs have been recouped); whereas, in cases where the data show a manufacturer has not recouped R&D costs, such information may inform an upward adjustment to MFP.

Patents and Exclusivities

For IPAY 2028, CMS seeks "comment on…whether CMS should put greater emphasis on certain section 1194(e)(1) factors when adjusting the preliminary price," or "whether CMS should consider and potentially adjust the preliminary price based on" the data described in item D above (data on pending and approved patent applications and exclusivities) "independent of considering other section 1194(e)(1) factors in totality."[209]

First, it is not clear what CMS means by "consider[ing] and potentially adjust[ing] the preliminary price based on" on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act for the drug "independent of considering other section 1194(e)(1) factors in totality." For example, it is not clear whether this statement means that CMS is considering giving this factor more weight than all other factors, and if so, how much weight. Nor is it clear whether CMS would increase or reduce the preliminary price based on the described

[207] DiMasi J.A., Grabowski H.G., Hansen R.W. (February 2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *J Health Econ*. Available at: https://pubmed.ncbi.nlm.nih.gov/26928437/
[208] Parry B., Moss R. (July 2024). Making more medicines that matter. McKinsey and Company. Available at: https://www.mckinsey.com/industries/life-sciences/our-insights/making-more-medicines-that-matter
[209] IPAY 2028 Draft Guidance, at 137

patents, exclusivities, and marketing applications. ***PhRMA requests that CMS clarify how it intends to consider and weigh the 1194(e)(1) factors and confirm that it will not use these factors to reduce prices.*** Moreover, in describing patents, exclusivities, and approvals that fall under item D above, CMS appears to have changed the term "related" (used to describe patents in the IPAY 2027 Guidance)[210] to "relevant,"[211] and it is not clear whether this change is substantive. CMS should clarify the significance of this change (if any) in the final Guidance.

Second, ***PhRMA urges CMS to consider the data described in item D—i.e., pending and approved patent applications, exclusivities, and pending or approved marketing applications—as markers of a product's innovative nature, the investment that the manufacturer made in developing the product, and the lack of therapeutic alternatives, all of which are factors that weigh in favor of increasing the preliminary price.***

Request for Comment on "Forward-Looking" Market Data

In section 50.1 of the draft Guidance, CMS solicits comment on the collection of additional, forward-looking "market data" for the selected drug. CMS suggests this data could include forecasted net revenue and volume data for the selected drug for future periods and provides examples of a manufacturer's annual forecast of U.S. net revenue, volume by indication, and net pricing for the selected drug itemized by the relevant market channel (e.g., Medicare, Medicaid, commercial or other); and annual gross-to-net ratio trend for the selected drug across all market channels and market share percentages and volume, by indication. CMS states that "these types of data are consistent with the section 1194(e)(1)(E) factor of 'market data and revenue and sales volume data for the drug in the United States.'" "Forward-looking" market data is inappropriate for collection as both a policy and legal matter. As a policy matter, forward-looking data is a forecast that may or may not be realized. Moreover, CMS requires primary manufacturers to certify that the data submission is "complete and accurate," and that notification will occur if information has changed.[212] Forecasts, by definition, constantly evolve based upon new information and changes to the business environment. Thus, it would be impossible to regularly notify CMS when information has "changed." In addition, requiring a delegated official to certify to the "completeness" and "accuracy" of what is merely a forecast places undue, unfair responsibility on such certifiers, who cannot reasonably opine as to whether the predictions will occur. Finally, a forecast does not constitute "data." In interpreting statutes, agencies must use the "ordinary meaning of terms unless context requires a different result."[213] The ordinary meaning of "data" is "factual information (such as measurements or statistics) used as a basis for reasoning, discussion, or calculation."[214] A prediction is not empirical, factual information akin to a "measurement" or a "statistic." In the case of MFPs, CMS' example of the gross-to-net ratio trend is particularly inapt, given that MFP will have a direct impact on net sales. Indeed, CMS may understand that it is stretching the meaning of the statute, as the agency states that its request for forecasted data is merely "consistent" with section 1194(e)(1)(E). This may

[210] IPAY 2027 Final Guidance, at 309
[211] IPAY 2028 Draft Guidance, at 210
[212] Centers for Medicare and Medicaid Services. (November 2024). IPAY 2027 Negotiation Data Elements Form, CMS 10849. Available at: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202411-0938-010. (Note: PhRMA continues to recommend that CMS revise the certification so that it applies *only* to the information available to the individual at the time of the certification)
[213] *Gonzales v. Carhart*, 550 U.S. 124, 152 (2007)
[214] Merriam-Webster. (n.d.) data. Merriam-Webster.com. Available at: https://www.merriam-webster.com/dictionary/data

indicate that the agency understands the statute does not clearly permit collection of predictions. ***For the above reasons, CMS should not collect "forward-looking" forecasts in its ICR.***

III. Evidence About Alternative Treatments [1194(e)(2)]

Emphasizing 1194(e)(2) Factors Related to Patient Benefit

Section 1194(e)(2) (hereinafter referred to as the (e)(2) factors) of the IRA allows for all stakeholders to submit evidence on the selected drug's performance in the real world. The previous Administration declined to provide any insight or clarity into CMS' methodology including, but not limited to, any information or structure around how the different sections will be weighted. ***As PhRMA and other key stakeholders[215] have previously recommended, CMS should (a) assign a greater weight to (e)(2) factors as compared to the (e)(1) factors; and (b) within such (e)(2) factors, assign greater weight to those that actually reflect the benefit the selected drug brings to patients, caregivers, and society and will help encourage the generation of additional evidence on the comparative health benefits of different treatments. As a corollary, to the extent (e)(1) factors are considered, CMS should place less weight on the (e)(1) factors that would diminish medicines' benefits and could stagnate innovation if overweighted***. Basing prices for medicines on costs incurred by the manufacturer, instead of the value and benefits conferred by the innovation, sends perverse, unintended signals to manufacturers that devalue and disincentivize R&D and pose a significant threat to innovation and progress for future medicines. Manufacturers require a clear understanding as to whether innovation and progress will be valued under CMS' price setting framework. As such, ***CMS should provide greater transparency on the types of evidence it will rely on when evaluating data, such as the extent to which a selected drug represents a therapeutic advance or addresses an unmet medical need, and the effects of the selected drug on specific populations.***

Therapeutic Alternative Selection

Identification of therapeutic alternatives represents a critical element of the MFP process, yet it is also a notoriously difficult element of any process for evaluation of the comparative costs and benefits of different medicines or other health care interventions. To date, CMS Guidance has not provided meaningful clarity on the evidence or process the agency uses to select therapeutic alternatives, a shortcoming that is retained in the IPAY 2028 draft Guidance. This is illustrated by CMS' release of MFP explanations for the IPAY 2026 drugs, which indicate that the agency considered an average of 6.5 therapeutic alternatives across each of the ten selected drugs (ranging from one to ten therapeutics alternatives per selected drug) but provided little specific information about how the agency ultimately selected specific therapeutic alternatives beyond vague statements on use of a "holistic" approach.[216] Selection of clinical comparators can be highly variable, raising questions about whether the decision was

[215] McElwee F., Cole A., Garrison L.P., Towse A. (June 2024). Federal Support Should Not Be A Factor In Determining Pharmaceutical Prices Under The IRA. *Health Affairs Forefront*. Available at: https://www.healthaffairs.org/content/forefront/federal-support-should-not-factor-determining-pharmaceutical-prices-under-ira

[216] National Pharmaceutical Council. (January 2025). "Maximum Fair Price" Explanations for IPAY 2026 Drugs. Available at: https://www.npcnow.org/sites/default/files/2025-01/MFP%20Explanation%20Files%20IPAY%202026%20NPC%20Policy%20Evidence%20Brief%202025_01.pdf

informed by other factors or objectives of the government's decision-making, rather than clinical appropriateness.[217]

As PhRMA has stated previously, therapeutic alternative selection should be based on the most clinically appropriate alternative informed by conversations with and data submissions from experts with real-world experience, including patients, practicing physicians, and pharmaceutical manufacturer(s). However, the agency's extremely compressed timetable for input, combined with vague, poorly defined standards for therapeutic alternative selection, makes it exceptionally difficult for manufacturers and other stakeholders to efficiently provide meaningful input on a selected drug relative to its therapeutic alternatives, and raises the risk that CMS will not identify the most clinically appropriate options. Especially as Part B medicines become eligible for price setting in IPAY 2028, introducing further complexities, CMS must also ensure maximum transparency on the process and mechanics of how they are utilizing therapeutic alternatives to calculate a product's MFP. Without these necessary insights, manufacturers will have no visibility into whether there are gaps or issues in the process, which could ultimately impact pricing. As such, ***CMS should publish the potential therapeutic alternative(s) under consideration for each selected drug when selected drugs are announced and allow data submitters to comment on CMS' proposal as part of their data submission package***. This would significantly reduce stakeholder burden by allowing data submitters to tailor their submissions to CMS and limit the potential scenarios stakeholders currently need to consider when preparing ICR responses.

Consideration of Non-Drug Therapeutic Alternatives

PhRMA appreciates the Agency seeking feedback on whether health care services payable under Part A or B could be considered as therapeutic alternative(s), but we do not believe that would be an appropriate step at this time. CMS has not yet provided clear enough standards or an open enough process to provide assurance that the agency will consistently select appropriate therapeutic alternative even among competing medicines. Expanding therapeutic alternatives to include health care services would increase the risk of CMS selecting clinically inappropriate comparators, while at the same time creating increased burden on data submitters to submit even more information and analysis. There is also a lack of visibility into the Agency's selection of therapeutic alternatives which creates no pathways for stakeholders to provide input on CMS' selection even when they believe CMS' selection may be incorrect. Because of these unaddressed issues, ***it would be premature for the Agency to broaden the consideration of potential therapeutic alternatives to non-drug alternatives.***

Starting Point for Initial Offer

PhRMA is opposed to the use of alternative starting points for initial offers such as those for which CMS solicits comments in the draft guidance. In particular, we are concerned by consideration of a starting point between the price of the therapeutic alternative(s) and the "unit cost of production and distribution," or potential use of "domestic reference prices."[218] As noted above, this approach fails to consider the important clinical and quality of life benefits provided by MFP-selected medicines. As a result, it would devalue treatment advances and discourage continue progress against unmet medical needs, significantly

[217] Hernandez I., et al. (December 2023). Medicare drug price negotiation: The complexities of selecting therapeutic alternatives for estimating comparative effectiveness. *J Manag Care Spec Pharm*. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC10909583/

[218] IPAY 2028 Draft Guidance at p. 131, § 60.3.2

exacerbating the damaging effects of the Program. **PhRMA strongly encourages CMS to reject consideration of alternative methodologies for establishing a starting point for negotiation such as domestic reference pricing or unit cost of production and distribution.**

Stakeholder Engagement

While PhRMA appreciates CMS' attempts to improve stakeholder engagement with patients, caregivers, patient advocates, and practicing physicians, the MFP process still falls well short of supporting meaningful patient engagement. For example, CMS frequently releases important information too late in its process, which prevents engagement. In the case of the stakeholder events, CMS failed to release the redacted transcripts from April 2025's events until over a month later in June – after CMS sent impacted manufacturers the Agency's initial offer for IPAY 2027. CMS also held its stakeholder events in the middle of a weekday, on short notice, placing a barrier on patients, caregivers, or practicing clinicians who needed to work or faced another type of conflict. By doing so, CMS severely limited who could participate and as a result, reduced the valuable insight that could impact CMS' evaluation of evidence and its MFP determination. Similarly, allowing these stakeholders only one month to complete the 1194(e)(2) section of the ICR –an interpretation the Agency did not have to adopt under the statute[219] – creates additional barriers for many stakeholders including those who are disabled or underfunded, or otherwise come from a disadvantaged background. CMS also continues to rely on a black box process that may discourage stakeholders from spending their time providing input that they fear the Agency will not take into consideration. For example, the IPAY 2026 MFP explanations primarily repeated existing Guidance instead of providing stakeholders with any insight into CMS' process or if CMS incorporated patient-centered data. ***As PhRMA has previously recommended, we urge CMS to make improvements in the process of soliciting stakeholder input and improve transparency into how this input influences the agency's decision-making. Without fundamental improvements, CMS risks creating the impression of tokenism in which patient and clinician input is sought but not actually considered.***

Quality-Adjusted Life Years

As PhRMA has repeatedly stressed in previous comments, cost-effectiveness metrics such as the Quality-Adjusted Life Year (QALY) should not be used by CMS in setting MFPs in accordance with section 1557 of the Affordable Care Act, section 504 of the Rehabilitation Act, as well as sections 1182(e) and 1194(e) of the Social Security Act. CMS' decision to continue considering analyses that include cost-effectiveness measures, including QALY-alternatives that use the same underlying and discriminatory math,[220] is both misguided and unnecessary. Using cost-effectiveness metrics as the basis for policy decisions risks undervaluing the lives of the elderly, the disabled, and other groups considered to have less than "perfect" health. While we understand that not all stakeholders will understand cost-effectiveness measures, given the breadth of data CMS considers (some of the MFP explanations included almost 300 sources), it is unlikely the Agency will be able to confirm that the studies do not use cost-effectiveness

[219] As PhRMA has previously noted, the statute does not specifically require that manufacturers and other stakeholders submit the information described in section 1194(e) by March 1. Instead, the March 1 deadline applies to non-FAMP data as well as certain other information, but does not cross-reference section 1194(e). SSA § 1194(b)(2)(A) cites to information described in § 1193(a)(4), which includes non-FAMP data as well as certain other information the Secretary absolutely "requires" to carry out price setting, but does not contain a reference to § 1194(e)

[220] National Council on Disability. (November 2022). Alternatives to QALY-Based Cost-Effectiveness Analysis for Determining the Value of Prescription Drugs and Other Health Interventions. Available at: https://www.ncd.gov/report/alternatives-to-qaly-based-cost-effectiveness-analysis-for-determining-the-value-of-prescription-drugs-and-other-health-interventions/

measures in a way that does not discriminate against certain populations. CMS should reconsider its decision to remove the attestation that prevents academics and other third parties from submitting data relying on these fatally flawed metrics. ***Instead, CMS should prioritize data from patients and doctors with prescribing experience, along with clinical effectiveness research that provides insight into a medicine's real-world performance, without undervaluing or discriminating against the lives of the elderly, the disabled, or the terminally ill.***

Appendix E: Renegotiation

I. CMS Cannot Rely Solely on the Existence of Part B Utilization to Justify Renegotiation

The Inflation Reduction Act (IRA) outlines clear requirements governing the identification of renegotiation-eligible drugs and the selection of drugs for renegotiation for years beginning with initial price applicability year (IPAY) 2028. Section 1194(f)(2) of the Social Security Act (SSA) limits "renegotiation-eligible" drugs to drugs that meet strict criteria:

> (1) A change in monopoly status occurs (for IPAY 2028 this is limited from a short-monopoly drug to a long-monopoly drug);
>
> (2) A new indication is added to the drug; or
>
> (3) The Secretary determines there has been a "material change" in any of the factors enumerated in SSA § 1194(e).

In addition, under SSA § 1194(f)(3), for criteria (2) and (3) the Secretary may select only those drugs for which the Secretary "expects renegotiation is likely to result in a significant change" in the maximum fair price (MFP).

The Centers for Medicare and Medicaid Services (CMS) states that it "anticipate[s] that selected drugs from [IPAYs] 2026 and 2027 with Part B utilization are likely to be determined to be "renegotiation-eligible drugs" and "selected for renegotiation" for IPAY 2028.[221] Yet, CMS does not explain: (1) why these drugs would qualify as "renegotiation-eligible drugs" under the statutory criteria; or (2) why they would meet the statutory requirements to be selected for renegotiation even assuming they fell within a category of "renegotiation-eligible drugs." Nor is the relationship between these statutory requirements and the existence of Part B utilization self-evident. ***Accordingly, there is no reason to conclude that a "Part D" selected drug with some Part B utilization necessarily or even probably meets the IRA's renegotiation criteria.***

The only possible basis for a selected drug to qualify as a renegotiation-eligible drug absent a change in monopoly drug status or a new indication is if the Secretary determines there has been a "material change" in any of the factors enumerated in paragraph (1) or (2) of SSA § 1194(e). The mere existence of Part B utilization is not listed in either the manufacturer-specific data elements in section 1194(e)(1) or the factors relating to therapeutic alternatives in section 1194(e)(2). Moreover, there is no reason why the existence of Part B utilization in a drug selected as a "Part D" drug would represent a *material change* in any of these factors. Importantly, we have heard nothing about selected drugs from IPAY 2026 or 2027 that acquired new Part B indications after their selection – and the continued existence of preexisting Part B utilization would not be any kind of change at all, let alone a "material change" in any of the section 1194(e) factors. The only "change" that has occurred is that, starting with IPAY 2028, the IRA's drug selection criteria takes into account Part B spending;[222] but this does not amount to a "material change" in the factors enumerated in section 1194(e) with respect to a selected drug.

[221] IPAY 2028 Draft Guidance § 130.1 at 190.
[222] SSA § 1192(d).

CMS similarly has failed to explain its conclusion that selected drugs from IPAYs 2026 or 2027 with Part B utilization would "likely" be selected for renegotiation. Absent a change in monopoly drug status, CMS may only select renegotiation-eligible drugs for which it "expects renegotiation is likely to result in a significant change" in the MFP.[223] But there is no basis for expecting a significant change in the MFP with respect to a previously selected drug with Part B utilization, as the continued existence of Part B utilization does not alter the factors outlined in section 1194(e), let alone "materially" change any of those factors in a way that would be expected to result in a significant change in MFP. These factors provide "the basis" for CMS to determine the "offers" and "counteroffers" during the renegotiation process, and therefore CMS cannot consider other data or information.[224]

Finally, the possibility of a "significant change" in MFPs from including selected drugs from IPAYs 2026/2027 with Part B utilization in the first renegotiation cycle conflicts with CMS' own statements. CMS recognizes that renegotiation eligibility and selection will begin approximately 15 months after the end of the price setting period for IPAY 2026 selected drugs and immediately after the end of the price setting period for IPAY 2027 selected drugs. Given this short timeframe, CMS states that it "does not expect" that it would be likely that renegotiation would result in a "significant change" to the MFPs for drugs selected for IPAYs 2026 and 2027, "except in unanticipated or unusual circumstances."[225] CMS states that such unusual circumstances could include a new indication being added to the drug shortly after the end of the price setting period, or unit costs increasing significantly due to a shortage of a key ingredient shortly after the end of the price setting period. CMS does not provide any reasoning as to why Part B utilization alone would constitute a "significant change" in the MFP.

CMS' statement that it "anticipate[s]" that IPAY 2026/2027 selected drugs with Part B utilization likely will be selected for renegotiation[226] conflicts with CMS' stated expectation that renegotiation of IPAY 2026/2027 selected drugs will not result in a "significant change" to MFPs absent "unanticipated or unusual circumstances."[227] The continued existence of Part B utilization is not an "unanticipated or unusual circumstance[]." The draft guidance does not attempt to reconcile its contrasting statements about renegotiation of IPAY 2026/2027 selected drugs, nor does it identify any connection between the existence of Part B utilization for a selected drug from IPAY 2026 or 2027 and the statutory requirements for renegotiation eligibility and selection.[228] If Congress meant for Part B utilization alone to be a categorical trigger for renegotiation selection, it could have expressly stated as such when it enumerated the statutory requirements for selection.

II. Outside of Monopoly Status Changes, No IPAY 2026 or IPAY 2027 Selected Drugs Should Be Selected for Renegotiation in IPAY 2028 (Unless Requested by the Selected Drug Manufacturer)

As described above, CMS itself recognizes in the draft program guidance that it is unlikely drugs selected for IPAYs 2026 or 2027 would experience a "significant change" to the product's MFP, given the short

[223] SSA § 1194(f)(3)(C).
[224] SSA § 1194(f)(4)(B) (requiring the renegotiation process to be consistent to the extent practicable with the statutory methodology and process for negotiation, including reliance on the factors enumerated in section 1194(e)).
[225] Draft Guidance § 130.2.1 at 197.
[226] Draft Guidance § 130.1 at 190.
[227] Draft Guidance § 130.2.1 at 197.
[228] See *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211 (2016) (explaining that where an agency has failed to "give adequate reasons for its decisions," "its action is arbitrary and capricious and so cannot carry the force of law").

time between the end of negotiation for these IPAYs and the start of process for IPAY 2028. CMS should thus affirmatively commit to not selecting for renegotiation any IPAY 2026 or 2027 drugs (outside of the statutorily-required change in monopoly status or in the absence of the manufacturer requesting renegotiation). An affirmative commitment would avoid CMS and manufacturers engaging in the resource-intensive, but unnecessary and duplicative, price setting process so close in time to the original negotiation.

III. CMS Should Raise the Threshold of a "Significant Change" in the MFP for Renegotiation Selection

CMS proposes a two-pronged, "holistic inquiry" approach for determining if renegotiation would lead to a "significant change" in the MFP for the purpose of determining renegotiation eligibility for drugs that have a new indication and/or a "material change" in any of the Section 1194(e)(1) or (e)(2) factors. Under the proposed approach, CMS would require that the selected drug meet both of the following two criteria: (1) that renegotiation is likely to result in a 15 percent or greater change in the MFP; and (2) that the expected change in the MFP would have a significant impact on the Medicare program (e.g., program spending, beneficiary cost-sharing).

PhRMA is generally supportive of CMS utilizing specific criteria in its "holistic inquiry" approach for determining renegotiation eligibility. However, we urge the Agency to consider not just whether a "significant change" in the MFP would have financial impacts on the Medicare program and beneficiaries, but also whether that change would lead to greater value to patients. CMS should also work to ensure that there is as much transparency as possible in its determination of renegotiation eligibility—especially for drugs that meet eligibility criteria through a "material change" in the negotiation factors that CMS determines would cause a "significant change" in the MFP. However, most notably, PhRMA believes that CMS should raise the threshold for determining whether an expected change in a drug's MFP would be "significant."

Using CMS' own reasoning it should raise the expected percent change in the MFP threshold from 15 percent to at least 35 percent. CMS notes in the draft program guidance that a 15 percent or greater expected change in the MFP "is consistent with the range of percent reductions in the ceiling price that is statutorily defined for drugs selected for renegotiation due to monopoly status changes." However, it remains unclear how CMS reached 15 percent as a consistent comparator based upon statutorily defined non-federal average manufacturer price (non-FAMP) ceiling changes when a selected drug switches monopoly status.

For drugs selected for initial price applicability years prior to IPAY 2030, the change in non-FAMP ceiling when a selected drug changes monopoly status equals 35 percent, not 15 percent. Section 1194(c)(4)(B)(ii) of the Act explicitly excludes drugs selected for IPAYs 2026 – 2029 from the definition of an "extended-monopoly drug" where the manufacturer has entered into an agreement. CMS acknowledged this, stating: "no selected drug will have a monopoly status change to extended-monopoly for purposes of renegotiation-eligibility" in 2028. Accordingly, the only drugs eligible for renegotiation selection for IPAY 2028 based upon a change in monopoly status will be those that change from short-monopoly to long-monopoly status. Using CMS' own reasoning that a "significant change" in the MFP should be consistent with percent reductions in the statutory non-FAMP ceiling price for different monopoly lengths, CMS should re-define the threshold to equal at least 35 percent. Setting the threshold

to at least 35 percent for expected change in the MFP if a drug were to undergo renegotiation due to either a new indication or material change in the section 1194(e) factors would align with the percentage change in the non-FAMP applicable percentage between short-monopoly (75 percent) and long-monopoly (40 percent) drugs, which would achieve the very consistency CMS cites as its goal in defining a "significant change" in the MFP.

In addition, even if CMS were to include in its analysis the non-FAMP ceiling applicable to extended-monopoly drugs, its proposal for a 15 percent change is arbitrary and does not follow the statute. The applicable percentages included in statute range from 75 percent of non-FAMP for short-monopoly drugs, to 65 percent of non-FAMP for extended-monopoly drugs (10 percentage point, or 13 percent change from short-monopoly), to 40 percent of non-FAMP for long-monopoly drugs (25 percentage point, or 38 percent change from extended monopoly). Put another way, none of the changes in monopoly status are associated with either a 15 percent or 15 percentage point reduction in the applicable percentage of the non-FAMP for determining the statutory ceiling price. As noted above, agencies are required to provide "adequate reasons" for their decisions.[229] CMS has failed to explain how its proposed 15 percent threshold accords with the statutory provisions on the various non-FAMP ceilings of 75, 65 and 40 percent. CMS should adopt the threshold of at least 35 percent starting in 2028, and extend it through 2030, during which the only changes in monopoly status for selected drugs will be from short-monopoly to long-monopoly.

Finally, raising the threshold to at least 35 percent will reduce the time and resource burden for both the Agency and manufacturers of selected drugs, especially if the price setting program continues to grow by CMS newly selecting and/or renegotiating already selected drugs. CMS is required to ensure that its renegotiation process is, "to the extent practicable … consistent with the methodology and process established" for annual price setting under section 1194(b) of the Act.[230] To ensure both manufacturers and CMS can adequately and thoughtfully engage in the offer and counter-offer process, and that the renegotiation process includes the patient and clinical voices essential to understanding each treatment's clinical value, CMS should choose a threshold that does not result in an inordinate number of medicines being chosen for renegotiation. Doing so could also reduce market volatility that may occur if a drug is selected for renegotiation each time a new indication or material change in the 1194(e) factors leads to an expected 15 percent or greater change in the drug's MFP.

IV. CMS Should Reduce Mandatory Data Submission Burden on Manufacturers of Drugs Selected for Renegotiation

CMS details in the IPAY 2028 draft program guidance that it will utilize both voluntary and mandatory data submissions to inform the renegotiation process. CMS notes that while the statute does not require the Agency to collect data from primary manufacturers to determine if there is a new indication or material change in the section 1194(e) factors, it will collect a subset of new (e)(1) data as a voluntary submission from the primary manufacturers whose product does not have a change to monopoly status for the purposes of renegotiation eligibility. Once a drug is selected for renegotiation, CMS will collect new information for all section 1194 (e)(1) data elements. This data submission will be *mandatory* for

[229] *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211 (2016).
[230] SSA § 1194(f)(4)(B).

primary manufacturers to submit via the negotiation data elements ICR (data elements ICR) and will share the same submission deadline as the ICR for the annual price setting process.

PhRMA appreciates the voluntary nature of the data submission to support the determination of eligibility for renegotiation. However, as PhRMA has previously stated[231] and further articulates in Appendix D of our IPAY 2028 draft program guidance comments, CMS' information collection request (ICR) forms are currently egregiously burdensome to stakeholders and continue to fall short of the three-prong regulatory test established by the Paperwork Reduction Act (PRA).[232] Yet, meaningful changes to rectify those concerns and comply with the PRA have not materialized, leaving data submitters spending countless staff hours compiling arbitrary data under intense compliance pressure. To date, it remains unclear how CMS uses the data elements required for ICR responses in the price setting process, or how it intends to use the information during the renegotiation process.

In order to address concerns regarding the overly burdensome data submission required for renegotiation, ***CMS should allow primary manufacturers to submit updates to the original data elements ICR, rather than requiring them to submit an entirely new ICR. To support this process, CMS should allow primary manufacturers to attest to ICR responses that have not significantly changed since the submission of the original data elements ICR. CMS should also be as transparent as possible with manufacturers on how they are using newly submitted information and recalculating the MFP for drugs selected for renegotiation.***

Subjecting manufacturers of selected drugs to repeated negotiation and renegotiation processes is burdensome, inefficient, and out of line with the Administration's focus on reducing needless regulation that hinders innovation and economic growth. A survey of PhRMA members reports that staff labor to populate the data elements ICR exceeds 7,700 hours on average across various business functions, consultants, and outside counsel. These demands will only be amplified if manufacturers are forced to resubmit the entire 73-page ICR for drugs selected for renegotiation. Allowing manufacturers to attest that information has not significantly changed will reduce the overall resource burden on stakeholders and introduce greater efficiency into the renegotiation process.

[231] See PhRMA comments on Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR) (CMS-10849, OMB 0938-1452).
[232] 5 C.F.R. § 1320.5(d)(1)(i)-(iii).