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August 17, 2026

VIA ELECTRONIC FILING – drugs@finance.senate.gov

The Honorable Ron Wyden
United States Senate
221 Dirksen Senate Office Building
Washington, D.C., 20510

Re: Request for Information: Commonsense Policy Options to Lower Drug Prices for Patients

Dear Senator Wyden:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide comments in response to your request for information on "Commonsense Policy Options to Lower Drug Prices for Patients."

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are 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. PhRMA member companies have invested more than $900 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.[1,2]

We share your objective of ensuring that medicines are accessible for American patients while supporting a policy environment that allows incentives to continue to exist for ongoing biopharmaceutical innovation and manufacturing in the U.S. We look forward to working with you as you consider legislation aimed at these goals. PhRMA's responses, which we provide more detail on below, are summarized in the attached Executive Summary and as follows:

Americans have more medicine choices than people living anywhere else in the world.

America's leadership in medicine research and development powers global innovation and domestic economic growth. To maintain this edge against rising international competition, we must continue to prioritize and protect the ecosystem that makes American innovation possible. PhRMA urges

[1] PhRMA. (August 2026). ICYMI: Biopharmaceutical Companies in American Hit New Investment Milestone. Available at: https://phrma.org/blog/icymi-biopharmaceutical-companies-in-america-hit-new-investment-milestone
[2] TECONOMY. (May 2024). The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. Available at: https://cdn.aglty.io/phrma/policy-issues/research-ecosystem/economy/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf

policymakers to reject flawed Most Favored Nation (MFN) policies, which would cause grave and irreparable harm to U.S. biopharmaceutical innovation, depriving patients of future cures and treatments.

Fixing the pill penalty is essential to addressing disincentives established under the Inflation Reduction Act (IRA) that may discourage future innovation with meaningful benefits for patients. The pill penalty discourages companies from researching and developing innovative small molecule medicines, resulting in fewer lower-cost treatment options, fewer convenient and accessible medications and fewer treatments that are essential in the fight against cancer, mental illnesses and other diseases. Early-stage funding for small molecule development has fallen by nearly 70 percent since the IRA was passed, while the number of innovative products in the pipelines of Chinese companies has nearly doubled in the last three years.[3,4]

The unmet need for patients with rare diseases is tremendous, but developing medicines for small patient populations is particularly challenging, underscoring the need to preserve incentives for orphan drug development. The Orphan Cures Act helps restore critical incentives for orphan drug development that were undermined by the IRA's Medicare drug price setting provisions and exacerbated by the Centers for Medicare and Medicaid Services' (CMS) approach to implementation. These changes are critical to preserving the incentives created by the Orphan Drug Act for manufacturers to pursue initial indications in rare disease populations. Absent these changes, companies could be disincentivized from seeking approval for orphan indications first, potentially delaying or preventing the development of new treatments for patients with rare diseases.

Our unique system balances innovation and affordability.

The competitive market dynamics for prescription medicines in the U.S. successfully balance innovation, patient access and cost containment. However, that balance is increasingly threatened by misaligned payer incentives and conflicts of interest. Aggressive consolidation and vertical integration among insurers, pharmacy benefit managers (PBMs), pharmacies and other entities have resulted in a small number of corporations exerting outsized influence over patient access to medicines. Vertical integration of the pharmaceutical supply chain enables behaviors that can increase costs and limit access, such as when PBMs steer patients to the pharmacies they own. Further, the growth of excessive utilization management may cause critical delays in patients' ability to obtain treatments, and patient access to generics and biosimilars is increasingly threatened by misaligned incentives driving anticompetitive PBM behavior. Increased transparency and oversight are needed, and proposals to address these challenges should focus on correcting the market distortions created by vertical integration.

Insurer abuses and existing program shortcomings challenge patient access.

As health insurance companies and their PBMs increasingly shift the cost of care onto patients, more than 80 million Americans in high deductible health plans must pay the full list price of their medicines until they reach their deductible, even when their PBM or insurer is receiving a steep discount.[5] Rebates and

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[3] Schulthess, D.G., O'Loughlin, G., Askeland, M. et al. The Inflation Reduction Act's Impact Upon Early-Stage Venture Capital Investments. Ther Innov Regul Sci 59, 769–780 (2025). https://doi.org/10.1007/s43441-025-00773-3

[4] Chen et al. (2024). Chinese innovative drug R&D trends in 2024. *Nature Reviews Drug Discovery, **23**,* 810-811, doi: https://doi.org/10.1038/d41573-024-00120-5

[5] Cohen R., Briones E. (December 2024). Enrollment in High-Deductible Health Plans Among People Younger than Age 65 with Private Health Insurance: United States, 2019–2023. *Centers for Disease Control and Prevention*. Available at: https://www.cdc.gov/nchs/data/nhsr/nhsr214.pdf

discounts can reduce the net prices PBMs and insurers pay by 50 percent or more,[6] but these savings are rarely passed along to patients at the pharmacy counter. The Committee should consider a range of policies that enable patients to benefit more directly from savings in the system and to take steps to improve upon existing programs designed to improve affordability for patients. The Committee must also ensure that access and affordability go hand-in-hand by addressing insurer abuses such as inappropriate coverage denials that prevent patients from accessing the medicines their doctors prescribe.

A strong R&D ecosystem is essential to maintaining the United States' leadership in biomedical innovation.

PhRMA appreciates the focus on advancing U.S. biopharmaceutical innovation at a time of intensifying global competition. Sustaining America's leadership in research, development and manufacturing requires continued commitment to the foundational policies that enable private-sector investment, including strong intellectual property protections, effective regulatory data protections, science-based and predictable regulatory review, federal support for basic and translational scientific research and reimbursement systems that reward innovation. These principles have helped establish the U.S. as the world's leading biopharmaceutical innovation ecosystem for decades.

As Congress considers policies to strengthen domestic competitiveness, it is critical to avoid measures that would weaken the incentives that drive biomedical investment. Proposals that expand government price setting, import foreign pricing systems, tie access to federal research assets to pricing concessions or otherwise diminish market-based returns risk undermining the very environment that attracts R&D and manufacturing investments to the U.S. Strengthening America's leadership position will require policies that reinforce, rather than erode, our long-standing biomedical innovation ecosystem.

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Section I: Lowering Drug Prices

PhRMA strongly opposes the expansion of price setting policies, as they will inevitably have significant negative impacts on patients, innovation and the U.S. economy. As it stands, the U.S. has relied on a policy framework that balances incentives for innovation with robust competition following time-limited periods of intellectual property protection. Rather than relying on government price setting, the U.S. system has historically encouraged competition from other innovators, generic medicines and biosimilars—a framework that has consistently driven down prices over time, without sacrificing incentives for developing new treatments and cures. As a result of this framework, approximately 90 percent of prescriptions written in the U.S. are filled with generics and biosimilars.[7] And because of this robust competition, prescriptions filled through Medicare and Medicaid cost 18 percent less, on average, than in other developed countries.[8]

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[6] MedPAC. (July 2026). *A Data Book: Health Care Spending and the Medicare Program*. Available at: https://www.medpac.gov/wp-content/uploads/2026/07/July2026_MedPAC_DataBook_SEC.pdf

[7] IQVIA. (April 2026). U.S. Medicine Use Trends Report. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/us-medicine-use-trends-2026

[8] Philipson, T., Zhang, D., Zhao, Q. (June 2025). International Comparison of Prices for Drug Prescriptions. *University of Chicago.* Available at: https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2025/06/Policy-Brief-International-Price-Differences-for-Drug-Prescriptions-June-7.docx.pdf

Price setting, whether through the Inflation Reduction Act's (IRA's) Medicare Drug Price Negotiation Program (MDPNP) (or expansion thereof) or the referencing of drug prices set in foreign nations, would undermine this framework.

- Research shows that since the passage of the IRA, funding for early-stage development of small molecule medicines has declined by nearly 70 percent.[9]
- Over a ten-year period, expansive price controls would result in 500 fewer new treatment options for patients.[10]

As discussed later in this section, price setting is already undermining the generic and biosimilar market and the affordability gains that result from a competitive marketplace. Expansion of price controls, including the proposals set forth in this RFI, would only exacerbate these effects. In fact, new research estimates that by weakening incentives for generic and biosimilar competition, the IRA could increase the average price of medicines subject to price setting in 2026 and 2027 by 21 percent over the 35-year period after the MFPs go into effect.[11]

Further, expanded price controls could harm the U.S. economy.

- The biopharmaceutical sector currently supports more than five million high wage jobs with a manufacturing footprint in 48 states.[12]
- Since 2025, PhRMA member companies have committed to over $500 billion in new U.S. manufacturing and infrastructure investments, which could deliver another 100,000 jobs.[13]
- Expanded price controls could undermine this investment, and in turn, American workers. Research has shown that broad price setting proposals could eliminate approximately 337,000 biopharma jobs and over 1.5 million jobs in total across the U.S. economy.[14]

Evidence to date suggests the MDPNP is eroding incentives for innovation without delivering lower out-of-pocket costs for patients—undermining the very rationale offered for these policies. In fact, analysis suggests that downstream effects of the program will cause patients to pay more for their medicines.

- For instance, under the IRA, two-thirds of Medicare beneficiaries are enrolled in Part D plans where their cost sharing is expected to increase for many drugs subject to price setting.[15]

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[9] Schulthess, D.G. et al. (April 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

[10] Philipson T.J. et al. (September 2025). The Impact on Patient Health of Most-Favored-Nation Pricing of Already Marketed Drugs. *The University of Chicago.* Available at: https://ecchc.economics.uchicago.edu/2025/09/29/policy-brief-the-impact-on-patient-health-of-most-favored-nation-pricing-of-already-marketed-drugs/

[11] Philipson T. et al. (August 2026). The Impact of Price Controls on Longterm Prescription Drug Prices. *The University of Chicago.* Available at: https://ecchc.economics.uchicago.edu/project/the-impact-of-price-controls-on-longterm-prescription-drug-prices/

[12] TEConomy. (2024). The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. Available at: https://cdn.aglty.io/phrma/policy-issues/research-ecosystem/economy/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf

[13] PhRMA. (September 2025). PhRMA Announces Major Actions as Part of Industry's Commitment to American Patients and Workers. Available at: https://phrma.org/resources/phrma-announces-major-actions-as-part-of-industry-s-commitment-to-american-patients-and-workers

[14] Vital Transformation. (September 2025). Most Favored Nation (MFN) Reference Pricing in Medicare: Impacts on Jobs, Innovation, and State Budgets. Available at: https://vitaltransformation.com/2025/09/most-favored-nation-mfn-reference-pricing-in-medicare-impacts-on-jobs-innovation-and-state-budgets/

[15] Magnolia Market Access (2026). When Lower Prices Don't Mean Lower Costs: How Part D Benefit Design Changes Are Shifting Out-of-Pocket Spending in 2026 Under the Inflation Reduction Act. Available at: https://www.magnoliamarketaccess.com/insight/medicare-part-d-cost-sharing-changes-2026/

- Further, actuaries project that nearly all (93 percent) of Part D beneficiaries will see no reduction in annual out-of-pocket spending from the first ten price set drugs.[16]
- In Medicare Part B, virtually no beneficiaries are expected to benefit from lower out-of-pocket costs under the MDPNP. Because approximately nine in ten Medicare fee-for-service (FFS) beneficiaries are already enrolled in supplemental insurance plans that cover their out-of-pocket costs for Part B drugs, and because utilization of the Part B drugs likely to be subject to MDPNP price setting is low, the program is expected to yield cost savings for less than one percent of Medicare FFS beneficiaries.[17]

Expanding the IRA as described in the RFI also will not address the access barriers faced by many Part D beneficiaries. As it stands, the IRA requires Part D plans to cover selected drugs but offers no further guarantees that patients will be able to obtain drugs for which the government dictates the price. Recent research shows that in the first quarter of 2026, patients attempting to initiate therapy with immunology and oncology medicines selected for the first round of Medicare price setting faced initial rejection rates of 59 percent and 67 percent, respectively.[18]

We also encourage the Committee to take a more nuanced approach to examining the prices of brand medicines, particularly when comparing them to prices in foreign countries.

- For instance, the U.S. is the only country in the world subject to a system where entities that don't make medicines take 50 percent of every dollar spent on them.[19] Notably, rebates and fees received by pharmacy benefit manager (PBM) middlemen can exceed the cost of the same medicines abroad by as much as 900 percent.[20]
- In addition, tax-exempt hospitals increasingly rely on the 340B program as a significant source of revenue, driving up costs for patients, taxpayers and employers alike, and hospital markups can exceed prices abroad by 700 percent.[21]

These cost drivers are unique to the U.S. system and have an attenuated—if any—relationship with the price of the medicine itself, yet are routinely ignored in international price comparisons.

More broadly, such comparisons overlook the fact that medicines are not the primary driver of differences in overall health care spending between the U.S. and other wealthy nations. In fact, less than ten percent of the gap in health spending between the U.S. and other developed countries is attributable to the cost of medicines.[22] Importing foreign government price controls would therefore do little to address the broader drivers of health care spending, while weakening the market-based framework that has enabled the U.S. to lead the world in biomedical innovation.

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[16] Milliman. (August 2026). Assessing the Beneficiary Out-of-Pocket Impact of the MDPNP. Available at: https://www.milliman.com/en/insight/assessing-beneficiary-out-of-pocket-impact-mdpnp
[17] Avalere Health. (December 2024). IRA Negotiation Impact on Part B Beneficiary OOP Costs. Available at: https://advisory.avalerehealth.com/insights/ira-negotiation-impact-on-part-b-beneficiary-oop-costs
[18] IQVIA (August 2026). Rejection Rates Unchanged by MFP Drug Coverage Requirement. Available at: https://www.iqvia.com/locations/united-states/blogs/2026/07/rejection-rates-unchanged-by-mfp-drug-coverage-requirement
[19] BRG. (January 2025). The Pharmaceutical Supply Chain, 2013 – 2023. Available at: https://cdn.aglty.io/phrma/global/blog/import/pdfs/PhRMA_Supply-Chain-2013-2023_White-Paper_V484.pdf
[20] Pacific Research Institute. (June 2025). The 340B Discounts Hospitals Receive Will Often Exceed Total Drug Prices in Europe. Available at: https://www.pacificresearch.org/the-340b-discounts-hospitals-receive-will-often-exceed-total-drug-prices-in-europe/
[21] *Ibid.*
[22] Magnolia Market Access. Prescription Drug Spending and the U.S. health Spending Gap Compared with OECD Countries. Available at: https://www.magnoliamarketaccess.com/insight/prescription-drug-spending-and-the-u-s-health-spending-gap-compared-with-oecd-countries/

The Committee should closely examine the flaws inherent in the MDPNP, including how it has been implemented by CMS under two different Administrations. For example, the MDPNP decision making process is effectively a black box to all stakeholders. CMS' maximum fair price (MFP) explanations, which CMS is required by statute to provide, fail to offer any insight into CMS' decision making and rather reiterate Program Guidance. Further, CMS has failed to incorporate the opinions and lived experiences of key stakeholders, and the role of clinicians in the process is negligible. These decisions undermine collaboration and engagement with stakeholders who have significant expertise in the disease areas selected for the MDPNP, with the lack of meaningful input about the factors that matter to patients resulting in a systematic undervaluing of selected drugs. Before the Committee considers expanding the scope of the MDPNP to impact a greater number of drugs and beneficiaries, it should repair what is clearly not working in the statute as currently written and conduct oversight over CMS' implementation of the law.

Below we describe our concerns regarding the Committee's specific proposals to expand price setting in the U.S.

Factoring International Pricing into the MDPNP

In the RFI, the Committee recognizes that consideration of international pricing is not permitted under current law and proposes factoring it into the MDPNP. Incorporating foreign prices into the MDPNP would import the flawed pricing systems of foreign governments—systems that systematically undervalue and limit access to innovative medicines, discourage investment in future cures and fail to reflect the value American patients place on access to medical innovation.

First, foreign reference pricing, or Most Favored Nation (MFN) pricing, imports policy judgments that are incongruent with American values. It is not merely a pricing mechanism—it imports the underlying coverage and reimbursement decisions made by foreign governments, many of which rely on discriminatory methodologies such as the quality-adjusted life year (QALY) to determine whether, and which, patients should have access to innovative therapies.

QALYs assign numerical values to patients' lives based on age, disability or health status. As part of the Affordable Care Act, Congress explicitly prohibited Medicare from using QALYs in coverage and payment determinations because they discriminate against older adults, individuals living with disabilities and patients with chronic illness—an exclusion that extends to the IRA's MDPNP. Many Organisation for Economic Co-operation and Development (OECD) countries previously included as reference countries in MFN policies formally or informally rely on QALYs in making coverage decisions.[23] Consequently, foreign reference pricing would effectively incorporate into the U.S. health care system discriminatory foreign assessments that Congress—including Congressional Democrats—has already rejected as inconsistent with American values.

The discriminatory impact of QALYs extends beyond age and disability status to race as well. Because QALY metrics assign lower values to the lives of vulnerable populations, they can systematically undervalue treatments for older adults, individuals with disabilities and communities of color. For example, because Black Americans have a lower average life expectancy than White Americans, QALY-based methodologies can value a life-saving treatment for Black patients up to ten percent less than the

[23] Copenhagen Economics. (February 2026). QALY Use in Selected OECD Countries. Available at: https://copenhageneconomics.com/publication/qaly-use-in-oecd/

same treatment for White patients.[24,25] Similarly, a White patient with diabetes and visual impairment may be valued 15 percent more than a Black patient with the same conditions.[26] Incorporating foreign reference prices into U.S. drug policy would reinforce this discrimination, embedding it into decisions about which American patients can access innovative medicines.

These concerns are shared by voters and clinicians alike. More than 80 percent of voters express high levels of concern about importing QALY-based decision-making through MFN policies.[27] Independent analyses reinforce this concern, demonstrating that foreign health agencies substantially undervalue innovative medicines. For example, more than 95 percent of U.S. physicians report that several chronic disease therapies provided greater clinical value than German assessments reflected, and research shows that Canadian and German coverage recommendations undervalued medicines by approximately 90 percent.[28,29]

Second, these values also translate into more limited patient access in other developed countries. Lower prices in these systems are frequently achieved by delaying or denying access to innovative therapies.

- In the U.S., 88 percent of new medicines are reimbursed by Medicare, compared to only 25 percent under Australia's public health insurance program and 23 percent under Canada's.[30]
- Patients in the U.S. can access new medicines in an average of three months after regulatory approval, while patients in other developed countries must wait an average of nearly three years.[31]
- These delays carry real medical consequences for patients in need of innovative treatments. For instance, patients in America are, per capita, 12 times more likely to receive the newest cancer medicines than patients in the U.K.[32]

For these reasons, PhRMA urges the Committee to reject proposals that incorporate MFN pricing into the MDPNP or otherwise extend foreign government price controls into the U.S. commercial market. Such proposals would weaken incentives for future innovation, import discriminatory foreign valuation methodologies and fail to address the true drivers of patient costs.

Negotiating Lower Prices on More Drugs & Earlier in the Lifecycle

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[24] Scientist.com. (July 2021). Is Cost-Effectiveness Racist? Available at: https://www.scientist.com/blog/is-cost-effectiveness-analysis-racist

[25] National Black Caucus of State Legislators. (2024). Policy Resolution HHS-24-36. Available at: https://nbcsl.org/public-policy/resolution/hhs-24-36/

[26] McCollister K.E. et al. (2012). Racial Disparities in Quality-Adjusted Life Years Associated with Diabetes and Visual Impairment. *Diabetes Care.* Available at: https://diabetesjournals.org/care/article/35/8/1692/29892/Racial-Disparities-in-Quality-Adjusted-Life-Years

[27] Survivors for Solutions. (September 2025). Survey on QALYs and Most Favored Nation (MFN) Pricing. Available at: https://survivorsforsolutions.org/news-and-updates/most-favored-nation-amp-qaly-survey-memo

[28] Let My Doctors Decide. (September 2025). Survey Shows Vast Majority of U.S. Doctors Place Higher Value on Medicines vs. German Health Authorities. Available at: https://www.actionforpatients.org/post/survey-shows-vast-majority-of-u-s-doctors-place-higher-value-on-medicines-vs-german-health-authori

[29] No Patient Left Behind. (April 2025). Foreign Countries Rely on Flawed and Outdated HTA or "Value Assessment" Methods to Justify Low Prices for Medicines. Available at: https://www.nopatientleftbehind.org/resource-materials/ex-us-report

[30] PhRMA. (May 2026). Access to New Medicines in the United States vs. Other High Income Countries. Available at: https://phrma.org/resources/access-to-new-medicines-in-the-united-states-vs-other-high-income-countries

[31] *Ibid.*

[32] PhRMA. (March 2026). Leadership in Biopharmaceutical R&D Provides U.S. Patients the Greatest Access to Innovative Medicines. Available at: https://phrma.org/blog/leadership-in-biopharmaceutical-r-d-provides-u-s-patients-the-greatest-access-to-innovative-medicines

The RFI proposes allowing the Secretary to price-set additional qualifying single source drugs each year beyond the current statutory limit, and to shorten the length of time medicines are on the market before selection for MDPNP takes place. This proposal comes despite the fact that the MDPNP's long-term impacts remain uncertain. The first MFPs only took effect on January 1, 2026, and with the program still in its inaugural year, early evidence on its real-world effects already points to potential harms to patient access and innovation. Expanding the MDPNP's scope before those effects can be comprehensively assessed would be premature.

Expanding the IRA would significantly exacerbate existing disincentives to invest in high-risk biopharmaceutical research and further erode the incentives necessary to sustain U.S. global leadership in biopharmaceutical innovation. The existing scope of the IRA already prevents manufacturers from earning the market-based returns necessary to recover the substantial capital required for—and to offset the high failure rates inherent in—developing innovative new medicines, let alone the returns needed to incentivize continued investment in future innovation. This is borne out in how the industry allocates its resources, and the revenue that would be lost for future high-risk R&D if price setting were expanded. Congress should focus on correcting the flaws in the IRA before it considers expansion.

Recently released research shows that only 26 percent of a medicine's lifetime revenue is realized by year five of its lifecycle.[33] Given that expected and realized revenue are significant drivers of R&D investment, slashing revenue would have material and lasting effects on future innovation. Moving price setting eligibility even earlier than under current law, or expanding the number of drugs subject to it, would substantially reduce the period during which innovators can recover and earn a sufficient return on R&D investments, making many future research programs economically unsustainable.

References to biopharmaceutical industry profitability in the RFI obscure these concerns by perpetuating the misleading claim that the industry earns significantly higher profit margins than other parts of the health care sector. Yet, when measured on a comparable basis, UnitedHealth Group's profit margin matches the average earned by the ten largest biopharmaceutical companies—despite operating a lower-risk business model that spends 93 percent of operating costs on marketing and administration and nothing on R&D.[34] In contrast, innovative biopharmaceutical companies reinvest approximately 33 percent of revenues into research and development, compared to just 3.8 percent for all other U.S. industries.[35]

The risks of expanding price setting under the IRA are not merely theoretical; they are already being quantified.

- Economic analysis projects that the IRA's current framework will reduce R&D investment in small molecule medicines by approximately $232 billion over the next 20 years, resulting in an estimated 188 fewer small molecule advances.[36]

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[33] IQVIA. (August 2026). Price-Control Policy and Lifetime Sales Trajectory of Medicines. Available at: https://www.iqvia.com/locations/united-states/blogs/2026/08/price-control-policy-and-lifetime-sales-trajectory-of-medicines

[34] Pham N.D. (August 2026). What Health Insurance Companies Do Not Tell You About Their Profits. *Insurance Watchdog Coalition.* Available at: https://insurancewatchdogcoalition.com/wp-content/uploads/2026/08/UHG-Profits-Study_August-2026.pdf

[35] Pacific Research Institute. (January 2026). Drug Manufacturers Earn a Lower Return on Capital Than PBMs and Health Insurers. Available at: https://www.pacificresearch.org/wp-content/uploads/2026/01/OnePager_ReturnonCapital.pdf

[36] Philipson T.J., Ling Y., Chang R. (October 2023). The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act. *The University of Chicago.* Available at: https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2023/10/Small-Molecule-Paper-Final-Oct-5-2023.pdf

- Additionally, a 2026 analysis found that, in the nearly two-and-a-half years following the enactment of the IRA, clinical trials declined by 25 percent for certain medicines, while trials studying new uses for previously approved medicines declined by 30 percent for small molecules and 13 percent for biologics.[37]
- Another analysis found that small molecule R&D investment among early-stage biopharmaceutical companies has declined by nearly 70 percent since the IRA was introduced.[38]

These early signals are consistent with concerns that the current statutory framework is already discouraging investment in small molecule innovation.

Earlier selection eligibility would also jeopardize important progress that occurs after a medicine's initial approval. Investment in post-approval R&D can expand the use of medicines for new diseases or patient populations and represents an important driver of therapeutic advances. An IQVIA analysis found that nearly one-third of the roughly 200 post-approval new uses for the top 50 novel medicines were developed late in their lifecycle (e.g., five or more years after initial approval).[39] Further, developing these post-approval new uses is often time-intensive and costly, and may not be viable until scientific knowledge advances enough to determine whether a medicine can benefit new patient populations. An accelerated selection timeline could therefore place many future treatment advances out of reach. This is particularly significant in oncology, where 90 percent of cancer medicines approved between 2000 and 2021 underwent at least one post-approval clinical trial, with 25 to 50 percent of additional uses developed after or near the point at which the medicines would become eligible for MDPNP selection.[40] Accelerating the timeline would threaten not only future medicines, but also important new uses for medicines already on the market.

Slashing the price setting timeline for biologic medicines—which treat many of the most complex diseases—from 13 years to five years would make R&D investment untenable and leave almost no time to conduct post-approval research.

- Post-approval R&D on biologic medicines is an important source of new treatment options: of the 32 biologic medicines approved from 2006 through 2012, 72 percent received at least one additional approval after the initial Food and Drug Administration (FDA) approval (i.e., post-approval new uses).[41]
- Eleven percent of post-approval new uses for biologic medicines were approved as many as 11 or more years after initial approval.[42] The loss in return on investment (ROI) would incapacitate an industry at the forefront of making progress against cancer, Alzheimer's disease and chronic diseases that disproportionately affect the Medicare population.

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[37] Long G. (March 2026). Trends in Industry-Sponsored Clinical Trial Activity Since Passage of the Inflation Reduction Act. *Journal of Medical Economics.* Available at: https://www.tandfonline.com/doi/full/10.1080/13696998.2026.2646075
[38] Vital Transformation. (January 2025). The Inflation Reduction Act's Impact Upon Early-Stage Venture Capital Investments. Available at: https://vitaltransformation.com/2025/01/preprint-new-research-the-inflation-reduction-acts-impact-upon-early-stage-venture-capital-investments/
[39] IQVIA. (January 2026). Impacts of the Proliferation of Innovation. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/impacts-of-the-proliferation-of-innovation
[40] Grabowski H., DiMasi J.A., Long G. (October 2024). Postapproval Innovation for Oncology Drugs and the Inflation Reduction Act. *Health Affairs.* Available at: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2024.00202
[41] ADVI. (March 2025). Implications of the Inflation Reduction Act Price Setting Provisions on Post-Approval New Uses for Biologics. Available at: https://advi.com/publication/implications-of-the-inflation-reduction-act-price-setting-provisions-on-post-approval-new-uses-for-biologics/
[42] *Ibid.*

- For example, 70 percent of all cancer treatment uses are developed following initial approval, and 50 to 65 percent are developed five years or more after initial FDA approval.[43]

These are the types of advances that are at the greatest risk of being diverted, halted or never pursued.

Beyond its effects on innovation, expanding the MDPNP would also threaten the competitive prescription medicine lifecycle that has historically produced the greatest long-term savings for patients. As detailed in the following section, researchers project that the IRA's chilling effect on generic competition would result in significant unrealized annual savings for medicines affected by price setting, representing billions in forgone generic and biosimilar savings. Rather than strengthening competition or affordability, expanding the MDPNP risks reducing both future innovation and the robust generic and biosimilar competition that has historically delivered the largest reductions in medicine costs.

PhRMA strongly opposes proposals that would shorten the statutory eligibility timeline for Medicare drug price setting or expand the number of drugs subject to the MDPNP.

PhRMA is additionally concerned that accelerating timelines for Medicare drug price setting could negatively influence investment decisions by generic and biosimilar manufacturers. 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. Over time, this system delivers long-term affordability as branded medicines are followed by generics and biosimilars, which now account for approximately 90 percent of prescriptions filled and have saved $3.4 trillion over the past decade.[44] Despite this success, the IRA's price setting program threatens to dismantle these incentives by allowing the government to impose prices on biologics and small molecule medicines that do not have biosimilar or generic competitors much earlier than competition can typically occur. As a result, generic and biosimilar manufacturers may no longer find it viable to enter the market.

With regard to small molecule medicines, the IRA undermines existing incentives for generic competition by implementing price setting nine years after FDA approval as long as there is no marketed generic competitor, far earlier than the average time to generic entry: 13 to 14 years.[45] As generic manufacturers rely on the ability to offer deeply discounted prices to attract market share from brand competitors, forcing generic manufacturers to enter the market to compete against an already low government-set price fundamentally alters the economic incentives for market entry. Specifically, the IRA undermines the statutory framework that rewards first-to-market generics, weakening the ability for generic manufacturers to compete and recoup investments. A key feature of the Hatch-Waxman Act was the establishment of a 180-day exclusivity period for the first generic to challenge brand patents and market a low-cost generic to incentivize faster generic access. The prospect of this window of profit opportunity encourages multiple generic manufacturers to attempt to be the first-to-market, therefore positioning the market for multiple competitors to drive down prices significantly over time. However, if brand sales have been reduced by price setting at the point of generic entry, fewer generic entrants will have an incentive to enter the market and drive savings.

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[43] Axelson K., Grabowski H., Long G. (December 2024). The IRA and Post-Approval Clinical Research for Cancer Medicines. *Health Affairs.* Available at: https://www.healthaffairs.org/content/forefront/ira-and-post-approval-clinical-research-cancer-medicines

[44] Association for Accessible Medicines. (September 2025). 2025 U.S. Generic & Biosimilar Medicines Savings Report. Available at: https://accessiblemeds.org/resources/reports/2025-savings-report/

[45] Grabowski H., Long G., Mortimer R., Bilginsoy M. (January 2021). Continuing trends in U.S. brand-name and generic drug competition. Journal of Medical Economics. Available at: https://pubmed.ncbi.nlm.nih.gov/34253119/

The IRA's price setting framework further imposes uncertainty for biosimilar manufacturers. Biologics may be eligible for price setting after they have been approved for 11 years and so long as there is no marketed biosimilar competitor. Furthermore, CMS imposed an unfounded requirement that the biosimilar not only be licensed and marketed but be "bona fide marketed." Unfortunately, the timing for a biologic to be exempt from eligibility for price setting under the IRA is at odds with the Biologics Price Competition and Innovation Act (BPCIA), which does not allow FDA to approve a biosimilar until at least 12 years after the first licensure of the reference product. As a result, the IRA includes a "Special Rule" to potentially delay selection and price setting of eligible biologics for which a relevant biosimilar manufacturer obtains a "pause" before the brand biologic product is selected for price setting to allow time for biosimilar market entry. Despite inclusion of the "Special Rule," the IRA's statutory language and CMS' interpretation of the law ultimately fails to provide manufacturers with the assurances needed to invest resources towards development of biosimilars, which can take six to nine years to develop and cost between $100 million and $300 million.[46] Moreover, these companies cannot accurately predict which biologics will be selected for price setting, and biosimilars may not be able to succeed in a market where they must compete against a biologic with an already low government-set price.

Projected changes in generic and biosimilar investment are substantial. One analysis estimated that the IRA's chilling effect on generic competition would result in unrealized annual savings of 81 percent to 88 percent of brand sales per affected small-molecule drug and 54 percent of brand sales per affected biologic, meaning that for a given blockbuster medicine, either $3 billion in generic savings or $1.9 billion in biosimilar savings would be lost, annually.[47] Consistent with this dynamic, new research estimates that the IRA's weakening of the incentives for generic and biosimilar competition could increase the average price of medicines subject to price setting in 2026 and 2027 by 21 percent over the 35-year period after the MFPs go into effect.[48]

Accelerating timelines would dramatically reduce brand sales and further disrupt first-to-market generic incentives for competition. To illustrate the tradeoff inherent in weakening incentives for generic competition under price setting policies such as MFN, one recent analysis estimated that for every additional $140 million in branded sales in the year before generic entry, there is approximately one more generic entrant. Conversely, dramatic reductions in branded sales through lowered prices or shorter life cycles for branded products would lead to fewer generic entrants and less savings—ultimately undermining the tremendous success of the generics market in the U.S.

For the biosimilars market, accelerating timelines for Medicare price setting could be devastating: the market already faces significant headwinds that threaten the pipeline's sustainability and could limit biosimilar savings well beyond Medicare.

Evidence suggests PBM dynamics are driving market distortions that prevent the biosimilars market from reaching its potential, largely by blocking access to biosimilars on formularies. Experts have noted that PBMs' current compensation models, which are often tied to a medicine's list price, can incentivize

[46] McKinsey. (August 2022). Three Imperatives for R&D in Biosimilars. Available at: https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars

[47] Matrix Global Advisors. (July 2025). Long-Term Effects of Medicare Price Negotiations on Drug Competition. Available at: https://accessiblemeds.org/wp-content/uploads/2025/07/Matrix_Global_Advisors_Long-Term_Effects_of_Medicare_Drug_Price_Negotiations.pdf

[48] Philipson, T, Zhang, D, Fisher, N, and Seyrafi, C. (2026). The Impact of Price Controls on Longterm Prescription Drug Prices. *The University of Chicago.* Available at: https://ecchc.economics.uchicago.edu/project/the-impact-of-price-controls-on-longterm-prescription-drug-prices/

PBMs to prefer medicines with higher list prices over lower cost alternatives, like biosimilars.[49,50] Beginning in 2018, the big three PBMs began excluding biosimilars from their formularies for patients with commercial insurance and the prevalence of this practice has skyrocketed since then. As of 2025, 37 biosimilars have been excluded from the formulary of at least one of the three largest PBMs, representing a 164 percent increase since 2022 alone.[51]

As recognized by this RFI and discussed in greater detail in our comments, over the past few years each of the big three PBMs have commercialized private-label biosimilars through affiliates and contractors, preferencing coverage for these products while excluding non-PBM-affiliated biosimilars from formularies, even when they are the least costly option.[52] The limited inroads that non-PBM affiliated biosimilars have been able to make into this market impose substantial uncertainty for biosimilar manufacturers considering investing in future biosimilar development.

PhRMA supports solutions to ensure a robust biosimilar marketplace moving forward and appreciates the Committee's request for policy ideas that would help boost the biosimilar market. In support of this goal, it is critical that Congress implement reforms to address misaligned incentives that may lead PBMs to favor medicines with high list prices and high rebates. For example, requiring the rebates, discounts, and other price concessions that PBMs receive from pharmaceutical manufacturers to be passed on to patients at the point-of-sale would help to realign the incentives that may encourage PBMs to favor higher priced medicines. Additionally, the Committee should explore policies to address market distortions, conflicts of interest and self-preferencing behaviors that have enabled private-label biosimilars. These policies are detailed in Section II. Fixes are also needed to address the IRA's barriers to biosimilar market entry. Under the IRA, biosimilar manufacturers cannot predict, with any accuracy, which biologics will be subject to price setting, creating significant uncertainty regarding whether there will be an opportunity to recoup the investments required to develop a biosimilar competitor. Congress should simplify the process for application of the "Special Rule," allow biologics that are selected for price setting to exit the program more promptly upon the approval and marketing of a biosimilar and eliminate the extra-statutory "bona fide marketing" standard invented by CMS.

In the absence of implementing these fundamental system reforms to address disincentives for biosimilar manufacturers to enter the market, we believe many of the concepts proposed in the RFI are likely to fall short of ensuring the future sustainability of the biosimilars market.

Eliminating the Orphan Cures Act

Roughly 95 percent of the 7,000 rare diseases that are known today still do not have an FDA-approved treatment, including many severe and life-threatening pediatric diseases.[53] This significant unmet medical need only underscores the importance of maintaining targeted incentives created under the Orphan Drug

[49] 84 Fed. Reg. 2341 (February 2019).
[50] Young, C.L. (March 2025). Medicare's recent actions to promote access to lower cost drugs. Brookings. Available at: https://www.brookings.edu/articles/medicares-recent-actions-to-promote-access-to-lower-cost-drugs/
[51] Cencora. (July 2025). Persistent growth in PBM formulary exclusions continues to raise concerns about patient access. Available at: https://cdn.aglty.io/phrma/global/resources/import/pdfs/Report%20-%20Persistent%20Growth%20in%20PBM%20Formulary%20-%20August%202025.pdf
[52] Drug Channels. (January 2025). The Big Three PBMs' 2025 Formulary Exclusions: Humira, Stelara, Private Labels, and the Shaky Future for Pharmacy Biosimilars. Available at: https://www.drugchannels.net/2025/01/the-big-three-pbms-2025-formulary.html
[53] Fermaglich L. & Miller K. (June 2023). A comprehensive study of the rare diseases and conditions targeted by orphan drug designations and approvals over the forty years of the Orphan Drug Act. Available at: https://link.springer.com/article/10.1186/s13023-023-02790-7

Act (ODA) of 1983 and reaffirmed by the Orphan Cures Act (OCA). ***We strongly disagree that a replacement framework for the OCA is needed.***

The targeted incentives included in the ODA have proven essential in spurring development for patients with rare diseases where small patient population sizes and R&D challenges have significantly limited development incentives.

- In the decade before the ODA passed, only ten drugs for rare diseases were brought to market. In the four decades since, the FDA has approved nearly 800 orphan drugs, bringing treatments, and sometimes cures, to patients who previously had limited or no treatment options.[54]
- Importantly, the ODA also successfully encouraged companies to invest in post-approval R&D to identify new uses of existing medicines in additional orphan diseases. Between 1990 to 2022, 35 percent of orphan drugs were approved for multiple uses (20 percent for both rare and non-rare diseases, 15 percent for solely orphan conditions).[55]
- This outcome is particularly important as orphan drugs with multiple rare disease indications provide more than three times the survival gains as non-orphan drugs.[56]

While the IRA provided a specific exclusion from price setting for certain orphan drugs, this exclusion was far too narrow, and CMS' implementation has only exacerbated the issue. Under the IRA as originally enacted, only products with a single orphan designation and indication(s) within that lone designation qualified for an exclusion from price setting. But products with multiple orphan designations or approved for additional indications, for either a rare or non-rare condition, were not exempt. Unfortunately, this construct was detrimental to ODA incentives that had successfully encouraged companies to seek multiple orphan designations and to conduct research to seek new uses of existing medicines in additional rare and non-rare diseases.

The OCA partially addressed the IRA's original, narrow exemption by ensuring orphan drugs that are approved only for rare diseases, even with multiple approvals, are excluded from Medicare price setting, helping better preserve the ODA's incentives. The OCA also addressed the IRA's narrow exemption by ensuring orphan drugs that have multiple designations, including those being studied in early-stage development in multiple orphan diseases, are also excluded from Medicare price setting.

Additionally, for orphan drugs that are subsequently approved for a non-orphan use and lose eligibility for the exclusion, the OCA confirmed that the clock for price setting eligibility will begin when the product loses eligibility for the exclusion rather than when the drug was originally approved. This fix, in particular, helps to restore the incentive to launch first in rare indications, a desirable outcome for patients with rare disease and rare cancers. In fact, 63 percent of oncology trials starts in 2025 were evaluating medicines for rare cancers.[57] Before this fix, when CMS interpreted the eligibility clock to begin at initial approval, the law may have incentivized companies to seek approval for larger indications first, rather than developing the drug for a rare population.

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[54] Analysis of FDA Orphan Drug Product designation database. Available at: https://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm

[55] Miller K. L., Lanthier M. (2024). Orphan Drug Label Expansions: Analysis Of Subsequent Rare And Common Indication Approvals. *Health Affairs.* Available at: https://pubmed.ncbi.nlm.nih.gov/38190603/

[56] FTI Consulting. (2025). Quantifying the Value of Orphan Drugs and the Impact of the IRA Sole Orphan Exclusion. Available at: https://www.fticonsulting.com/insights/articles/health-economics-market-access-insights

[57] IQVIA Institute. (March 2026). Global R&D Trends 2026. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-r-and-d-trends-2026

Upending orphan drug incentives that were preserved under the OCA based on misleading claims that the law delays negotiation of "expensive drugs" would be shortsighted and detrimental to rare disease patients. These claims misrepresent how price setting works under the IRA. When the selection of a drug for Medicare price setting is delayed, CMS still selects another drug for price setting in its place (i.e., the total number of selected drugs does not change). Additionally, drugs with delayed selection may still be selected in a future year once they are eligible, allowing price setting to go into effect.

Taken together, any delays in price setting for selected drugs with orphan indications in accordance with OCA fixes, which were enacted with bipartisan support, will have a negligible impact on the broader price setting framework. But the OCA's impact in terms of addressing broad disincentives to orphan drug development are immensely important for facilitating continued research to meet the needs of patients with rare diseases.

Modifying and Extending Medicare Inflation Rebates

PhRMA strongly opposes changes to the Medicare Part B and Part D inflation rebate programs to re-base the rebate benchmark dates to an earlier year, to extend the Medicare rebate programs to the commercial market and to extend the Part B inflation rebate program to Medicare Advantage (MA) units.

Re-basing Benchmark Dates

In the IRA, Congressional Democrats established benchmark dates for medicines already on the market as the third quarter of 2021 for the Part B inflation rebate program and the first through third quarters of 2021 for the Part D inflation rebate program. In selecting these dates (which fall roughly one year prior to the passage of the IRA), Democrats were observing prior legislative precedent for imposing inflation penalties which set benchmark dates at or close to the date of enactment, not multiple years earlier. For example, when Congress extended Medicaid inflation rebates to generic drugs as part of the Bipartisan Budget Act of 2015, the benchmark date for generic drugs already on the market was set to October 1, 2014, roughly one year before the law's passage.[58] And when Congress originally established the Medicaid Drug Rebate Program as part of the Omnibus Budget Reconciliation Act of 1990, the benchmark date for brand medicines already on the market was set at October 1, 1990, a little over one month prior to the passage of the act.[59]

Indeed, the precedent of not punishing individuals or corporations by "moving the goal posts" is broadly observed by Congress even beyond prescription drug policy. The RFI states plainly that it targets price increases that occurred prior to 2021. Here, the request is clear that the intent of legislation would be to penalize companies for activities that have already occurred—a clear violation of the principle that the populace should be able to rely on the laws enacted by Congress. This is especially the case for an industry that relies on innovation, making investment decisions decades in advance. PhRMA urges the Committee to refrain from moving the goal posts and altering the Part B and Part D inflation rebate benchmarks after the fact.

Extension to the Commercial Market

[58] *See sec. 602.* Available at: https://www.congress.gov/bill/114th-congress/house-bill/1314/text
[59] *See sec. 4401, p. 148.* Available at: https://www.congress.gov/bill/101st-congress/house-bill/5835/text

Extending the Part B and Part D inflation rebate programs to the commercial market is an unnecessary overreach that ignores existing market dynamics. Commercial insurers already utilize a number of strategies to keep drug costs down, including by imposing price protection rebates.[60]

In addition, the pricing metrics utilized for the Part B and Part D inflation rebate programs—generally, the Average Sales Price (ASP) and Average Manufacturer Price (AMP), respectively—already capture prices paid by many commercial purchasers, including large providers, group purchasing organizations, wholesalers and retail community pharmacies, among others. As such, the Medicare program is already accounting for commercial price growth in the inflation rebates currently being assessed.

Finally, extending the Part B and Part D inflation rebate programs to the commercial market would fail to address a major driver of commercial health costs. Hospitals, along with insurers, PBMs, and others receive 50 cents of every dollar spent on brand medicines[61] and can force patients to pay more for medicines than the hospital or insurer pays to acquire them. Limiting growth in the prices drug manufacturers charge does not rein in charges by hospitals and insurers that are driving up commercial insurance costs and premiums.

Extension to MA Units

While MA plans administer benefits to Medicare enrollees, they are not administered by the federal government, but by private insurers that are not bound by all the same rules as the fee-for-service program. For example, MA plans are not required to reimburse providers for physician-administered drugs based on ASP, and historically, a significant share have chosen to use a different metric. For instance, in 2016 for physician office-based care, 38 percent of MA-covered lives were reimbursed on a basis other than ASP.[62] An inflation rebate that measures excess price growth in ASP is not logically suited for a program where ASP is not the required basis of reimbursement.

In addition, MA plans can also already employ the same strategies that commercial health plans and PBMs do to contain drug costs, making application of the Part B inflation rebates to MA unnecessary.

Subscription Models

We appreciate the Committee's interest in expanding access to GLP-1 medications for patients living with obesity and related chronic conditions. In support of this goal, we urge the Committee to take a market-based approach that seeks to expand the universe of covered patients while minimizing disruptions in care for those who rely on these chronic disease treatments.

Innovative contracts—also known as value-based contracts or alternative financing arrangements—for biopharmaceuticals are voluntary agreements between manufacturers and other entities, such as health plans, states, or risk-bearing providers, that can help improve patient care and optimize health care spending. Manufacturers and payers engage in a variety of contract types, including subscriptions, offering flexible approaches to pay for the value of various medicines while enabling coverage and access for different patient populations in an evolving medical landscape. Exploring such arrangements for GLP-1s may offer opportunities the potential to broaden access to chronic disease treatments while also addressing financing concerns.

[60] IQVIA. (July 2023). Trends in Price Protection. Available at: https://www.iqvia.com/locations/united-states/blogs/2023/06/trends-in-price-protection
[61] Berkeley Research Group. (January 2025). The Pharmaceutical Supply Chain, 2013–2023. Available at: https://cdn.aglty.io/phrma/global/blog/import/pdfs/PhRMA_Supply-Chain-2013-2023_White-Paper_V484.pdf
[62] Magellan. (2016). Magellan Rx Medical Pharmacy Trend Report. Figure 92.

However, a mandatory subscription framework that consolidates purchasing outside of traditional reimbursement or incorporates a reference-price conflicts with the spirit of a value-based arrangement and may result in unintended consequences. For example, such an approach could create incentives for plans or other payers to redesign benefits around the subscription arrangement, which could risk disruptions in care for chronic disease patients. These risks highlight why preserving a range of market-based innovative contracting arrangements provide the best path forward, allowing payers and manufacturers to tailor flexible solutions to patient needs while avoiding the unintended consequences of a one-size-fits-all mandatory framework.

Chronic diseases are a leading driver of health care costs, imposing a heavy burden on our health care system and economy. Six in ten Americans have at least one chronic condition and 42 percent have two or more.[63] The cost of treating chronically ill patients accounts for 90 percent of the nearly $5.3 trillion spent on health care in the United States each year.[64] Looking ahead, the number of individuals with three or more chronic conditions is projected to more than double by 2039, greatly increasing the economic burden imposed by these illnesses.[65]

Better disease management and improved health achieved through optimal use of medicines has long been credited with avoiding health complications and spending on other costly health care services such as emergency room visits, hospital stays, surgeries, and long-term care. Notably the ability for medicines to reduce spending on other costly medical care has also been shown to curb overall health care spending. For example, between 1999 and 2012, Medicare experienced a marked slowdown in spending growth with one quarter of that slowdown attributed to greater use of cardiovascular medicines that prevent or mitigate cardiovascular disease complications.[66]

GLP-1s offer similar transformative effects, with evidence pointing to substantial economic benefits of weight loss due to reduced chronic illness. One analysis estimated that, in Medicare, just a five percent reduction in individuals' weight among those living with overweight or obesity could reduce spending by $1,262 (seven percent) per person annually, while a 25 percent reduction could lower spending by an average of $5,442 (31 percent) annually for each beneficiary.[67] In employer-sponsored insurance, a 25 percent reduction in weight was estimated to reduce spending by nearly $3,000 per person on average annually. [68]

Expanded use of GLP-1s can also yield substantial downstream savings through avoided comorbidities and associated costs, generating significant benefits for the health care system and the economy. For example, researchers at the University of Southern California (USC) have projected that expanding insurance coverage of GLP-1s to treat obesity could produce $175 billion in Medicare savings over the next 10 years and generate $1 trillion in cumulative societal benefits through lower health care costs and

[63] Buttorff C., Ruder T., Bauman M. (May 2017). Multiple Chronic Conditions in the United States. *Rand Corporation.* Available at: https://www.rand.org/pubs/tools/TL221.html
[64] CDC. (May 2026). Fast Facts: Health and Economic Costs of Chronic Conditions. Available at: https://www.cdc.gov/chronic-disease/data-research/facts-stats/index.html
[65] Partnership to Fight Chronic Disease. What Is The Impact Of Chronic Disease In The United States? Available at: https://12860544-bc49-4b5c-9d49-f592cc453792.usrfiles.com/ugd/128605_dcf1fd8434644230aaf899ed090179e2.pdf
[66] Cutler D.M. et al. (February 2019). Explaining the Slowdown in Medical Spending Growth Among the Elderly. *Health Affairs.* Available at: https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2018.05372
[67] Thorpe K.E., Joski P.J. (December 2024). Estimated Reduction in Health Care Spending Associated With Weight Loss in Adults. *JAMA Network Open.* Available at: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2827550?resultClick=1
[68] Thorpe K.E., Joski P.J. (December 2024). Estimated Reduction in Health Care Spending Associated With Weight Loss in Adults. *JAMA Network Open.* Available at: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2827550?resultClick=1

improved quality of life.[69] Another recent study from USC researchers found that broad access to GLP-1s across the health care system could return 13 percent annually to the U.S. economy, generating $10 trillion in lifetime value to society as individuals live with less chronic disease—representing nearly double the rate of U.S. stock market returns this century.[70] Real-world evidence points in the same direction: an Aon analysis of commercial medical and pharmacy claims from more than 192,000 GLP-1 users found that sustained use lowered medical cost growth by up to nine percentage points for members managing diabetes and up to seven percentage points for those using GLP-1s for weight loss.[71]

The economic and clinical value of GLP-1s to patients and society is the result of decades of sustained research and development that have yielded multiple approved therapies offering a variety of choices and clinical benefits to meet a wide range of patient needs. Despite this enormous progress, a significant unmet medical need remains for patients with obesity, cardiovascular diseases, metabolic syndrome, and related conditions not adequately addressed with existing therapies. Addressing these needs with the next generation of chronic disease therapies will undoubtedly be influenced by a reimbursement environment that ensures patients can access therapies through existing insurance coverage and any new payment model(s) directed towards GLP-1s.

It is worth noting, GLP-1s as a class illustrate how incentives for research investment to meet unmet medical needs combined with market-based competition can meaningfully contain costs. GLP-1s are situated in a highly competitive therapeutic class, with discounts and rebates reported to have lowered net prices for insurers and PBMs between 41 percent and 59 percent across public and private payers.[72] This competitive dynamic benefits payers and patients and should be carefully preserved in the design of any new payment model.

As the Committee notes, coverage of GLP-1s for obesity has not been uniform across health insurance markets in the United States. This variation reflects delayed recognition of obesity as a chronic disease by some public and private payers, despite well-established consensus within the medical community. CMS' outdated interpretation of the statutory exclusion of weight loss drugs, even when used for the treatment of obesity, has prohibited coverage of these medications in Medicare and permitted coverage in Medicaid to remain voluntary. Even where coverage exists, particularly among employer health plans, significant utilization management barriers such as clinical eligibility criteria, limitations on eligible medications, or required participation in weight management programs can further limit appropriate patient access to treatment.[73] To address many of these gaps, individual manufacturers have developed direct purchase programs to enable patients to access medicines at lower costs outside of insurance coverage. While direct purchase programs have served an important role in bridging gaps in coverage, they are a supplement to, not a substitute for, comprehensive insurance coverage.

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[69] Sexton Ward A. et al. (April 2023). Benefits of Medicare Coverage for Weight Loss Drugs. *USC Leonard D. Schaeffer Institute for Public Policy & Government Service.* Available at: https://schaeffer.usc.edu/research/benefits-of-medicare-coverage-for-weight-loss-drugs/

[70] Sexton Ward A. et al. (March 2025). Lifetime Social Returns from Expanding Access to Anti-Obesity Medications. *USC Leonard D. Schaeffer Institute for Public Policy & Government Service.* Available at: https://schaeffer.usc.edu/research/lifetime-social-returns-from-expanding-access-to-anti-obesity-medications/

[71] Aon plc. (January 2026). Aon's Latest GLP-1 Research Reveals Long-Term Employer Cost Savings and Significant Reductions in Cancer Risk for Women. Available at: https://www.prnewswire.com/news-releases/aons-latest-glp-1-research-reveals-long-term-employer-cost-savings-and-significant-reductions-in-cancer-risk-for-women-302659076.html

[72] Hernandez I., Sullivan S.D. (January 2024). Net prices of new anti-obesity medications. *Obesity (Silver Spring)*. Available at: https://pubmed.ncbi.nlm.nih.gov/38228492/

[73] Business Group on Health. GLP-1 Costs Loom Large for Employers, Forcing Challenging Coverage Decisions. Available at: https://www.businessgrouphealth.org/newsroom/news-and-press-releases/press-releases/2026-glp-1-survey

We appreciate the Committee's interest in expanding access to GLP-1s for the treatment of obesity through exploring alternative financing arrangements. As noted above, any such arrangements should remain voluntary and independently negotiated between manufacturers and public and private payers. More generally even beyond GLP-1s, innovative contracting arrangements provide flexible approaches to pay for, and expand access to, a range of therapies for a variety of patient populations. ***To advance the objectives outlined in this RFI, the Committee should explore policy actions to reduce regulatory barriers to market-based negotiations that can limit wider adoption of innovative contracting arrangements.***

- For example, while CMS granted biopharmaceutical companies some flexibility for certain innovative contracts in a 2020 rule,[74] biopharmaceutical companies must still adhere to a complex set of government price-reporting rules for calculating Best Price and AMP in Medicaid. To help incentivize the uptake of these contracts as a market-based solution, the Committee could explore exemptions from government price reporting requirements.
- Additionally, despite the potential benefits of innovative contracting arrangements, uncertainty regarding the Federal Anti-Kickback Statute (AKS) may be chilling more widespread adoption. The AKS is a broadly worded statute enacted several decades ago that can inadvertently discourage beneficial low-risk health care arrangements through the threat of civil, criminal, and/or administrative sanctions. As such, the Committee should explore options—such as those discussed in the Medicaid VBPs for Patients Act—that would more clearly protect these contracts by acknowledging that innovative contracts can be protected under AKS.

Addressing Launch Prices

The Committee has also expressed interest in exploring payment models to address "high launch prices," noting that median annual list prices for new drugs in the United States have doubled in recent years. However, it is important to note that the Committee's statements warrant important context. Most analyses of list prices and launch prices fail to adjust for the types of medicines used, or the fact that many new medicines treat very small patient populations. As one drug pricing expert described this approach: "This method wildly overstates average prices, by overweighting costly new drugs that treat ultra-rare conditions. It's like creating a consumer price index that averages the prices of a banana, a TV and a Rolls Royce."[75] Recent IQVIA data confirm that median annual launch prices for medicines used across broad patient populations have been effectively flat for the past five years.[76] Further, when weighted by market share, average list price growth for brand medicines was negative in 2026.[77]

Section II: Enhancing Prescription Drug Affordability

PhRMA appreciates and shares the Committee's interest in finding solutions to ensure patients can access and afford the medicines they need. A strong, stable Part D market, including adequate choice among standalone Part D plans, is critical to ensuring seniors and people with disabilities can find and afford appropriate coverage. However, coverage is not an accurate predictor of actual patient access, and too

[74] 85 Fed. Reg. 8700, Dec. 31, 2020
[75] Drug Channels. (June 2022). A New JAMA Study Misleads About Drug Prices—And Launches a New Attack on Patients with Ultra-Rare Diseases. Available at: https://www.drugchannels.net/2022/06/a-new-jama-study-misleads-about-drug.html
[76] IQVIA. (April 2026). U.S. Medicine Use Trends Report. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/us-medicine-use-trends-2026
[77] 46brooklyn. (January 2026). 2026 drug pricing reload: Out with the old, in with the new. Available at: https://dev-46brooklyn.squarespace.com/news/2025-year-in-review-and-2026-early-look-n84h9t

often insurers and PBMs create barriers through unnecessarily burdensome utilization management requirements and formulary designs that may result in beneficiaries having to pay a significant or even the full cost out of pocket to obtain their medicine. PBMs also typically base coinsurance on the list price rather than the net price, meaning rebates paid by manufacturers are not going to benefit patients directly. We offer a range of considerations for the Committee that would hold insurers accountable for delays and denials of care, address growing consolidation and help ensure patients can access available savings in the market.

First, we encourage the Committee to look closely at opportunities to ensure that policies and programs are benefiting the populations they are intended to serve. For example, in this section, we point to considerable evidence that the Medicare Prescription Payment Plan and low-income subsidy are not realizing their full potential to increase beneficiaries' affordable access to medicines, and we offer specific policy suggestions to improve their administration and uptake. Additionally, we provide options to enable patients, employers and plan sponsors to access and fully benefit from lower available prices in the market, whether through novel direct contracting arrangements between manufacturers and employers or plan sponsors, or through alternative mechanisms through which a patient may choose to access their medicine, such as direct purchase program (DPPs).

Further, we encourage the Committee to explore a range of policies addressing the impact of vertical integration and PBM practices. Today, PBMs and their affiliated entities exercise substantial control over formulary development, benefit design, pharmacy reimbursement and cost-sharing structures that directly affect patients' out-of-pocket obligations and access to medicines. These entities may use this control in ways that increase their own revenues while raising costs or limiting access for plan sponsors and patients. In this section, we offer a series of recommendations to address payers' misaligned incentives stemming from vertical integration and to help ensure that the best treatments reach providers and patients, rather than being sidelined by PBMs, consolidated 340B covered entities and other affiliated entities whose financial interests may not align with patient care.

Below we explore the Committee's proposals and inquiries and provide considerations for Committee action to address the root cause of patients' barriers to care.

Out-of-Pocket Caps

Since the enactment of the Medicare Prescription Drug Improvement and Modernization Act of 2003 two decades ago, the number of medicines available to Part D beneficiaries has grown substantially, broadening treatment options across a range of illnesses. By providing affordable access to medicines that treat serious diseases and chronic conditions, Medicare Part D has also been shown to reduce other health care spending.[78]

PhRMA has long advocated for requiring PBMs and health plans to share the savings they receive on medicines from rebates, discounts and other price concessions directly with patients at the pharmacy counter. As discussed in the section below regarding how coinsurance and deductibles shift undiscounted drug prices to patients, policies are needed to ensure patients directly benefit from the significant rebates and discounts available to health plans and PBMs. Passing through rebate savings at the point-of-sale would achieve this goal, particularly for patients taking highly rebated medicines for chronic conditions.

[78] Congressional Budget Office. (November 2012). Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services. Available at: https://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf

The implementation of the Part D maximum out-of-pocket limit (MOOP) has been transformative for patient affordability and is already associated with improved access to medicines.

- For example, one recent study found an increase in oral cancer medication fill rates following Part D cost-sharing changes in 2024.[79]
- By contrast, recent analysis suggests that price setting has had a limited impact on out-of-pocket spending. In 2026, 93 percent of beneficiaries are not expected to see lower out-of-pocket costs from price setting, and among those who do, nearly 50 percent already have their spending capped by the MOOP.[80] In these cases, the MOOP provides greater financial protection, as beneficiaries reach the same spending cap regardless of the government-set price.
- More broadly, the majority of Part D beneficiaries experience relatively low out-of-pocket costs for their covered medicines: a recent analysis found that nearly 72 percent of non-low-income Part D beneficiaries not enrolled in employer plans had average out-of-pocket costs of less than $120 annually—or just $10 per month.[81]

In addition to the MOOP, the IRA also created an important new program to support affordability in Part D: the Medicare Prescription Payment Plan (MPPP or "smoothing"). This program allows beneficiaries to "smooth" the cost of their medications across the plan year instead of paying all at once at the pharmacy counter. When combined with the $2,100 annual out-of-pocket cap in Medicare Part D, the MPPP presents a significant opportunity to improve drug affordability for some of the sickest and most vulnerable beneficiaries, particularly those managing multiple chronic and high-cost conditions.

Unfortunately, to date, too few beneficiaries are taking advantage of this important program. In 2025, adoption of the MPPP was lower than expected, limiting the reach of this opportunity to help beneficiaries.

- Data from early 2025 showed that in the initial months, only 0.4 percent of beneficiaries had enrolled in the program.[82]
- That rate had not appreciably improved by the end of 2025, when only one percent of non-low-income subsidy (non-LIS), non-employer-group waiver plan (EGWP) Part D beneficiaries filled a claim using MPPP.[83]
- Further, of the roughly 5.4 million beneficiaries who reached the MOOP in 2025 and therefore would likely benefit from MPPP, only 3.8 percent were enrolled.[84]
- This represents a small fraction of the beneficiaries CMS initially estimated could benefit from the program,[85] a gap that may reflect a lack of beneficiary awareness and understanding of this beneficial, but complex, offering.

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[79] Lin J.K. et al. (2026). Specialty Oral Anticancer Prescription Fill Rates After Medicare Part D Cost-Sharing Changes in 2024. *JAMA*. Available at: https://pubmed.ncbi.nlm.nih.gov/41460645/
[80] Milliman. (August 2026). Assessing the Beneficiary Out-of-Pocket Impact of the MDPNP. Available at: https://www.milliman.com/en/insight/assessing-beneficiary-out-of-pocket-impact-mdpnp
[81] Avalere. (July 2026). New Analysis Highlights Opportunities to Improve MPPP Uptake. Available at: https://advisory.avalerehealth.com/insights/new-analysis-highlights-opportunities-to-improve-mppp-uptake
[82] Milliman. (April 2025). MedIntel Insights: Early look at Medicare Prescription Payment Plan enrollment. Available at: https://www.milliman.com/en/insight/medintel-insights-early-look-m3p-enrollment
[83] Avalere. (July 2026). New Analysis Highlights Opportunities to Improve MPPP Uptake. Available at: https://advisory.avalerehealth.com/insights/new-analysis-highlights-opportunities-to-improve-mppp-uptake
[84] *Ibid*.
[85] Milliman (April 2025). MedIntel Insights: Early look at Medicare Prescription Payment Plan enrollment. Available at: https://www.milliman.com/en/insight/medintel-insights-early-look-m3p-enrollment

To ensure patients are able to utilize this program to improve medication affordability and access, we recommend the Committee re-imagine this program in several ways. These solutions address three primary challenges with the current program: 1) plans are not incentivized or required to adequately engage with or enroll beneficiaries in the program; 2) many beneficiaries are unaware of the program or do not enroll, even when it would clearly benefit them; and 3) the formula is unduly complex.

First and foremost, the Committee should remove Part D plan sponsors from the process of smoothing and change the program to be administered centrally, through a single contractor. Currently, the program is administered by individual Part D plan sponsors, and beneficiaries must actively enroll by contacting their plan. In part, because plans are responsible for the bad debt associated with beneficiary non-payment of expenses, they have limited incentives to proactively identify, educate and enroll beneficiaries. A 2025 survey from the Partnership to Fight Chronic Disease found that nearly 75 percent of seniors said they had heard little to no information about the program.[86] By administering the program centrally, CMS could leverage their single website (Medicare.gov) and toll-free number (1-800-MEDICARE) for enrollment, which would ease beneficiary confusion and allow other stakeholders such as providers to easily direct their patients to a single point of entry. CMS could also incorporate smoothing enrollment election into the Medicare Plan Finder experience by creating a seamless mechanism to enroll in both a Part D plan and smoothing, particularly for beneficiaries who identify they take medicines for which the out-of-pocket cost likely exceeds the catastrophic threshold.

Central administration of smoothing could also increase the value and uptake of the program. Rather than receiving bills in the mail, beneficiaries could elect to have smoothed payments deducted directly from their Social Security benefits, similar to the current process for Part B and Part D plan premiums. This would likely reduce the potential for delinquency. Additionally, the current smoothing program is of little value to beneficiaries with new, high out-of-pocket expenses in the latter half of the year because it is confined to the plan year. For example, a beneficiary who faces a new $2,100 expense in November only has the option to smooth those costs over two months. If administered outside of the plan mechanism, beneficiaries could instead elect to smooth their costs over a rolling 12-month period.

In re-imagining the smoothing program, the Committee should also consider the lessons from the LIS program, in which the majority of beneficiaries are enrolled through "deeming" due to their Medicaid status,[87] and consider auto-enrollment, with the option to opt-out, for beneficiaries who are nearly certain to benefit. Currently, beneficiaries must initially elect into smoothing and must re-elect if they change plans. Recent analysis from Avalere Health identified several groups of beneficiaries likely to benefit from auto-enrollment or more effective targeted outreach:

- More than 2.6 million beneficiaries who reached the catastrophic threshold in 2025 also had high out-of-pocket spending in the prior year.[88] This suggests there is a high level of consistency among higher-spending beneficiaries, and that prior year spending could be a strong predictor of the following year for the purposes of auto-enrollment. Despite their high out-of-pocket spending

[86] Partnership to Fight Chronic Disease. (April 2025). New Poll: Majority of Seniors with Medicare Prescription Drug Coverage Remain Unaware of New Payment Options. Available at: https://www.fightchronicdisease.org/post/new-poll-majority-of-seniors-with-medicare-prescription-drug-coverage-remain-unaware-of-new-payment
[87] Loh, F. E. et al. (2025). How lack of subsidized prescription drug coverage affects medication use by low-income Medicare beneficiaries. *Health Affairs Scholar.* Available at: https://doi.org/10.1093/haschl/qxaf186
[88] Avalere. (July 2026). New Analysis Highlights Opportunities to Improve MPPP Uptake. Available at: https://advisory.avalerehealth.com/insights/new-analysis-highlights-opportunities-to-improve-mppp-uptake

two years in a row, just 70,000 (less than 3 percent) of these beneficiaries enrolled in smoothing in 2025.[89]

- More than 1.4 million beneficiaries filled a single prescription in the first quarter of 2025 that either moved them directly from the deductible phase to the catastrophic phase or generated out-of-pocket costs of $600 or more.[90] Under the current MPPP, these beneficiaries should have received a "Likely to Benefit" Notice at the pharmacy. Despite this, among these beneficiaries, fewer than 6 percent (approximately 81,000) enrolled in the program when the high-cost prescription was filled.[91]

In conjunction with the recommendation to sever smoothing enrollment from Part D plan sponsors, we also offer several policies to improve medication affordability by strengthening this program. Currently, the calculation used for MPPP involves a first month calculation and subsequent month cap calculation. The formula involves a patient's out-of-pocket incurred costs and requires monthly summation. ***Instead, the Committee could replace the current formula by simply calculating the annual maximum out-of-pocket divided by the number of months remaining in the plan year at the time of enrollment***.

A significant gap in MPPP's implementation is an efficient and low-effort option for beneficiaries to elect MPPP at the point-of-sale. Beneficiaries, once educated on the potential benefits of MPPP, should be able to easily enroll and avoid one-time high out-of-pocket costs that could otherwise lead them to abandon their prescriptions. While we understand that CMS has identified certain technological and operational challenges, these should not be viewed as barriers but rather as a call to action. ***We encourage the Committee to mandate that CMS begin working with relevant stakeholders to lay the groundwork for a fully functional point-of-sale election pathway that supports timely and seamless beneficiary access to the MPPP no later than CY 2028***.

As the program currently exists, there are limited incentives for plans to proactively identify and enroll beneficiaries. ***The Committee may consider policy options to incentivize plans to assist Part D beneficiaries, such as by either creating plan incentives or penalties for high or lower than expected enrollment***.

Given the importance of the program and the strikingly low Part D beneficiary enrollment, Congress should recognize that CMS' policy of deferring to plan sponsors to "accurately convey" program information is not working. PhRMA previously recommended that CMS require plan sponsors to include a notification about the MPPP program on the plan's home page, linking to more detailed information and any CMS-developed tools to illustrate potential beneficiary out-of-pocket costs, such as a real-time calculator. ***We now urge the Committee to require CMS to engage more directly in beneficiary outreach and education (for example, by including information about the program prominently on Medicare Plan Finder), hold plans accountable for their educational efforts (potentially including "Secret Shopper" oversight) and monitor and publicly report on enrollment at a plan-level on a regular basis***.

The Committee also states that it is exploring options to introduce an out-of-pocket cap in Medicare Parts A and B. PhRMA appreciates the Committee's recognition that many Medicare beneficiaries continue to face significant out-of-pocket costs for needed care. While the vast majority of FFS Medicare beneficiaries have supplemental coverage (such as a Medigap plan) that limits their exposure to Part B cost sharing, approximately ten percent of these beneficiaries do not have supplemental coverage and therefore remain exposed to coinsurance obligations on Part B drugs and services. And even for

[89] *Ibid.*
[90] *Ibid.*
[91] *Ibid.*

beneficiaries that have supplemental insurance, premiums can represent a significant financial commitment. As Congress considers opportunities to strengthen Medicare, it is appropriate to examine whether there are targeted approaches to reduce cost-sharing exposure for beneficiaries who remain financially vulnerable.

As the Committee evaluates potential policy options, it should also recognize that affordability considerations extend beyond traditional Medicare. Medicare Advantage beneficiaries generally do not have supplemental insurance and may face significant cost-sharing obligations for Part B medicines before reaching the $9,250 maximum out-of-pocket limit. Any effort to improve beneficiary affordability should therefore take a comprehensive view of cost sharing across the Medicare program, rather than focusing exclusively on one delivery system or one policy mechanism. At the same time, policymakers should carefully consider the fiscal implications of any proposal. Congress should prioritize balanced approaches that improve financial protections for beneficiaries, strengthen the stability of Medicare coverage options, including the Part D market, and avoid unintended consequences for patient access.

Improvements to Medicare Low-Income Assistance Programs

The LIS program helps nearly 13 million Part D beneficiaries afford their prescription drug coverage and remains a vital source of financial assistance. However, underutilization of the LIS program has been a persistent challenge since its inception in 2006. Roughly 25 percent, or more than 5 million, beneficiaries eligible for the LIS are not enrolled.[92] Although the IRA expanded access to full LIS benefits for all LIS enrollees, it did not address low participation rates. Low enrollment, particularly among those who must apply rather than being automatically enrolled, has frequently been attributed to a lack of awareness about the program, difficulties navigating the application process and administrative burden associated with income verification.[93]

Further, the number of premium-free standalone drug plans available to LIS beneficiaries has fallen more than 50 percent since the IRA was enacted, to a low of 88 options nationwide in 2026.[94,95] In 21 states and Washington, D.C., LIS beneficiaries have two or fewer benchmark plans to select from.[96] Medicare beneficiaries who lose LIS benefits are likely to face challenges in accessing their medicines as they encounter higher premiums for Part D coverage and higher out-of-pocket costs, which may result in adverse health outcomes and increased mortality.[97] A recent study found that in 2019, Part D beneficiaries eligible but not enrolled in the LIS filled 39 percent fewer prescriptions and were 1.4 times more likely to report cost-related nonadherence than those receiving the LIS.[98] We discuss options to maintain access to premium-free standalone plans in the section focused on Part D market stabilization.

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[92] Loh F.E. et al. (March 2024). Medicare Part D low-income subsidies expanded in January 2024, but more needs to be done to ensure that eligible beneficiaries enroll. *J Manag Care Spec Pharm*. Available at: https://pubmed.ncbi.nlm.nih.gov/38324387/ ; and Loh, F. E. et al. (October 2025). How lack of subsidized prescription drug coverage affects medication use by low-income Medicare beneficiaries. *Health Affairs Scholar*. Available at: https://doi.org/10.1093/haschl/qxaf186

[93] Roberts E.T. et al. (September 2021). The relationship between take-up of prescription drug subsidies and Medicaid among low-income Medicare beneficiaries. *J Gen Intern Med*. Available at: https://pubmed.ncbi.nlm.nih.gov/32959349/

[94] Avalere Health. (October 2025). Part D Choices Continue to Shrink with Fewer PDPs in 2026. Available at: https://advisory.avalerehealth.com/insights/part-d-choices-continue-to-shrink-with-fewer-pdps-in-2026.

[95] KFF. (October 2025). A Current Snapshot of the Medicare Part D Prescription Drug Benefit. Available at: https://www.kff.org/medicare/a-current-snapshot-of-the-medicare-part-d-prescription-drug-benefit/

[96] *Ibid.*

[97] Brownstein M. (May 2025). Loss of Medicare Part D subsidy linked to higher mortality among low-income older adults. Available at: https://hsph.harvard.edu/news/loss-of-medicare-part-d-subsidy-linked-to-higher-mortality-among-low-income-older-adults/

[98] Loh F.E. et al. (2025). How lack of subsidized prescription drug coverage affects medication use by low-income Medicare beneficiaries. *Health Affairs Scholar.* Available at: https://doi.org/10.1093/haschl/qxaf186

To ensure beneficiaries gain the full value of this program, CMS could consider options such as targeted outreach to LIS beneficiaries who are enrolled in plans where they pay premiums to ensure they know about the availability of premium-free options; incentives for brokers to help LIS-eligible beneficiaries access the subsidy; and improved messaging on Medicare.gov and Plan Finder for beneficiaries to elect to receive personal outreach and more information.

PhRMA strongly supports medication affordability in Part D. ***To close remaining gaps in affordability, we urge the Committee to build on their prior successes and ensure beneficiaries can access the existing programs for which they are eligible, including smoothing and the low-income subsidy.***

Distortions in Coinsurance & Deductibles

Manufacturer rebates can reduce the cost of medicines for insurers and PBMs by 50 percent or more,[99] but these savings rarely make their way directly to patients at the pharmacy counter. Instead, PBMs and insurers typically require patients with deductibles and coinsurance, who pay a percentage of the cost of their medicine rather than a fixed copayment, to pay based on the undiscounted list price, rather than the discounted net price paid by the PBM. Notably, the pharmacy benefit is the only major benefit category where this is the case. In the medical benefit, patient cost sharing is typically based on the negotiated rate, even when a patient is in their deductible or paying coinsurance. This practice can result in patients paying more for their medicines than the PBM or plan did.

- The Government Accountability Office (GAO) found that for 79 of the top 100 highly rebated medicines in Medicare Part D, the total costs to beneficiaries exceeded the total net costs to plan sponsors by nearly 400 percent ($21 billion vs. $5.3 billion).[100]
- In the commercial market, two-thirds of patients taking brand medicines fill prescriptions in the deductible or with coinsurance, based on the undiscounted list price. These prescriptions represent a disproportionate share (60 percent) of total patient spending on brand medicines.[101]
- Furthermore, more than 80 million Americans are in high-deductible plans that force them to pay the full list price of the medicine, even when their PBM or insurer is receiving a steep discount.[102,103]

PhRMA has long highlighted problematic PBM business practices and conflicts of interest that distort market competition and drive up costs for patients, employers, and taxpayers, and we applaud policymakers' recent actions to begin reining in PBMs' abusive and anticompetitive behaviors, including the bipartisan passage of federal legislation to delink PBM compensation from list prices in Medicare Part D and require PBMs and affiliates to pass through all rebates and discounts to plan sponsors in the private market.[104]

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[99] MedPAC. (July 2026). A Data Book: Health care spending and the Medicare Program. Available at https://www.medpac.gov/wp-content/uploads/2026/07/July2026_MedPAC_DataBook_SEC.pdf.
[100] GAO. (September 2023). Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending. Available at: https://www.gao.gov/assets/gao-23-105270.pdf
[101] PhRMA. (November 2022). Deductibles and Coinsurance Drive High Out-Of-Pocket Costs for Commercially Insured Patients Taking Brand Medicines. Available at: https://phrma.org/resources/deductibles-and-coinsurance-drive-high-out-of-pocket-costs-for-commercially-insured-patients-taking-brand-medicines
[102] CDC. (June 2025). Health Insurance Coverage: Early Release of Estimates From the National Health Interview Survey, 2024. Available at: https://www.cdc.gov/nchs/data/nhis/earlyrelease/insur202506.pdf
[103] CDC. (December 2024). Enrollment in High-deductible Health Plans Among People Younger Than Age 65 With Private Health Insurance: United States, 2019–2023. Available at: https://www.cdc.gov/nchs/data/nhsr/nhsr214.pdf
[104] H.R.7148 - Consolidated Appropriations Act, 2026. (February 2026). Available at: https://www.congress.gov/bill/119th-congress/house-bill/7148/text

To further address problematic PBM incentives and business practices, PhRMA supports ensuring that patients fully benefit from rebates at the pharmacy counter across Part D and the commercial market. This is particularly critical in the deductible and when patients face coinsurance instead of fixed copays.

Rather than ensuring patients have rapid access to generics, biosimilars and lower price therapies, PBMs increasingly deny or restrict coverage for these medicines.[105,106] A recent analysis shows how extensively the big three PBMs have excluded low-cost generics and biosimilars from commercial formularies in recent years. The study found a 900 percent increase in generic exclusions since 2014 and a 164 percent increase in biosimilars excluded from at least one of the big three PBMs' formularies since 2022, when several biosimilar medicines entered the market.[107]

In addition, and as noted in the RFI, the Health and Human Services (HHS) Office of Inspector General (OIG) has observed that PBMs may be incentivized to penalize manufacturers for reducing list prices, including removing medicines from the formulary or placing them on a less-preferred formulary tier.[108] Other experts have argued that it would be difficult or impossible for manufacturers to lower list prices without adverse consequences because "cutting the list price means wholesalers make less money, pharmacies make less money, PBMs make less money and payers get fewer rebate dollars."[109]

When PBM revenue is tied to drug prices through percentage-based fees and rebates, PBMs profit from higher drug prices while shifting costs to patients at the pharmacy counter. Instead of deriving revenue as a percentage of list prices, PBM fees should be flat, fixed and reflect the fair market value of the services they provide.

To further address problematic PBM incentives and business practices while ensuring that patients fully benefit from rebates at the pharmacy counter across markets, ***PhRMA urges the Senate Finance Committee to work with other committees of jurisdiction to extend the policy enacted under the 2026 Consolidated Appropriations Act (CAA) that eliminates this list price-based compensation in Medicare Part D to the commercial market***.

Direct Purchase Programs

In addition to problematic incentives that can distort patient cost sharing and limit patient access to lower-cost therapies, insurers and PBMs may also create barriers to timely patient access to medically necessary treatments through the expanded use of formulary exclusions, prior authorization, embedded step therapy (in which payers impose opaque treatment-sequence requirements through ostensible prior authorization criteria)[110] and coinsurance-based cost sharing for covered drugs. These utilization management practices are frequently justified on patient safety grounds, but patient safety in prescribing and dispensing is already facilitated through other checks in the system, including prescriber clinical judgment, pharmacist review and Risk Evaluation and Mitigation Strategies (REMS) programs. Instead, insurer and PBM-

[105] Association for Accessible Medicines. (September 2025). 2025 U.S. Generic & Biosimilar Medicines Savings Report. Available at: https://accessiblemeds.org/resources/reports/2025-savings-report/
[106] Biosimilars Council. (January 2024). Humira Biosimilar Landscape: Still Waiting. Available at: https://biosimilarscouncil.org/resource/humira-biosimilar-landscape-still-waiting.
[107] Cencora. (July 2025). Persistent growth in PBM formulary exclusions continues to raise concerns about patient access. Available at: https://cdn.aglty.io/phrma/global/resources/import/pdfs/Report%20-%20Persistent%20Growth%20in%20PBM%20Formulary%20-%20August%202025.pdf.
[108] 84 Fed. Reg. 2341 (February 2019)
[109] Johnson C. (June 2018). In May, Trump predicted the pharmaceutical industry would cut prices in two weeks. It hasn't happened yet. *The Washington Post.* Available at: https://www.washingtonpost.com/news/wonk/wp/2018/06/25/in-may-trump-predicted-the-pharmaceutical-industry-would-start-cutting-prices-in-two-weeks-its-been-three/.
[110] Avalere Health Advisory. (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

imposed utilization management functions primarily as a cost and utilization-control tool rather than a safety check.[111]

In light of the cost and access barriers described above, some companies, including PhRMA members, have developed direct purchase programs (DPPs), which can make it easier for patients to buy medicines directly from manufacturers at lower costs, without barriers or hidden markups.[112] DPPs provide patients with additional avenues to access their medicines when met with barriers imposed by payers to physician-recommended care. Despite the greater choice DPPs offer, patients may be penalized for choosing the pathway that best meets their needs, as plans generally do not count patient DPP spending toward a patient's deductible or annual cost sharing limit. ***PhRMA recommends the Committee explore a series of policy approaches to recognize DPPs and enable patients to realize lower costs.***

First, to improve and preserve patient access to medicines available via DPPs, the Committee should clarify that a medication's inclusion in a DPP cannot be used to justify narrowing covered benefits or shifting additional costs onto patients. Without this guardrail, insurers could have an incentive to respond to DPPs by dropping those medicines from formularies, moving them to higher cost-sharing tiers or otherwise scaling back coverage through reasoning that patients can simply purchase the medicine directly instead. That outcome would convert DPPs from a supplement to insurance into a substitute for it, undermining the comprehensive coverage for which patients pay premiums.

Second, and working in tandem with the clarification above, the Committee should require that DPP purchases of covered medicines count toward a patient's benefit progression, including deductibles and maximum out-of-pocket amounts. This can ensure that patients are not penalized with uncapped out-of-pocket costs simply because they obtained a covered medicine outside the insurer's preferred distribution channel. These two policies should be adopted together, as each addresses a gap the other would otherwise leave open. Requiring DPP spending to count toward benefit progression gives plans a greater financial stake in those purchases, which could otherwise incentivize plans to drop DPP-available medicines from formularies or narrow coverage. The guardrail described above closes that gap by prohibiting plans from making coverage decisions on that basis, ensuring plans cannot evade the benefit-progression requirement by hollowing out the underlying coverage instead.

Third, the Committee should consider mechanisms to adjust patient cost sharing based on lower prices publicly available in the market, such as those offered through DPPs. Under this approach, a plan would be required to use a publicly available price for a covered medicine, such as a manufacturer's DPP, when calculating a patient's cost sharing. There are several operational mechanisms to consider for this approach. For instance, a patient could identify a lower price available for their covered drug through a manufacturer DPP and flag it for their plan or PBM at the point-of-sale, requiring the insurer or PBM to adjust patient cost sharing. Alternatively, there could be options to require insurers and PBMs to apply these prices automatically where pricing information is reasonably accessible to them. These approaches can help ensure that no patient pays more out of pocket than a price already available to the public, create a backstop for situations where plan-negotiated cost sharing fails to reflect the lowest available price and put competitive pressure on plans and PBMs to keep their cost-sharing calculations current.

Part D Market Impact

[111] American Medical Association. (2025). 2025 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

[112] PhRMA. (September 2025). PhRMA Announces Major Actions as Part of Industry's Commitment to American Patients and Workers. Available at: https://phrma.org/resources/phrma-announces-major-actions-as-part-of-industry-s-commitment-to-american-patients-and-workers.

PhRMA appreciates the Committee's recognition of the importance of balancing the inherent tradeoffs in reducing beneficiaries' out-of-pocket costs and improving access with maintaining affordable premiums and preserving a sufficient range of plan options to meet beneficiaries' needs. In particular, the standalone PDP market faces substantial challenges, with significant plan withdrawals and premium increases over the past several years.[113] The IRA's premium stabilization provisions were insufficient to address the growing gap in premiums between Medicare Advantage prescription drug plans (MA-PDs) and standalone PDPs, and the Part D Premium Stabilization Demonstration provided a temporary stopgap rather than a sustainable policy solution. While CMS recently announced they would not continue the demonstration, the impact on 2027 premiums and plan availability is not yet clear. The number of PDPs has continued to fall, and one analysis suggests that enrollment-weighted average PDP premiums for beneficiaries who do not receive the LIS increased by 32 percent among plans offered in both 2025 and 2026.[114] When plan choices diminish and premiums rise, beneficiaries enrolled in PDPs may experience increased financial strain and have difficulty finding coverage that meets their specific prescription needs. Despite growing MA-PD enrollment, a strong PDP market is essential to ensure beneficiaries still have access to traditional Medicare with Part D coverage, and PDPs are crucial for beneficiaries receiving the LIS as well as seniors living in rural areas, who are more likely to remain in traditional Medicare.[115]

As the Committee pursues policies to strengthen the stability of the standalone PDP program and promote efficiency and stability in the Part D program, it also must protect beneficiary access to choice of medicines and address barriers to clinically appropriate care. Below, PhRMA provides specific recommendations intended to strengthen the Part D program through improved risk adjustment accuracy, improved payment accuracy and better access to LIS benchmark plans.

Improve Risk Adjustment Accuracy

Risk adjustment is an important tool to avoid adverse selection in the Part D program by adjusting plan payments based on whether a specific enrolled individual is higher or lower risk than the average Part D beneficiary. Part D redesign increased liability for plan sponsors in the catastrophic phase, thus making premium payments, the direct subsidy and the accuracy of risk adjustment applied to the direct subsidy, increasingly significant. The current Prescription Drug Hierarchical Condition Category (RxHCC) model's tendency to underpredict costs for PDP beneficiaries and to overpredict those of MA-PD beneficiaries is just one of several factors that continue to put pressure on the PDP market and contribute to disruption. As MedPAC has observed, PDPs on average have lower risk scores but higher gross costs than their MA-PD counterparts.[116] This has contributed to year-over-year declines in available PDP options: between 2025 and 2026, the number of PDPs decreased from 464 to 360, a decrease of 22 percent, following a 35 percent decrease in plan offerings between 2024 and 2025.[117]

[113] KFF (2025). The Uncertain Future of Medicare's Stand-Alone Prescription Drug Plan Market and Why it Matters. Available at: https://www.kff.org/medicare/the-uncertain-future-of-medicares-stand-alone-prescription-drug-plan-market-and-why-it-matters/
[114] Avalere Health. (October 2025). Part D Choices Continue to Shrink with Fewer PDPs in 2026. Available at: https://advisory.avalerehealth.com/insights/part-d-choices-continue-to-shrink-with-fewer-pdps-in-2026
[115] KFF. (July 2025). Medicare Advantage Enrollment Update and Key Trends. Available at: https://www.kff.org/medicare/medicare-advantage-enrollment-update-and-key-trends/
[116] MedPAC. (April 2025). Structural Differences Between the Part D PDP and MA-PD Markets. Available at: https://www.medpac.gov/wp-content/uploads/2025/04/Tab-D-Structural-issues-in-Part-D-April-2025.pdf
[117] Collin D., Hamilton J., Klaisner J. (October 2025). Continued concentration and sustained stabilization: A 2026 Medicare prescription drug plan market overview. *Milliman*. https://www.milliman.com/en/insight/concentration-stabilization-medicare-pdp-2026

One widely identified concern with the current risk adjustment model is the ongoing data lag. The 2026 RxHCC model is calibrated using 2022 medical diagnoses and 2023 prescription drug costs, but plans are paid in 2026 based on enrollees' 2025 medical diagnoses.[118] This means the current risk adjustment model is calibrated with pre-IRA data, despite the post-IRA market reality, which has seen changes in utilization rates for different populations and among different drug types.[119,120] ***The Committee could consider pursuing policies addressing this data lag and other shortcomings in the underlying structure of the RxHCC model that may lead to inaccuracies in predicting plan costs, including the current use of medical diagnosis codes to adjust spending rather than actual prescription drug utilization.***

The significant data lag in the RxHCC model calibration leads to discrepancies in risk model coefficients relative to expected plan costs. Under CMS' methodologies, 2026 utilization of selected drugs would not appear in the RxHCC model until 2029, yet CMS has adjusted the 2027 RxHCC model to incorporate 2026 MFP pricing.[121] However, this change addresses pricing only and does not fully capture changes in utilization patterns or beneficiary behavior resulting from the significant changes introduced by the IRA. CMS ordinarily does not adjust medicine prices in the RxHCC model to account for year-over-year pricing changes that arise from other factors, such as the introduction of competing brand medicines or generics.

Another discrepancy arises from recalibrating the RxHCC model using what are effectively maximum net prices, but for selected drugs alone. For all other medicines, CMS will continue to use gross pricing. This structural difference could magnify disadvantages faced by selected drugs, and further prompt PDP sponsors to limit access to such drugs and thus discourage beneficiaries taking them from enrolling.

Ultimately, these flaws diminish the RxHCC model's predictive capability. As a result, the RxHCC model may not accurately predict costs for certain conditions, potentially leading to unintended consequences for plan decision-making. This situation can adversely affect patients, subjecting them to disruptive formulary changes or limiting their treatment options.

Improve Payment Accuracy

In recent years, CMS has implemented policies to more accurately reflect cost differentials between the MA-PD and PDP market, including implementation of separate normalization factors and separate coefficients for MA-PD and PDP plans under the risk adjustment model. While these changes have helped to mitigate the relative instability of the PDP market, certain payment parameters, such as the calculation of the national average monthly bid amount (NAMBA)—which drives the base beneficiary premium—are set in statute. Currently, statute requires that the NAMBA is calculated using both MA-PD and PDP bid data and does not include special needs plans (SNPs). Recent data from MedPAC shows that average total beneficiary premiums for PDPs are nearly ten percent higher than for MA-PDs in 2026 ($97 vs $89), prior to the reductions from the IRA base beneficiary premium growth cap and MA rebate buy-

[118] Robb, M., Rodrigues D. (September 2025). Assessment of potential enhancements to the Part D risk adjustment (RxHCC) model: Considerations for ensuring risk adjustment adequacy in an evolving Part D environment. *Milliman*. Available at: https://www.milliman.com/en/insight/potential-enhancements-part-d-rxhcc-model

[119] Duke, D., Cline, M., Liner, D. (April 2025). Early 2025 Medicare Part D claims show continued increase in non-low income specialty drug spend. *Milliman*. Available at: https://www.milliman.com/en/insight/2025-medicare-part-d-increase-specialty-drug-spend

[120] Cline, M., Madden, R., Holcomb, K. (April 2025). Part D trend insights: 2024 trend analysis reveals sharp increase in specialty drug utilization among non-low income beneficiaries. *Milliman*. Available at: https://www.milliman.com/en/insight/part-d-trend-insights-analysis-specialty-drug-utilization

[121] Haddock, N., Klein, M., Petroske, J. (November 2023). Potential IRA Interactions with Medicare Part D Risk Adjustment. *Milliman*. Available at: https://www.milliman.com/-/media/milliman/pdfs/2023-articles/11-7-23_ira-medicare-part-d-risk-adjustment.ashx

downs.[122] Additionally, the IRA capped the annual increase in the base beneficiary premium at 6 percent through 2030, but applies the cap across the entire Part D market, despite the fact that PDP premiums have increased more quickly post-IRA, in part because these plans cannot access the same rebate dollars MA-PDs use to buy down premiums.[123]

SNPs may have been excluded from the NAMBA calculation at the inception of Part D because they represented a tiny fraction of MA enrollment. However, as the program has grown and changed over the past two decades, so too has SNP enrollment. Enrollment in SNPs grew from just 1.3 million beneficiaries in 2010 to 8.2 million in 2026.[124] Further, SNP enrollment accounted for 85 percent of the net increase in Medicare Advantage enrollment from 2025 to 2026.[125]

The Committee could consider several changes to MA and Part D payment methodologies to more accurately reflect the underlying costs between the two programs and further stabilize the PDP market. Potential reforms could include requiring the NAMBA to be calculated separately for MA-PDs and PDPs; including SNPs in the NAMBA calculation; adjusting the IRA base beneficiary premium cap to apply the 6 percent limit separately for MA-PD and PDP premium; requiring plan sponsors offering MA-PDs to offer at least one PDP in each region; and exploring opportunities for PDPs to access funds to mitigate liability to create parity with MA-PD rebate dollars, such as creating explicit links between FFS accountable care organization savings and PDP stabilization.

Due to the complexity and size of the Part D program, the Committee must carefully consider the intended and unintended consequences of all payment changes. PhRMA looks forward to collaborating with the Committee to develop policies that reflect the current state of the market and continue to ensure that seniors and people with disabilities can rely on a robust set of plan choices that meet their affordability and health needs.

LIS Benchmark Calculations

Certain PDPs qualify as benchmarks in a region every year when their bids fall below a regional threshold. These plans offer premium-free coverage to beneficiaries who receive the LIS and can receive enrollment through auto-assignment. Because both MA-PD and PDP bids are used to calculate the LIS benchmark, but only PDPs are designated as benchmark plans, lower MA-PD bids relative to PDP bids can drive down the LIS benchmark, making it more difficult for PDPs to qualify as LIS benchmark plans. This reduction in plan choice could force LIS beneficiaries into plans that do not meet their needs, either by not covering their medicines or by imposing new utilization management requirements. ***The Committee could consider policies, such as only using PDP bids to calculate LIS benchmarks to improve access to LIS plans across regions and address how the Part D market has evolved between PDPs and MA-PDs.***

"Games & Abuses Due To Vertical Integration"

PhRMA shares the Committee's concerns regarding the impact of vertical integration across the prescription drug supply chain and challenges associated with insurer compliance with Medical Loss Ratio (MLR) requirements. After years of aggressive consolidation and integration, a small number of

[122] MedPAC (January 2026). The Medicare prescription drug program (Part D): Status Report. Available at: https://www.medpac.gov/wp-content/uploads/2025/08/Tab-L-Part-D-status-report-Jan-2026.pdf
[123] *Ibid.*
[124] KFF. (June 2026). Medicare Advantage in 2026: Enrollment Update and Key Trends. Available at: https://www.kff.org/medicare/medicare-advantage-in-2026-enrollment-update-and-key-trends/
[125] *Ibid.*

corporate giants now wield outsized influence and control over health care decisions that impact patients. This extensive consolidation has substantial implications for patients' access, choice and affordability; costs borne by payers, taxpayers and the broader health care system; and the stability of the competitive market.

There are more than 70 PBMs in operation, yet just three of them (CVS Caremark, Express Scripts and OptumRx) control 80 percent of prescriptions dispensed in the United States.[126] These same companies are vertically integrated with the three largest health insurance companies: Aetna, Cigna and UnitedHealthcare, respectively.[127] Each also owns a specialty and mail order pharmacy, and has built a growing presence in care delivery through the acquisition of provider groups.[128] CVS also owns the largest retail-chain pharmacy in America. According to a 2024 Federal Trade Commission (FTC) report on PBM business practices, the parent companies of the three largest PBMs and Humana (including Humana Pharmacy Solutions) comprised 22 percent of all national health expenditures in 2023, an increase of eight percentage points since 2016.[129]

As a result, three large, vertically integrated health care conglomerates exert unprecedented control over what medicines patients have access to, what they pay out of pocket, what pharmacies they visit and the barriers and delays they may face. Additionally, as insurer consolidation with provider groups expands, these entities are increasingly positioned to influence prescribing pathways and patient referral patterns in addition to formulary and pharmacy access decisions. A recent report published by IQVIA found that:

- Patients who attempted to fill oncology and immunology prescriptions at non-PBM-affiliated pharmacies were more likely to face coverage denials. The report noted that 86 percent of oral oncology and 92 percent of immunology patients who attempted to initiate treatment with brand medicines at non-PBM-affiliated pharmacies had their prescriptions initially rejected, whereas patients who filled prescriptions in those therapeutic areas at PBM-affiliated pharmacies faced lower rejection rates (i.e., 58 percent in oncology and 71 percent in immunology).[130]
- IQVIA's report also found that patients who filled prescriptions at non-PBM-affiliated pharmacies experienced average coverage delays of 32 days for immunology and 17 days for oral oncology drugs, compared to 16 days and ten days respectively for patients filling at a pharmacy affiliated with their PBM.[131]

Pharmacy Steering

Because the big three PBMs own or are affiliated with retail, specialty and mail-order pharmacies, they have both the ability and financial incentive to direct patients toward pharmacies within their corporate

[126] FTC. (July 2024). Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies. Available at: https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.
[127] Fein A. (June 2026). The Top Pharmacy Benefit Managers of 2025: Market Share and Key Industry Developments (Rerun). *Drug Channels Institute*. Available at: https://www.drugchannels.net/2026/06/the-top-pharmacy-benefit-managers-of.html.
[128] Fein A. (April 2026). Mapping the Vertical Integration of Insurers, PBMs, GPOs, Specialty Pharmacies, and Healthcare Services: DCI's 2026 Update. *Drug Channels Institute*. Available at: https://www.drugchannels.net/2026/04/mapping-vertical-integration-of.html.
[129] Federal Trade Commission. (July 2024). Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies. Available at: https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.
[130] Ehrenberg R., Copley K., Johnson P. (March 2026). How PBMs' Vertically Affiliated Pharmacies Shape Access Pathways for Oncology and Autoimmune Patients. *IQVIA*. Available at: https://www.iqvia.com/locations/united-states/library/white-papers/how-pbms-vertically-affiliated-pharmacies-shape-access.
[131] Ehrenberg R., Copley K., Johnson P. (March 2026). How PBMs' Vertically Affiliated Pharmacies Shape Access Pathways for Oncology and Autoimmune Patients. *IQVIA*. Available at: https://www.iqvia.com/locations/united-states/library/white-papers/how-pbms-vertically-affiliated-pharmacies-shape-access.

enterprise. Patients may be subjected to network designs, reimbursement policies, utilization management requirements or other practices that effectively channel prescriptions to affiliated pharmacies, often at the expense of patient choice and independent community pharmacies. When the entity responsible for designing and administering the pharmacy benefit also owns the pharmacy receiving the prescription, the PBM can profit not only from their traditional benefit capabilities but also from dispensing the drug.[132]

Vertical integration also allows PBMs to influence competition within pharmacy networks they control. PBMs establish network participation terms and reimbursement rates and can offer affiliated pharmacies more favorable treatment than independent competitors. At the same time, PBMs may steer high-cost prescriptions to affiliated pharmacies or reimburse affiliated pharmacies at levels that increase revenue within the corporation, raising costs for plan sponsors and government programs.[133] These arrangements can place independent pharmacies at a competitive disadvantage and contribute to market consolidation.

To address these practices, PhRMA recommends the Committee explicitly prohibit pharmacy steering in the commercial and Medicare Part D markets through policies that ban required use of PBM-affiliated pharmacies and the use of more favorable cost sharing terms to patients as an inducement to use affiliated pharmacies over other in-network alternatives. Further, PhRMA recommends the Committee advance policies that enhance transparency regarding transactions with PBM-affiliated pharmacies. Looking ahead, the Committee should explore whether further structural remedies related to pharmacy ownership could address these steering challenges while limiting any disruption to patient access.

Group Purchasing Organizations (GPOs)

PBMs have created so-called Group Purchasing Organizations (PBM GPOs), also known as rebate aggregators, in the commercial market, claiming these entities provide their clients with greater bargaining power to lower costs. However, inquiries by members of Congress, industry experts, state Attorneys General and federal oversight agencies indicate the opposite may be true.[134] For example, federal audits conducted in 2024 found that Express Scripts and its PBM GPO, Ascent Health Services, overcharged two Federal Employee Health Benefits Program plans by $63 million over a 6-year period, including $26 million in rebates pocketed by Ascent that should have been passed through to the plan sponsors.[135,136] The Ohio Attorney General has also sued PBMs and PBM GPOs, alleging that these entities are engaging in anticompetitive behavior that distorts the market to their advantage and increases the cost of medicines for patients and employers.[137]

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[132] FTC. (July 2024). Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies. Available at: https://www.ftc.gov/reports/pharmacy-benefit-managers-report

[133] FTC. (January 2025). Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers. Available at: https://www.ftc.gov/reports/specialty-generic-drugs-growing-profit-center-vertically-integrated-pharmacy-benefit-managers

[134] PBM GPOs collect rebates, discounts and fees from drugmakers in exchange for favorable formulary position, and other preferential coverage in the commercial market. PBM GPOs differ from traditional GPOs that assist health care entities (e.g., hospitals, nursing homes) in aggregating purchasing volume and leveraging discounts with drug and device manufacturers, distributors and other vendors.

[135] OPM Office of the Inspector General. (March 2024). Audit of the American Postal Workers Union Health Plan's Pharmacy Operations as Administered by Express Scripts, Inc. for Contract Years 2016 through 2021. Available at: https://www.oversight.gov/sites/default/files/documents/reports/2024-10/2022-SAG-029.pdf.

[136] OPM Office of the Inspector General. (November 2024). Audit of Compass Rose Health Plan's Pharmacy Operations as Administered by Express Scripts, Inc. for Contract Years 2017 through 2022. Available at: https://www.oversight.gov/sites/default/files/documents/reports/2025-01/2023-SAG-019.pdf.

[137] The Capitol Forum. (April 2023). Healthcare Antitrust Weekly: Ohio AG Sues PBMs for Using "Rebate Aggregators" to Fix Prices; DOJ Decision Not to Litigate CVS/Signify Further Boosts Odds of Section 2 Investigation into U.S. Healthcare

PBM GPOs can also influence MLR calculations. A recent report published by Milliman noted that an insurer's MLR would increase if a PBM GPO retained a larger share of manufacturer rebates, whereas it would decrease if the PBM GPO retained fewer rebates in the commercial market.[138] Milliman's report demonstrated how this approach simultaneously can enhance the PBM GPO's revenue and profitability so that, by controlling the flow of manufacturer rebates in the commercial market, the PBM GPO can contribute to the overall financial optimization of the integrated entity without reducing the profitability of the payer.[139]

In broad terms, PBMs have vast discretion to assess fees, and other market players generally must respond to the market created by such PBMs, due to their bargaining power. Higher administrative fees and new types of fees—based on service arrangements largely dictated by the PBM—may be assessed without obvious direct benefits for patients and other stakeholders. A September 2023 report found that total PBM compensation tied to manufacturer fees doubled from $3.8 billion in 2018 to $7.6 billion in 2022 and that this growth was fueled by increases in traditional administrative fees as well as the emergence of new data and PBM GPO fees, with these new fees growing from nearly zero to more than $1.7 billion in that time period.[140] The growth of these fees coincided with increasing scrutiny around PBM rebate retention practices.

To comprehensively address the concerning practices described above that stem from PBM ownership of PBM GPOs, the Committee should ensure any entity providing PBM services does not own, control, share common ownership or hold a beneficial interest in another entity that collects, negotiates or otherwise influences price concessions for a drug.

Medical Loss Ratio (MLR)

MLR standards require health insurers to spend a minimum share of premium dollars on patient care and quality improvement activities, limiting the share of premium dollars insurers can allocate to administrative costs and profits. MLR requirements apply to the individual, small group and large group commercial insurance markets, as well as Medicare Advantage, Medicare Part D and Managed Medicaid markets.[141] Insurers that fail to meet the minimum MLR threshold for a given market must refund the difference in the form of a rebate paid to policyholders or the government.[142] The common corporate ownership of issuers and related health care businesses may permit vertically integrated corporations to game their MLR requirements. As noted in a 2024 FTC report, by vertically integrating with PBMs, pharmacies, providers and other supply chain entities, insurers have discretion over how to characterize certain transactions between affiliated entities and can shift revenues to affiliates whose profits are not

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Behemoths. Available at: https://thecapitolforum.com/healthcare-antitrust-weekly-ohio-ag-sues-pbms-for-using-rebate-aggregators-to-fix-prices-doj-decision-not-to-litigate-cvs-signify-further-boosts-odds-of-section-2-investigation-int/.

[138] Robb M., Karcher J. (February 2026). Medical Loss Ratio Requirements: Challenges Posed by Vertical Integration. *Milliman*. Available at: https://media.milliman.com/v1/media/edge/images/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/2026-Articles/2-9-26_PhRMA-MLR-Paper.pdf

[139] Robb M., Karcher J. (February 2026). Medical Loss Ratio Requirements: Challenges Posed by Vertical Integration. *Milliman*. Available at: https://media.milliman.com/v1/media/edge/images/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/2026-Articles/2-9-26_PhRMA-MLR-Paper.pdf

[140] Percher E. (September 2023). Trends in Profitability and Compensation of PBMs and PBM Contracting Entities. *Nephron Research*. Available at: https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities/.

[141] 42 C.F.R. §§ 422.2420, 423.2420.; 45 C.F.R. § 158.221. Note: self-funded plans are not subject to MLR requirements under the Affordable Care Act.

[142] Centers for Medicare and Medicaid Services. (March 2026). Medical Loss Ratio. Available at: https://www.cms.gov/marketplace/private-health-insurance/medical-loss-ratio?

subject to MLR regulation.[143] This allows insurers to effectively sidestep MLR requirements by capturing more profit at the organizational level than the insurer's MLR limit would otherwise allow.[144]

Vertically integrated insurers can manipulate MLR requirements by reimbursing their affiliated pharmacies and providers at above-market rates. These inflated payments count towards medical care spending in the insurer's MLR calculation—making it easier to meet the minimum MLR threshold—while the excess reimbursement to the affiliated pharmacy or provider generates internal profit for the vertically integrated entity.[145] In this way, MLR manipulation allows vertically integrated entities to retain revenue in circumvention of MLR requirements, without providing the clinical improvements that the MLR rule intended. This practice may also incentivize entities to steer patients toward affiliated pharmacies and providers, since doing so allows them to capture the inflated reimbursement internally. Recent research has shown that vertically integrated insurers are manipulating MLR in the Part D market by inflating prices at affiliated pharmacies. For example, one National Bureau of Economic Research paper found that:

- Following the introduction of MLR regulations, vertically integrated Part D insurers increased prices at affiliated pharmacies by 9.5 percent per claim relative to non-affiliated pharmacies.[146]
- The paper also noted that vertically integrated insurers at risk of falling below the minimum MLR requirement increased prices nearly six times more than vertically integrated insurers who were not at risk. This behavior increased gross Part D drug spending by an estimated $1.2 billion from 2014 to 2016.[147]

Studies have also shown that vertically integrated insurers that own providers reimburse them at a rate higher than their competitors, suggesting manipulation of MLR requirements.

- A recent *Health Affairs* study found that UnitedHealthcare reimburses its affiliated Optum providers at rates 17 percent higher than the relative price of its competitors, a gap that widens to 61 percent in markets where UnitedHealthcare holds at least a 25 percent market share.[148]
- Overall, UnitedHealth Group sends 25 percent of its medical claim revenue to its Optum subsidiaries, while 13 percent of CVS Health's revenues come from its own pharmacies and providers.[149]

Through intercompany eliminations, payments made by a licensed health insurance issuer to affiliated PBMs, pharmacies or providers may be treated as patient care spending for MLR purposes, even when the profits from those payments ultimately accrue to the same corporate parent.

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[143] Federal Trade Commission. (July 2024). Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies. Available at: https://www.ftc.gov/reports/pharmacy-benefit-managers-report
[144] Robb M., Karcher J. (February 2026). Medical Loss Ratio Requirements: Challenges Posed by Vertical Integration. *Milliman*. Available at: https://media.milliman.com/v1/media/edge/images/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/2026-Articles/2-9-26_PhRMA-MLR-Paper.pdf
[145] Angeles J., Bailit M. (September 2025). How Insurers That Own Providers Can Game The Medical Loss Ratio Rules. *Health Affairs Forefront*. Available at: https://www.healthaffairs.org/content/forefront/insurers-own-providers-can-game-medical-loss-ratio-rules
[146] Kakani P. et al. (April 2026). Profit Regulation and Strategic Transfer Pricing by Vertically Integrated Firms: Evidence from Health Care. *National Bureau of Economic Research.* Available at: https://www.nber.org/papers/w35043
[147] *Ibid.*
[148] Arnold D., Fulton, B. (November 2025). UnitedHealthcare Pays Optum Providers More Than Non-Optum Providers. *Health Affairs*. Available at: https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2025.00155
[149] Arnold D., Fulton, B. (November 2025). UnitedHealthcare Pays Optum Providers More Than Non-Optum Providers. *Health Affairs*. Available at: https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2025.00155

To address the manipulation of MLR requirements more broadly across vertically integrated insurers, PhRMA recommends that the Committee add a further specification to the numerator of the MLR calculation to limit or exclude profit earned by affiliated pharmacies or providers from counting as reimbursement for clinical services provided to enrollees or for activities that improve health care quality.

For example, the MLR numerator could exclude the amount by which the reimbursement to the affiliated provider exceeds the costs expended by that entity directly related to the delivery of the item or service (effectively eliminating all profit margin for the affiliated provider). Alternatively, the monetary amount by which the reimbursement to an affiliated provider exceeds the reimbursement that would be provided for the item or service to an unaffiliated provider could be excluded from the MLR numerator. Additionally, PhRMA recommends these changes be paired with enhanced reporting requirements that would require insurers to report reimbursements paid to entities they own or are affiliated with.

PBM Private Label Drugs

PhRMA appreciates the Committee's interest in better understanding the impacts of PBM-owned private-label drugs. As discussed in Section I, the three largest PBMs have each commercialized private-label biosimilars through affiliates and contractors. Each of these companies has established affiliated private-label subsidiaries: CVS Health's Cordavis (2023, based in Ireland), Cigna/Express Scripts' Quallent Pharmaceuticals (2021, based in the Cayman Islands), and UnitedHealth Group/OptumRx's Nuvaila (2024, based in Ireland).[150] These entities commercialize generic and biosimilar medicines in an arrangement with manufacturers and re-market them under a PBM-affiliated label at prices the PBM's affiliate—not the manufacturer—sets.

Not surprisingly, evidence suggests the big three PBMs each provide preferential coverage for their own affiliated private-label products, even in cases where those products aren't the least expensive option. As the Committee notes, in the commercial market, the three largest PBMs favored their own private-label Humira biosimilars on their 2025 standard formularies while excluding nearly all non-affiliated biosimilars, including versions with materially lower list prices.[151] In 2025, CVS Health publicly reported that it had moved approximately 97 percent of patients on its major formularies to its Cordavis-branded Humira biosimilar and ceased reporting sales data on grounds that continued disclosure "was no longer in its best interest."[152] Evidence suggests these trends are continuing into 2026, with each PBM excluding non-affiliated Humira biosimilars even if they offered lower list prices.[153]

These dynamics allow the big three PBMs to profit multiple times as the medicine makes its way through the supply chain, including once when the product is commercialized by their affiliate, again when the product is preferentially placed on the PBM's formulary, and a third time when the prescription is filled at a pharmacy they own. The closed loop of profit generation creates a clear incentive for PBMs to favor coverage of products they have a financial stake in, and to pad their own bottom lines by steering patients

[150] FTC. (July 2024). Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies. Available at: https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf
[151] Drug Channels (January 2025). The Big Three PBMs' Formulary Exclusions. Available at: https://www.drugchannels.net/2025/01/the-big-three-pbms-2025-formulary.html
[152] Endpoints News. (July 2025). Why CVS stopped sharing sales data on its leading Humira biosimilar. Available at: https://endpoints.news/why-cvs-stopped-sharing-sales-data-on-its-leading-humira-biosimilar/
[153] Drug Channels. (January 2026). The Big Three PBMs' 2026 Formulary Exclusions: MFP, Private Label Biosimilars, and Direct-to-Patient Threats for PBMs. Available at: https://www.drugchannels.net/2026/01/the-big-three-pbms-2026-formulary.html

to fill those prescriptions at PBM-owned pharmacies.[154] As noted previously, PBMs increasingly deny or restrict coverage for generics and biosimilars they do not have a financial stake in, suggesting that formulary decisions may prioritize compensation potential over patient access to lower-cost alternatives.[155]

As discussed previously, the stakes of these self-preferencing dynamics have potential implications for the long-term stability of the biosimilar market itself. Robust biosimilar competition depends on manufacturers being able to achieve sufficient formulary access and market uptake to justify the substantial investment required to bring a biosimilar to market. It is projected that 118 biologic products are expected to lose exclusivity by 2034—representing an approximately $234 billion opportunity for biosimilar competition—yet biosimilars are in development for only about 10 percent of these products.[156] Combined with the price-control dynamics introduced by the IRA, which further complicate the return-on-investment calculus for biosimilar and biologic developers alike, anticompetitive PBM practices that limit the potential commercial success for non-PBM-affiliated biosimilars threaten to erode future market stability and forestall the price reductions that robust, multi-source competition is intended to deliver.

For these reasons, PhRMA does not support the Committee's proposal to require PBM-owned private-label biosimilars to meet a cost-plus pricing standard as a condition of Part D coverage. Layering a government-set pricing formula onto these products would treat a symptom rather than the underlying cause—the misaligned incentives created by vertical integration that allow PBMs to commercialize and preference their own affiliated products over lower-cost, non-affiliated competitors. The more durable path to lower prices is to strengthen the competitive dynamics that have worked successfully for decades to balance innovation and affordability through patient access to new medicines as well as low-cost generics and biosimilar medicines. That balance is increasingly threatened by the misaligned incentives and conflicts of interest that fuel PBM behavior today.

Instead of focusing on proposals that undermine the competitive marketplace for medicines and incentives for innovation, we encourage a more direct focus on addressing market distortions, conflicts of interest and self-preferencing behavior. ***The Committee should prohibit any entity providing PBM services from owning, controlling, sharing common ownership or holding a beneficial interest in an entity that commercializes a prescription drug***.

PBM Gag Clauses

PhRMA supports the Committee's efforts to ban the use of PBM non-solicitation (or exclusive negotiation agent) or "gag" clauses that restrict employers, Part D plan sponsors and manufacturers or other parties from pursuing innovative and non-traditional contracting arrangements. Many employers and Part D plan sponsors rely on PBMs to administer prescription drug benefits, negotiate manufacturer rebates and manage pharmacy networks. Given their clients' reliance on PBMs for these services, we are concerned that some PBMs have pushed for inclusion of contractual non-solicitation clauses. Non-solicitation clauses can bar employers or Part D plan sponsor clients from seeking alternative pricing, contracting or benefit-design arrangements directly with manufacturers or other vendors even if those

[154] Carrier M., Sachs R. (July 2025). Competitive Concerns from Pharmacy Benefit Managers Selling Their Own Drugs. Available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5372944
[155] Cencora. (July 2025). Persistent Growth in PBM Formulary Exclusions Continues to Raise Concerns About Patient Access. Available at: https://phrma.org/resources/persistent-growth-in-pbm-formulary-exclusions-continues-to-raise-concerns-about-patient-access.
[156] IQVIA. (February 2025). Assessing the Biosimilar Void in the U.S. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/assessing-the-biosimilar-void-in-the-us

arrangements could reduce costs or improve access for patients. Additionally, PBMs frequently engage in tactics such as spread pricing and pharmacy steering and impose formulary exclusions and utilization management restrictions that can further impede patient access.[157]

PBMs can use their market power to compel employers and plan sponsors to accept additional terms that may limit access and information and shift costs to patients:

- A 2025 study from Willis Towers Watson found that employers are less satisfied with coordination between PBMs and medical carriers to improve quality and lower costs, and in response to growing dissatisfaction with PBMs, employers are exploring different ways to work with them.[158]
- A recent article published by Mercer noted that 41 percent of employers are evaluating new PBM contracting models and 37 percent are evaluating new or emerging PBMs.[159]

In light of growing frustration with current PBM business models, some employers and Part D plan sponsors are reassessing how benefits are structured and leveraging innovative arrangements to administer pharmacy benefits. Some of these include non-traditional models such as DPPs and direct manufacturer-employer (DTE) contracting offered by drug manufacturers. Additionally, some insurers such as Blue Shield of California have adopted a "modular PBM" model where multiple vendors perform different PBM functions.[160]

According to the PBM Accountability Project, "PBMs' general lack of transparency is critical to their operations and allows them to buy a product or service from one stakeholder in the system and sell that product or service to another stakeholder at a higher price, without the payer understanding the true cost or inflationary nature of the services purchased—a practice known as 'arbitrage.'"[161] For example, PBMs often engage in spread pricing, a practice where they charge employers and other payers a higher amount for a medicine than they reimburse the pharmacy at the point-of-sale, keeping the difference as spread.[162] Similarly, vertically integrated PBMs and pharmacies can also increase profits by significantly marking up reimbursement rates for low-cost generic drugs.[163] An investigation by the *Wall Street Journal* (WSJ) revealed that generic drugs dispensed by PBM-affiliated pharmacies can cost thousands of dollars more than the very same generic drugs dispensed at independent pharmacies because of this practice. Across a selection of generic drugs analyzed by the WSJ, the prices that CVS Health and Cigna/ Express Scripts

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[157] House Oversight Committee. (July 2024). The Role of Pharmacy Benefit Managers in Prescription Drug Markets. Available at: https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf

[158] Willis Towers Watson. (October 2025). Healthcare Cost Pressures Drive Employers to Consider Disruptive Changes. Available at: https://www.wtwco.com/en-us/insights/2025/10/healthcare-cost-pressures-drive-employers-to-consider-disruptive-changes.

[159] Mercer. (June 2026). Employers are Shifting Health Care Costs to Employees but Also Leveraging New Approaches to Minimize Impact, According to Mercer Research. Available at: https://www.mercer.com/en-us/about/newsroom/employers-are-shifting-healthcare-costs-to-employees/.

[160] Diamond F. (August 2023). Blue Shield of California Ditches CVS Caremark as PBM, Unveils New Pharmacy Care Model. *Fierce Healthcare*. Available at: https://www.fiercehealthcare.com/payers/blue-shield-california-seeks-bypass-pbms-and-overturn-current-drug-pricing-system.

[161] PBM Accountability Project. (December 2021). New Report Shows PBMs Are Increasing Costs for Patients and the Health Care System. Available at: https://www.pbmaccountability.org/post/new-report-shows-pbms-are-increasing-costs-for-patients-and-the-health-care-system.

[162] Link B., Wine M., Ciaccia A. (June 2026). A Model of Financial Risk to Payers from Retrospective Price Concessions. *3 Axis Advisors on behalf of the National Alliance of Healthcare Purchaser Coalitions*. Available at: https://www.nationalalliancehealth.org/wp-content/uploads/Retrospective-Discounts-White-Paper-Final-6-1-2026.pdf

[163] FTC. (January 2025). Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers. Available at: https://www.ftc.gov/reports/specialty-generic-drugs-growing-profit-center-vertically-integrated-pharmacy-benefit-managers

charged to plan sponsors were 24 and 27 times higher, respectively, than the prices charged by the generic manufacturers themselves. For one generic cancer drug, CVS Health and Cigna/ Express Scripts reimbursed their own specialty pharmacies between $6,600 and $7,000 per prescription, while the same generic drug cost just $54 at a non-affiliated pharmacy.[164]

- A 2025 report published by the FTC similarly determined that the three largest PBMs marked up the cost of specialty generic drugs dispensed at their affiliated pharmacies to maximize revenue.[165]
- The report also found that between 2020 and 2022, the three largest PBMs reimbursed 63 percent of affiliated pharmacies at rates exceeding 100 percent of a drug's National Average Drug Acquisition Cost (NADAC) and reimbursed 22 percent of affiliated pharmacies at rates over 1,000 percent of NADAC.[166]
- Additionally, 44 percent of commercial specialty generic 30-day equivalent prescriptions were dispensed at PBM-affiliated pharmacies, compared with 72 percent of prescriptions for drugs marked-up more than $1,000 per prescription. This suggests that the three largest PBMs may be steering profitable prescriptions to their own pharmacies, allowing them to capture greater margins on each transaction.[167,168]

Beyond their direct cost impact, these markups incentivize PBMs to steer patients toward affiliated pharmacies and eliminate the savings that health systems would otherwise realize on specialty generic drugs. Given these findings, the FTC concluded that "specialty generic drug pricing and steering practices should receive further scrutiny" and that "legislative reforms may be warranted."[169]

PhRMA encourages the Committee to build on PBM reforms included in the Consolidated Appropriations Act of 2026 and the Department of Labor's PBM fee disclosure proposed rule that increase transparency into PBM business practices and prevent information blocking. We encourage the Committee to prohibit contractual non-solicitation and exclusivity provisions that prevent employers and Part D plan sponsors from directly engaging in lower-cost arrangements or exploring non-traditional access models.

Increasing PBM Accountability for Rising Drug Costs

PhRMA agrees with the Committee's goals of increasing PBM accountability and ensuring that PBMs have meaningful incentives to manage drug spending and deliver lower costs for Medicare Part D plans and beneficiaries. The Committee highlights the California Public Employee Retirement System's (CalPERS) PBM contract, which requires its PBM to put a multi-million dollar lump sum at-risk if annual

[164] Walker J. (September 2023). Generic Drugs Should Be Cheap, but Insurers Are Charging Thousands of Dollars for Them. *Wall Street Journal*. Available at: https://www.wsj.com/health/healthcare/generic-drugs-should-be-cheap-but-insurers-are-charging-thousands-of-dollars-for-them-ef13d055

[165] Federal Trade Commission. (January 2025). Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers. Available at: https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf.

[166] *Ibid.*

[167] Mulcahy A.W., Kareddy K. (October 2021). Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships. Department of Health and Human Services Assistant Secretary for Planning and Evaluation. Available at: https://aspe.hhs.gov/reports/prescription-drug-supply-chains

[168] Duy D., Geldsetzer P. (August 2021). Trends in Mail-Order Prescription Use among U.S. Adults from 1996 to 2018: A Nationally Representative Repeated Cross-Sectional Study. *American Journal of Preventive Med*. Available at: doi.org/10.1016/j.amepre.2021.02.017

[169] FTC. (January 2025). Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers. Available at: https://www.ftc.gov/reports/specialty-generic-drugs-growing-profit-center-vertically-integrated-pharmacy-benefit-managers

pharmacy trend exceeds 6.5 percent.[170,171] While the CalPERS effort stems from interest in greater PBM accountability, it is important to recognize that annual pharmacy trend is driven by a variety of factors including changes in utilization, shifts in formularies and benefit design and numerous state and federal regulatory changes for plans. Holding PBMs financially responsible for overall annual trend without accounting for these external drivers or the patient experience could discourage coverage of innovative therapies and create additional barriers to coverage, such as increased utilization management requirements.

Policies must be structured to value innovation, especially those that can have long-term benefits in terms of health outcomes and medical spending. PhRMA believes that policymakers' recent actions in the Consolidated Appropriations Act of 2026, including delinking PBM compensation from list prices in Medicare Part D and requiring PBMs and affiliates to provide increased transparency into their business practices across the Part D and commercial markets will assist in reining in PBMs' abusive and anticompetitive behaviors, improving value and ensuring PBMs are accountable for the outcomes they deliver.

Rather than adopting an inflation or trend-based cap, which could restrict patient access to newly approved, innovative medicines, PhRMA urges the Committee to consider options to strengthen and enforce Medicare Part D MLR requirements, as detailed above. Stronger MLR requirements would have the added benefit of increasing accountability for PBM performance and reducing incentives to prioritize administrative costs and profit over patient care.

MLR requirements apply to insurers, and not PBMs directly. However, as the three largest PBMs are owned by or affiliated with insurers, reforms to MLR calculations can function as one of the few requirements with reform potential to capture profit shifting by vertically integrated insurers and PBMs.

MLR requirements are intended to ensure insurers spend a minimum share of premium revenue on patient care and quality improvement activities, rather than administrative costs and profit. However, as PBMs have vertically integrated with insurers, pharmacies and PBM GPOs, they can shift revenue among affiliated entities in ways not contemplated by MLR requirements and not fully captured in current MLR reporting. This kind of shifting allows plans to comply with the letter of MLR requirements while directing a smaller proportion of premium revenue to patient care. PhRMA's recommendations described in the "Games & Abuses Due To Vertical Integration" would help to address the manipulation of MLR requirements while enhancing PBM accountability to provide quality patient coverage.

Addressing Price-Linked Compensation

The RFI solicits feedback on potential alternatives to Medicare's current payment methodology for Part B medicines. Medicare Part B currently reimburses providers based on a medicine's ASP plus a six percent add-on payment for physician-administered medicines.[172] This market-based reimbursement system helps providers cover the substantial non-drug costs associated with storing, handling and administering complex therapies at their practice. The add-on payment is particularly vital for smaller, independent

[170] CalPERS. (July 2025). CalPERS Announces New Pharmacy Benefits Contract With CVS Caremark to Foster Affordability and Improve Quality. Available at: https://www.calpers.ca.gov/newsroom/calpers-news/2025/calpers-announces-new-pharmacy-benefits-contract-with-cvs-caremark-to-foster-affordability-and-improve-quality

[171] CalPERS. (July 2025). CalPERS Pharmacy Benefits Contract Recommendation. Available at: https://www.calpers.ca.gov/documents/202507-full-day-2-1-2-presentation-pharmacy-contract/download?inline

[172] Under mandatory federal sequestration, the add-on is reduced to ASP + 4.3 percent.

physician practices that often lack the purchasing leverage of larger health systems and therefore may acquire medicines at prices closer to, or even above, the ASP.

Maintaining adequate and stable reimbursement is especially critical at a time when independent physician practices are facing significant financial pressure. Medicare physician payment has declined by approximately 33 percent since 2001, even as practice operating costs have continued to rise.[173] At the same time, physician consolidation has accelerated, with approximately half of physicians affiliated with a hospital system in 2024, compared to fewer than 30 percent in 2012.[174] Further reductions in Part B reimbursement would exacerbate these pressures, making it more difficult for independent providers to continue offering physician-administered medicines covered under Part B in the community setting. As practices close or consolidate with hospital systems, patients often face higher costs, longer travel distances and reduced access to care delivered close to home.

Despite the compounding pressures on independent practices' financial viability, providers will face yet another cliff in Medicare payments in the coming years. Under the IRA, providers will be reimbursed at sharply lower rates for price-set Part B medicines beginning in 2028. Following implementation of the IRA, an Avalere analysis projects that add-on payments to physicians could be reduced by up to 50 percent.[175] When facing financial strain of that magnitude, more than 90 percent of independent providers reported that they would be somewhat or very likely to stop offering price-set Part B medicines in their practice, while nearly 80 percent reported moderate or severe concern that reimbursement cuts would lead to negative treatment outcomes for their patients.[176]

Policies that would further reduce reimbursement for physicians—such as MedPAC's proposals to cap or tier add-on payments — risk accelerating consolidation and limiting patient access to local physicians who administer complex therapies***. Congress should therefore preserve a reimbursement framework that supports stability in the care delivery system, protects independent community practices and ensures Medicare beneficiaries continue to receive timely access to physician-administered medicines in the settings where they prefer to receive care.***

Inappropriate Pharmacy Rejections

PhRMA has long supported transparency initiatives that produce tangible patient benefits by increasing consumer choice, reducing out-of-pocket costs and promoting access to medicines. Today, PBMs and their affiliated entities control or administer coverage, utilization management and cost-sharing policies that directly impact patients, yet these practices are often opaque. There is a critical need for improved transparency to help patients understand their coverage and anticipate their health care costs. Many PBMs impose confusing requirements and conditions on coverage that lead to patients incurring surprise cost sharing obligations or having to navigate additional steps to access medicines.

As the Committee has recognized, prior authorization and other utilization management practices can create significant access challenges for patients.

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[173] AMA. (April 2025). Medicare Experts Back Tying Physician Payment to Inflation. Available at: https://www.ama-assn.org/practice-management/medicare-medicaid/medicare-experts-back-tying-physician-payment-inflation

[174] GAO. (September 2025). Health Care Consolidation: Published Estimates of the Extent and Effects of Physician Compensation. Available at: https://www.gao.gov/products/gao-25-107450

[175] 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

[176] Avalere Health. (September 2025). Provider Perspectives on Medicare Drug Price Negotiation: Implications for Part B Beneficiary Access, Practice Operations, and Reimbursement. Available at: https://advisory.avalerehealth.com/insights/white-paper-provider-survey-on-part-b-negotiation-impacts

- A recent IQVIA study found that 48 percent of all Medicare Part D patients experienced at least one coverage denial when attempting to initiate treatment with a brand medicine in 2024 and 30 percent of patients who were initially rejected still had not received approval for the medicine prescribed by their doctor one year later.[177]
- Similarly, IQVIA found that 70 percent of commercially covered patients were initially denied coverage when trying to start treatment with a brand medicine in 2025, up from 57 percent in 2021.[178]
- These barriers also persist among medicines selected for the first round of IRA price setting, where beneficiaries attempting to initiate selected immunology and oncology medicines faced initial rejection rates of 59 percent and 67 percent, respectively, in the first quarter of 2026.[179]
- Despite special CMS protections requiring broad coverage of medicines in the six protected classes, recent research shows that Medicare Part D patients attempting to fill new prescriptions for brand medicines in these classes were initially rejected 58 percent of the time.[180]

Delays in care, opaque denial rationales, inconsistent application of coverage criteria and the cumulative administrative burden associated with fragmented prior authorization processes can disrupt care, undermine treatment adherence and divert clinical resources away from patients with the greatest needs. Further, the administrative burden associated with prior authorization falls heavily on health care providers and their clinical teams, consuming valuable time and resources. Administrative weight can fall hardest on smaller and independent practices, who often lack dedicated staff to manage high volumes of utilization management requests, which may have impacts on patient access and outcomes. In fact, prior authorizations are estimated to account for $35 billion in U.S. health care administrative costs annually.[181]

Patients and providers currently lack meaningful visibility into how frequently prescription medicine prior authorization requests are denied, delayed or ultimately overturned on appeal. While CMS has begun to require public reporting of prior authorization metrics for medical items and services, comparable reporting for medicines has historically been limited or unavailable, constraining understanding, oversight and accountability. CMS' recent *Interoperability Standards and Prior Authorization for Drugs Proposed Rule*[182] seeks to address this gap by extending reporting and public disclosure requirements to prescription medicine-related prior authorization, enabling CMS to monitor utilization management trends across plans and markets and allowing patients, providers and other stakeholders to compare plan practices. ***PhRMA believes more can be done to build on existing transparency requirements to deliver meaningful information to patients, providers and the public and to hold insurers and PBMs accountable.***

[177] IQVIA. (March 2026). Increasing Payer Control for Medicare Patients Initiating Branded Medicines. Available at: https://www.iqvia.com/locations/united-states/blogs/2026/03/increasing-payer-control-for-medicare-patients-initiating-branded-medicines
[178] IQVIA (April 2026). Increasing Payer Control for Commercial Patients Initiating Branded Medicines. Available at: https://www.iqvia.com/locations/united-states/blogs/2026/03/increasing-payer-control-for-commercial-patients-initiating-branded-medicines
[179] IQVIA (August 2026). Rejection Rates Unchanged by MFP Drug Coverage Requirement. Available at: https://www.iqvia.com/locations/united-states/blogs/2026/07/rejection-rates-unchanged-by-mfp-drug-coverage-requirement
[180] IQVIA (August 2026). Protected Classes Are Not Immune to Payer Control. Available at: https://www.iqvia.com/locations/united-states/blogs/2026/08/protected-classes-are-not-immune-to-payer-control
[181] Health Affairs. (March 2026). The Current Prior Authorization Landscape. Available at: https://www.healthaffairs.org/content/briefs/current-prior-authorization-landscape
[182] CMS. (April 2026). 91 FR 19890. Available at: https://www.federalregister.gov/documents/2026/04/14/2026-07205/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-standards

PhRMA supports proposals to require payers to provide patients and providers with specific reasons for denying prior authorization requests. Providing clear, specific denial explanations is critical to enabling providers and patients to understand the basis for a decision, take appropriate corrective action and pursue appeals when warranted. Denial communications should clearly outline next steps in the process, including appeal rights and applicable timelines, to reduce confusion and promote continuity of care. This requirement should apply consistently across all markets to help patients better understand the reasons for denials and become better advocates for their own care.

PhRMA recommends the Committee direct payers in all markets to annually report prior authorization and step therapy denial rationales to CMS. Denial rationales should be reported using standardized status codes that clearly indicate whether a denial was due to incomplete or missing documentation, an administrative or procedural issue, a medical-necessity determination or another prior authorization or step therapy-related requirement, enabling stakeholders to better understand the underlying drivers of denials. Insight into payer denial rationale would provide CMS and other stakeholders with critical visibility into how prior authorization policies operate in practice across payer markets and patient populations. Evidence shows that prior authorization denials fall disproportionately on vulnerable populations. A recent study showed that some Medicaid patients face prior authorization denials at nearly five times the rate of Medicare beneficiaries and more than four times the rate of commercially insured patients.[183] These concerns may be compounded by longstanding access challenges in Medicaid, where beneficiaries often face difficulty finding participating providers, and provider practices may have limited administrative resources available to navigate increasingly complex prior authorization and step therapy requirements.[184] Data from Medicare Advantage shows that dually eligible beneficiaries, who are more likely to live in poverty and have higher rates of disability, are subject to denial rates up to twice those of non-dual enrollees, despite having fewer prior authorization requests on average.[185]

PhRMA requests the Committee consider policies that establish standardized reporting and public transparency measures to evaluate whether prior authorization and step therapy reforms are resulting in meaningful improvements for patients and providers. PhRMA supports proposals for public reporting of key metrics related to coverage denials resulting from formulary exclusions and utilization management, appeal and overturn rates and time from request submission to therapy decision. The big three PBMs and insurers have recently announced voluntary commitments to streamline prior authorization processes;[186] however, many of these initiatives lack clear metrics, reporting requirements, accountability mechanisms or specific commitments related to prescription drugs. Reported metrics should distinguish between brand and generic medicines, be disaggregated by therapeutic area, include reason for denials and separately identify denials related to step therapy. These measures are critical to understanding whether prior authorization is functioning as a clinical safeguard or instead acting as a barrier to timely treatment. Without transparent data on how frequently requests are denied, how often those denials are ultimately overturned and how long patients wait for decisions, policymakers, providers and patients lack the necessary information to fully assess where utilization management practices are

[183] MACPAC. (August 2024). Prior Authorization in Medicaid. Available at: https://www.macpac.gov/wp-content/uploads/2024/08/Prior-Authorization-in-Medicaid.pdf
[184] MACPAC (January 2024). Evaluating the Effects of Medicaid Payment Changes on Access to Physician Services. Available at: https://www.macpac.gov/wp-content/uploads/2024/01/05_January-Slides_Findings-from-Expert-Roundtable-on-Evaluating-the-Effects-of-Medicaid-Payment-Changes-on-Access-to-Physician-Services.pdf
[185] Georgetown University. (November 2025). CMS Suspends New Medicare Advantage Prior Authorization Transparency Rules Amid Public Concerns About Care Denials. Available at: https://medicare.chir.georgetown.edu/cms-suspends-new-medicare-advantage-prior-authorization-transparency-rules-amid-public-concerns-about-care-denials/
[186] AHIP. (June 2025). Health Plans Take Action to Simplify Prior Authorization. Available at: https://www.ahip.org/news/press-releases/health-plans-take-action-to-simplify-prior-authorization

appropriately calibrated or are contributing to unnecessary delays in care. These metrics would also provide beneficiaries with information necessary to compare plans based on how utilization management policies operate in practice, supporting more informed plan selection decisions during open enrollment.

PhRMA also recommends that any reporting be conducted at the plan level, rather than solely at the issuer, contract or program level and also disaggregated geographically. Plan-level reporting would better capture variation in utilization management practices and provide more meaningful insight into the experiences of patients and providers navigating specific plans. Further, the Committee should direct CMS to require disaggregated reporting at the geographic level, including by state, where feasible. State-level visibility into prior authorization denial and delay rates would enable regulators, patients and providers to identify regional disparities and assess whether utilization management practices vary in ways that overly burden certain patient populations or markets.

PhRMA recommends the Committee direct CMS to require public reporting of initial point-of-sale claim adjudications that result in rejection, in addition to metrics related to formal prior authorization requests. Payers should be required to report the total number and percentage of claims for which initial point-of-sale adjudication results in rejection, stratified by therapeutic class and reason for rejection and reported separately for brand and generic medicines. Point-of-sale rejections frequently serve as the first utilization management checkpoint and, in many cases, initiate — or effectively substitute for—the prior authorization process. As a result, these rejections can delay therapy even when no formal prior authorization request is ultimately submitted. Reporting the reasons for point-of-sale rejections would provide greater transparency into how utilization management operates at the pharmacy counter and help identify practices that may contribute to unnecessary delays or treatment disruption.

Further, PhRMA recommends considering potential future applications of payer-submitted data that can support informed decision-making for patients and accountability for payers. Transparency is a necessary foundation, but it is not sufficient on its own. While some proposals would impose valuable transparency into denial rates, disclosure alone creates no direct incentive for plans to change behavior. To meaningfully reduce inappropriate rejections, the Committee should evaluate methods to link performance on denial-related metrics to concrete financial and enrollment incentives and establish independent oversight of the underlying utilization management practices.

Specifically, PhRMA recommends the Committee direct CMS to consider the establishment of a new Part D Star Rating measure related to prescription drug utilization management, capturing metrics such as initial denial rates and the rate at which denials are overturned on appeal. Incorporating utilization management (i.e., prior authorization, step therapy, medical exceptions etc.) performance into the Star Rating system would create a direct, well-understood incentive for plans to reduce inappropriate rejections, given the measure's connection to quality bonus payments and plan competitiveness.

PhRMA recommends the Committee evaluate options to flag plan performance on denial-related metrics on the Medicare Plan Finder and, as applicable, on the Exchange websites, so that beneficiaries can readily compare plans based on how frequently they deny claims and how often those denials are overturned. Modifications to the enrollment process could also discourage high rates of medicine denials. Beneficiaries currently lack accessible information about how a plan's utilization management practices operate in the real world when making enrollment decisions. Surfacing this information at the time of plan selection would create a market-based incentive for plans to improve performance, rewarding those that appropriately calibrate utilization management and discouraging enrollment in plans with excessive denial rates.

Finally, PhRMA encourages the Committee to evaluate reforms that would better align broker and agent compensation with beneficiaries' interests and plan quality. Nearly one-third of Medicare beneficiaries use insurance agents or brokers to help choose their Medicare Advantage, Part D or Medigap plans.[187] Agents and brokers are paid commissions for enrolling beneficiaries in plans. While CMS sets maximum commission amounts annually, insurers set the exact amount they will pay, and those amounts vary regionally, based on whether an enrollment is an initial or renewal enrollment, and by plan type. As a result, agents and brokers may face financial incentives that are not always aligned with a beneficiary's financial or health interests.

In 2024, the HHS OIG issued a fraud alert regarding marketing arrangements tied to Medicare Advantage, warning of improper steering of Medicare enrollees toward particular plans based on lucrative incentives rather than what is most appropriate for the beneficiary.[188] The Committee could explore permitting or directing variable broker compensation tied to a plan's performance on denial-related metrics—such as drug claim denial rates or the rate at which denials are overturned on appeal—so that brokers are not incentivized to steer beneficiaries into plans with poor utilization management track records. This approach would complement the denial-performance framework described elsewhere in these comments and give brokers a direct stake in directing beneficiaries toward plans that provide reliable access to health care services, including medicines.

Section III: Bolstering Biopharmaceutical Innovation in the United States

PhRMA supports the Committee's efforts to bolster and invest in biopharmaceutical innovation in the U.S. at a critical time in the global biopharmaceutical R&D environment, provided such efforts reinforce the policy pillars that make private-sector R&D possible: strong and enforceable intellectual property rights, robust data protection, predictable and science-based FDA decision-making, support for academia and basic research and a market-based reimbursement system that rewards high-risk innovation. For over 40 years, these policies have made the U.S. the world leader in biopharmaceutical innovation. The question now is whether the U.S. is doing everything it can to remain the world's best place to research, develop and manufacture new medicines amid rising competition from China. Proposals in this RFI that further impose government price setting, import foreign reference pricing, condition access to federal research infrastructure on price concessions or weaken market-based returns would erode these very principles and undermine the R&D and manufacturing investment Congress seeks to attract to the United States. If Congress supports maintaining the U.S. as the world's leading environment for biomedical innovation, it must focus its efforts to strengthen the biopharmaceutical research and development ecosystem here in the U.S.

Bolstering Funding for Basic Research in the United States

Federally funded research and private biopharmaceutical investment are best understood as complementary, not substitutable components of the United States innovation ecosystem. Basic research broadens scientific understanding, while private companies assume the capital risk, regulatory risk,

[187] Commonwealth Fund. (October 2022). Traditional Medicare or Medicare Advantage: How Older Americans Choose and Why. Available at: https://www.commonwealthfund.org/publications/issue-briefs/2022/oct/traditional-medicare-or-advantage-how-older-americans-choose

[188] HHS OIG. (December 2024). Special Fraud Alert: Suspect Payments in Marketing Arrangements Related to Medicare Advantage and Providers. Available at: https://oig.hhs.gov/documents/special-fraud-alerts/10092/Special%20Fraud%20Alert:%20Suspect%20Payments%20in%20Marketing%20Arrangements%20Related%20to%20Medicare%20Advantage%20and%20P.pdf

manufacturing scale-up risk and post-approval obligations required to transform scientific insights into approved medicines for patients. Public-and private-sector scientists alike contribute to the basic research that expands our understanding of human biology and lays the groundwork for drug discovery. Beyond the National Institutes of Health (NIH), agencies including the National Science Foundation (NSF), the Department of Energy (DOE), Department of Defense (DOD), the Biomedical Advanced Research and Development Authority (BARDA) and the Advanced Research Projects Agency for Health (ARPA-H) fund early-stage research, train the scientific workforce and help de-risk early discovery, when private capital takes over. Each NIH dollar invested is associated with roughly $2.50 in short-term economic return[189] and an additional $8.30 in long-term private-sector R&D investment[190]—federal funding that crowds in, rather than displaces, private investment.

The Committee has asked what type of new funding streams Congress could create to fund NIH research through a new assessment on industry, based on the premise that the pharmaceutical industry is the primary financial beneficiary of basic research. This framing—that the biopharmaceutical industry is "the primary financial beneficiary" of NIH-funded basic research—does not reflect the best available evidence on how that research may translate into approved medicines. While federal funding of basic research plays an important upstream role in understanding human biology and laying the groundwork for the discovery and development of new medicines, the fact is that the preponderance of biomedical research and development is funded by the private sector, which also takes on the significant risk of drug development. A comparison of NIH to private industry funding illustrates this well: a peer-reviewed analysis estimated that, for a subset of new FDA-approved drugs, private-sector investment was greater than NIH funding by more than 60 to 1 prior to approval, demonstrating the substantial private capital needed to bring these innovations to patients.[191] Over the past decade, PhRMA members have invested $850 billion in the research and development of new medicines,[192] yet the vast majority of investigational medicines never reach patients, with the FDA approving only 12 percent of potential medicines that enter clinical trials.[193]

NIH's contribution to the biopharmaceutical R&D ecosystem is largely indirect: it funds basic science—foundational biology such as genetic mapping and cellular biology—that informs private-sector drug discovery and development, rather than contributing directly to commercialized medicines. Patent data bear this relationship out: while only nine percent of drugs approved by the FDA between 1988 and 2005 were linked to a patent assigned to a government agency or bearing a government-interest statement acknowledging federal funding, roughly half of the drugs approved in that period were built on patents that cited publicly funded research as scientific prior art.[194] That contribution, moreover, is shared broadly across academia, other federal agencies, foreign public research systems and the global scientific community—it is not something industry alone benefits from.

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[189] United for Medical Research. (2025). NIH's role in sustaining the U.S. economy. Available at: https://www.unitedformedicalresearch.org/annual-economic-report/

[190] Boles S. (March 2025). NIH Funding Delivers Exponential Economic Returns. Harvard Gazette. Available at: https://news.harvard.edu/gazette/story/2025/03/nih-funding-delivers-exponential-economic-returns/

[191] VitalTransformation. (May 2021). Who Develops Medicines? An Analysis of NIH Grants. Available at: https://vitaltransformation.com/2021/05/who-develops-medicines-an-analysis-of-nih-grants/

[192] PhRMA. (July 2025). 2025 PhRMA Annual Membership Survey. Available at: https://phrma.org/resources/2025-phrma-annual-membership-survey

[193] DiMasi J. A., Grabowski H. G., Hansen R. W. (February 2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics*. Available at: https://pubmed.ncbi.nlm.nih.gov/26928437/

[194] Sampat B. N., Lichtenberg F. R. (February 2011). What are the respective roles of the public and private sectors in pharmaceutical innovation? *Health Affairs*. Available at: https://pubmed.ncbi.nlm.nih.gov/21289355/

This point is worth highlighting because it offers useful context for how the RFI frames one of its central questions. When scientific discoveries are published openly or result in patented inventions and become part of the shared public knowledge base, they tend to benefit many entities at once, not just one. Diagnostics companies, university hospitals, the makers of lab tools and reagents, public health agencies and researchers all draw on the same NIH-funded discoveries that biopharmaceutical companies do. The Congressional Research Service[195] and the National Academies of Sciences, Engineering, and Medicine[196] have both documented this pattern: publicly funded research tends to generate benefits that spread broadly across sectors, rather than concentrating in any one industry. A discovery that diffuses broadly across scientific literature and publicly available patents is therefore, by definition, not one for which any single downstream industry can fairly be called the "primary" beneficiary.

Furthermore, the premise does not account for the reinvestment and repayment channels that already exist in the biopharmaceutical R&D ecosystem. Corporate income taxes paid by the biopharmaceutical sector already flow into the general fund from which NIH is appropriated; an additional sector-specific assessment would tax the same underlying activity twice. In addition, NIH owns the patents that result from its intramural research and then licenses those inventions to companies for further development. This licensing authority comes from the Federal Technology Transfer Act of 1986, which amended the Stevenson-Wydler Act. GAO found that 93 such NIH-owned patents contributed to 34 FDA-approved, commercially sold drugs, generating up to $2 billion in cumulative royalty revenue for NIH between 1991 and 2020.[197] ***As a result, PhRMA does not believe that a sector-specific assessment is warranted. Such an assessment would duplicate existing tax and royalty channels, mischaracterize the broad societal beneficiaries of basic research and reduce the same private R&D capital that converts early-stage scientific discoveries into approved medicines. Congress should instead fund NIH through predictable appropriations and preserve incentives that attract private investment, including Bayh-Dole licensing, patent certainty and voluntary technology-transfer models that do not attach pricing conditions to federally supported science.***

Increasing the Rigor of NIH funded Basic Research

Studies have documented that a meaningful fraction of published scientific findings—particularly in areas such as cancer biology and early-stage drug target validation—have proven difficult to replicate, with contributing factors that include publication bias, small sample sizes, inadequate controls and methodological weaknesses.[198,199,200,201] These concerns persist despite a congressionally mandated National Academies of Sciences, Engineering, and Medicine report recommending systematic improvements to research practices,[202] a statutory NIH rigor policy under the 21st Century Cures Act

[195] Congressional Research Service. (May 2026). National Institutes of Health (NIH) funding: FY1996–FY2026 (Report No. R43341). Available at: https://www.congress.gov/crs-product/R43341
[196] National Academies of Sciences, Engineering, and Medicine. (November 2019). The role of NIH in drug development innovation and its impact on patient access: Proceedings of a workshop. *The National Academies Press.* Available at: https://www.ncbi.nlm.nih.gov/books/NBK553542/
[197] U.S. Government Accountability Office. (October 2020). NIH Should Publicly Report More Information About the Licensing of Its Intellectual Property. Available at: https://www.gao.gov/assets/gao-21-52.pdf
[198] Freedman L. P., Cockburn I. M., Simcoe T. S. (June 2015). The economics of reproducibility in preclinical research. *PLOS Biology.* Available at: https://doi.org/10.1371/journal.pbio.1002165.
[199] Prinz F., Schlange T., Asadullah, K. (August 2011). Believe it or not: How much can we rely on published data on potential drug targets? *Nature Reviews Drug Discovery*. Available at: https://www.nature.com/articles/nrd3439-c1
[200] Begley C. G., Ellis L. M. (2012). Drug development: Raise standards for preclinical cancer research. *Nature.* Available at: https://doi.org/10.1038/483531a
[201] U.S. Government Accountability Office. (July 2022). Research reliability: Federal actions needed to promote stronger research practices. Available at: https://www.gao.gov/products/gao-22-104411
[202] National Academies of Sciences, Engineering, and Medicine. (2019). Reproducibility and replicability in science. *The National Academies Press.* Available at: https://doi.org/10.17226/25303

requiring grant applicants to address reproducibility[203,204] and two GAO audits finding that NIH has never assessed whether its own 2015 reproducibility policy is being followed.[205,206]

To improve scientific rigor in the scientific grant review process, while avoiding additional administrative burden that slows truly innovative research, PhRMA recommends the Committee consider the following reforms focused on prospective study design, transparent methods, and independent assessment of rigor and accountability for high-impact findings that inform downstream drug discovery investment.

First, Congress should codify preregistration and pre-analysis plans as a scored NIH grant review criterion. Congress should amend the Public Health Service Act to require NIH to incorporate preregistration of research plans—including hypotheses, methods and statistical analysis plans—as a mandatory scored criterion in peer review for research project grants. In addition, renewal funding should be made contingent on showing that the project is following the plan as originally registered, unless a scientifically valid rationale for adaptation is provided.

Congress should also amend the annual NIH appropriations law or the Public Health Service Act to explicitly support rigor in research. Congress should consider establishing a fixed additional funding allocation of NIH extramural research budgeted exclusively for independent, third-party replication of high-impact NIH-funded findings, with all results published regardless of outcome, and administered through a standing program with transparent selection criteria. Example findings for replication could include results with important policy or decision-making implications, results that are particularly surprising or novel, subject to controversy or bias or where future high-stakes studies would build upon the findings.[207]

Congress should direct NIH in statute to collect and report annually to the authorizing and appropriations committees of jurisdiction on a defined set of accountability indicators. Congress should direct NIH, in statute, to report metrics to Congress across its funded portfolio—including rates of preregistration compliance, sample size adequacy, data-sharing adherence and blinding and randomization practices—and to demonstrate measurable progress against short-term goals tied to its 2015 reproducibility and other quality oversight policies.

Furthermore, the Committee should direct the President and Congress to jointly establish a National Biomedical Research Enterprise Advisory Body with coordinating authority to galvanize national leadership and establish scientific rigor standards across federal funders. A permanent, cross-sector National Biomedical Research Enterprise Advisory Body (as recommended by the National Academy of Medicine)[208] could galvanize national leadership, develop a national strategic vision and coordinate

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[203] National Institutes of Health. (2016). *Rigor and reproducibility in grant applications.* Available at https://grants.nih.gov/grants/guide/notice-files/not-od-16-011.html

[204] National Institutes of Health. (February 2023). NIH encourages the use of the ARRIVE Essential 10 checklist in all publications reporting on the results of vertebrate animal and cephalopod research. Available at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-057.htm

[205] U.S. Government Accountability Office. (December 2024; reissued January 2026). National Institutes of Health: Assessing efforts to improve animal research could lead to greater human health benefits. Available at: https://www.gao.gov/products/gao-25-107140.

[206] U.S. Government Accountability Office. (July 2022). Research reliability: Federal actions needed to promote stronger research practices. Available at: https://www.gao.gov/products/gao-22-104411.

[207] National Academies of Sciences, Engineering, and Medicine. (2019). Reproducibility and replicability in science. *The National Academies Press.* Available at: https://doi.org/10.17226/25303

[208] National Academy of Medicine, Learning Health System Series. (2024). The state of the U.S. biomedical and health research enterprise: Strategies for achieving a healthier America. *National Academies Press.* Available at: https://doi.org/10.17226/27588

efforts and resources, and would be empowered to develop and set minimum standards to establish rigor in research that can be applicable across all federal biomedical research funders.

Finally, Congress should advance legislation that would improve the quality of important pre-clinical research. Congress should amend in statute or direct via authorizing or appropriations report language to require the Director of the NIH to establish a pre-grant review support program to assist researchers with their applications to ensure they have the necessary rigor and transparency before the formal grant review.

Improving Domestic Investments in Translational Research

The U.S. continues to struggle to efficiently translate early-stage scientific discoveries into clinical and commercial applications, particularly where promising biology lacks validated targets, scalable manufacturing pathways, regulatory-ready evidence packages or a clear path for private capital to assume development risk. Scholars and policymakers have long described this bottleneck as the "valley of death," the high-risk stage between early laboratory findings and their development into approved therapies.[209,210] The gap persists because the U.S. has not consistently and strategically invested in the infrastructure, incentives and dedicated funding mechanisms to carry discoveries through proof-of-concept to early clinical stage development.[211] The scale of the challenge is significant: the vast majority of drug candidates that enter human testing ultimately fail, frequently because early-stage models do not predict how a compound will perform in people, and the translational pathway that does succeed takes years and consumes a disproportionate share of total research and development costs.[212]

Congress' principal response to this gap was to establish the National Center for Advancing Translational Sciences (NCATS) and its Clinical and Translational Science Awards (CTSA) program to address translational bottlenecks, advance regulatory science, develop shared infrastructure and capabilities and de-risk promising science for further investment. While these programs have yielded important successes, they have also drawn sustained expert scrutiny that points in two directions: toward reforming how the CTSA program is prioritized and measured, and toward improving how NCATS is organized internally. On the first, an early review by the Institute of Medicine of the CTSA program—the extramural network of more than 60 academic hubs—called for sharper prioritization of the network's translational and training mission, stronger metrics for hub performance and better integration across each of the centers.[213] A more recent evaluation finds those concerns only partially resolved, because the CTSA network still lacks a systematic, shared framework for measuring the real-world impact of its translational activities.[214] On the second, the assessment is more favorable: a 2025 Milken Institute report points to NCATS' intramural model—which organizes scientists into cross-disciplinary teams targeting specific translational bottlenecks rather than siloed principal-investigator labs—as a template that should guide any broader

[209] Coller B. S., Califf R. M. (December 2009). Traversing the valley of death: A guide to assessing prospects for translational success. *Science Translational Medicine*. Available at: https://doi.org/10.1126/scitranslmed.3000265
[210] Davidson P. L. et al. (October 2025). Editorial: Impact evaluation using the translational science benefits model framework in the National Center for Advancing Translational Science Clinical and Translational Science Award program. *Frontiers in Public Health*. Available at: https://doi.org/10.3389/fpubh.2025.1707595
[211] Barbosu S., Fereydooni S. (December 2025). How NIH-funded science supports US biopharmaceutical innovation. *Information Technology and Innovation Foundation.* Available at: https://itif.org/publications/2025/12/15/how-nih-funded-science-supports-us-biopharmaceutical-innovation/
[212] ScienceInsights. (March 2026). What is translational science? Definition and examples. Available at: https://scienceinsights.org/what-is-translational-science-definition-and-examples/
[213] Institute of Medicine. (2013). The CTSA program at NIH: Opportunities for advancing clinical and translational research. *The National Academies Press.* Available at: https://doi.org/10.17226/18323
[214] Davidson P. L. et al. (October 2025). Editorial: Impact evaluation using the translational science benefits model framework in the National Center for Advancing Translational Science Clinical and Translational Science Award program. *Frontiers in Public Health*. Available at: https://doi.org/10.3389/fpubh.2025.1707595

reorganization of NIH's 27 institutes and centers, alongside recalibrating NIH's peer-review incentives to reward bold, cross-cutting proposals over safe, incremental ones.[215]

Complementing these institutional reforms, other researchers have proposed more targeted fixes: formal risk-assessment tools that help investigators and funders evaluate a translational project's prospects before committing resources,[216] restructured academic incentives and dedicated translational education tracks to build a stronger pipeline of translational scientists[217] and closer, earlier academia-industry partnerships to share the technical, regulatory and market risk that individual institutions cannot absorb alone.[218] Taken together, these strands of expert opinion suggest that closing the translational gap will require not just more funding but also structural changes to how NCATS and the CTSA network are organized, evaluated and connected to the broader research and industry ecosystem.

PhRMA offers the following concrete policy options to strengthen the domestic translational research ecosystem through public-private partnerships.

First, Congress should reauthorize NCATS through interconnected enhancements. Congress should reconstitute NCATS' core mission so its authorizing statute defines NCATS' job as de-risking translational research for qualified private-sector, academic and nonprofit partners to take forward—not building out a government-run parallel drug development enterprise. NCATS-supported projects should preserve clear IP ownership, enable voluntary licensing on commercially reasonable terms and avoid conditions that would undermine patent rights, data exclusivity or market-based reimbursement. The statute should encourage, for every NCATS-funded translational project, industry co-investment (a matched financial or in-kind contribution—such as cost-sharing, compounds, technology or staff time) and industry input on project design, rather than leaving industry involvement optional, with an exception process for areas where industry does not, historically has not or is not likely to invest.

Second, Congress should grant NCATS its own statutory Other Transaction Authority, modeled on BARDA's OTA under the Pandemic and All-Hazards Preparedness Act. Today NCATS can use other transactions only through the Cures Acceleration Network (CAN), where the authority is confined to CANs' statutory purpose of accelerating high-need cures, capped at 20 percent of CAN's annual appropriation, and dependent on CAN funding levels that leave only about $15 million available for such agreements in FY2026. Those limits prevent NCATS from using flexible, milestone-based agreements across its broader translational-level partnership mission and at a scale sufficient to attract a meaningful level of co-investment. A dedicated, center level authority, freed from the CAN purpose limitations and the 20 percent cap would allow NCATS to enter into flexible public-private partnership agreements with pharmaceutical and biotechnology companies.

Finally, Congress should remove or substantially modify the restriction on NCATS funding clinical trials beyond Phase II, but only in defined circumstances of market failure—such as rare diseases, antimicrobial resistance and neglected conditions—where there is demonstrated unmet medical need.

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[215] Krofah E., Choe S. H. (November 2025). The future of US biomedical research and innovation: Recommendations for action. *Milken Institute.* Available at: https://milkeninstitute.org/content-hub/research-and-reports/reports/future-us-biomedical-research-and-innovation-recommendations-action

[216] Coller B. S., Califf, R. M. (December 2009). Traversing the valley of death: A guide to assessing prospects for translational success. *Science Translational Medicine*. Available at: https://doi.org/10.1126/scitranslmed.3000265

[217] Gamo, N. J. et al. (February 2017). Valley of death: A proposal to build a "translational bridge" for the next generation. *Neuroscience Research*. Available at: https://doi.org/10.1016/j.neures.2016.11.003

[218] Fernandez-Moure J. S. (June 2016). Lost in translation: The gap in scientific advancements and clinical application. *Frontiers in Bioengineering and Biotechnology*. Available at: https://www.frontiersin.org/journals/bioengineering-and-biotechnology/articles/10.3389/fbioe.2016.00043/full

The legislative language should explicitly require that any NCATS engagement in Phase IIb or beyond be structured as a matched public-private partnership agreement, with industry co-investment requirements and pre-negotiated terms that clearly delineate each party's role. Any government's financial return on co-investment should be defined upfront in the partnership agreement—through commercially reasonable mechanisms such as royalties, revenue-sharing, equity or warrants or licensing rights to jointly developed IP, with no pricing conditions, compulsory licensing triggers, march-in expansion, reference-pricing requirements or other price controls attached to the award. Any returns received should flow back to NCATS/NIH to be reinvested in future translational partnership awards, rather than to Treasury general funds.

In addition, Congress should establish by statute a National Translational Science Investment Fund—administered jointly by NCATS and a newly constituted public-private governance board including pharmaceutical, biotechnology, patient group and venture capital representation. The new fund should provide federal matching capital for industry-identified translational bottlenecks at the T1 (bench-to-clinic) stage, with industry required to co-invest at a negotiated amount (and provides a mechanism to provide a government ROI through equity, royalties or revenue sharing). It should also prioritize investments in platform technologies, shared preclinical infrastructure and regulatory science tools that benefit multiple therapeutic programs rather than single proprietary programs. Finally, Congress should set a statutory target of increasing the translational share of NIH-adjacent federal research investment over a decade, with annual reporting to Congress.

PhRMA believes that the proposed governance board structure with voting seats for pharmaceutical companies, biotechnology associations, venture capital, patient and clinical research expertise and an observer seat for the FDA, would help ensure that investment priorities are shaped from the beginning by scientific feasibility, regulatory expectations, patient need, manufacturing scalability and the likelihood of attracting follow-on investment. Such an Investment Fund would provide a durable validation, replication and implementation pathway for addressing translational bottlenecks, complementing ARPA-H's role, which focuses on catalyzing time-limited, high-risk pursuits. The co-investment requirement would help ensure that government capital follows genuine industry commitment, rather than funding research that industry has already deemed commercially unviable.

Finally, Congress should direct NCATS to strengthen the 60+ CTSA hub institutions as a national delivery and learning network through the following improvements. First, it should establish a standing FDA Liaison Office and regulatory strategy capability, staffed with personnel experienced in investigational new drug application (IND) preparation and FDA engagement, to serve as the translational bridge between academic discovery and industry development by providing integrated nonclinical, clinical, chemistry, manufacturing, and controls (CMC), regulatory and operational support that improves IND readiness and execution.

Furthermore, NCATs should establish a national pre-competitive data sharing consortium—modeled on the Foundation for the National Institutes of Health Biomarkers Consortium—through which CTSA hubs, FDA and pharmaceutical company partners share de-identified clinical research data, biomarker data and failed compound data to accelerate target validation and reduce duplicative development failures.

Finally, CTSA hub award renewal should be conditioned on the ability to maintain formal co-development agreements with industry partners. Potential legislative vehicles to achieve this could include a statutory amendment to the CTSA program authorization within 42 U.S.C. § 287, requiring FDA Liaison Office capacity and industry co-development agreements as conditions of hub renewal. The pre-competitive data-sharing framework could be structured under NCATS' existing CAN authority (42

U.S.C. § 287a) with new interoperability standards obligations modeled on 21st Century Cures Act health data provisions. The FDA liaison function is partially contemplated in the Clinical Trial Modernization Act's (S.4440 / H.R.3521) FDA-NIH coordination provisions.[219]

Preserving the FDA Approval Framework That Drives Innovation

The policies discussed above are designed to produce more new medicines; sustaining that innovation depends equally on preserving the framework that ensures those medicines are safe and effective and that rewards the developers who invest to bring them to patients. The premarket-approval standard is the cornerstone of that framework, and the incentives reflected in the Federal Food, Drug, and Cosmetic Act (FDCA) depend on it. Compounding under sections 503A and 503B of the FDCA is intended to be a narrow, conditional exception intended to meet the individualized clinical needs of identified patients, not to provide broad commercial market access for mass-produced copies of medicines that have never been shown to be safe or effective. When the compounding provisions are used to supply unapproved copies of innovative medicines at scale, they become an alternative route to market that bypasses FDA review, exposes patients to the heightened risks of products that have not undergone premarket evaluation and, as FDA has recognized, reduces the incentive for applicants to seek FDA approval of drug products.[220] ***PhRMA urges Congress to protect this framework as a core component of bolstering U.S. biopharmaceutical innovation***.

Rigorous clinical development and FDA premarket review is the only reliable way to establish that a new medicine is safe and effective. A hypothesis about how a substance might perform, anecdotal experience, practitioner opinion and testimonials are not valid clinical evidence and cannot substitute for adequate and well-controlled clinical trials, and the studies supporting an innovative medicine cannot be assumed to apply to a copy that has not been shown to be therapeutically equivalent. History has repeatedly shown the human cost of dispensing drugs that have not met this standard: the 1962 Drug Amendments that required manufacturers to demonstrate substantial evidence of effectiveness, in addition to safety, to obtain FDA approval, followed the thalidomide tragedy, in which an untested teratogen prescribed to pregnant women caused an untold number of miscarriages, infant deaths and severe birth defects.[221] The E-Ferol crisis, in which an untested formulation of a simple vitamin killed more than 80 newborns, reinforced the same lesson.[222] Because premarket testing and approval are the only way to reliably prevent such tragedies, protecting the approval framework is critical to ensuring both patient safety and continued incentives for innovation.

The investment required to earn that approval is substantial, and the incentive to make it is not indestructible. As discussed above, developing a single innovative medicine takes roughly a decade and, by recent estimates, more than $2.6 billion,[223] and the risk of failure is high at every stage.[224] Even then, a sponsor must submit a marketing application supported by complete study reports and patient-level data, detailed labeling and manufacturing information, and a substantial user fee, after which roughly 10 percent of applications are not approved despite completed Phase 3 trials.[225] Manufacturers undertake this

[219] H.R.3521 – Clinical Trial Modernization Act. Available at: https://www.congress.gov/bill/119th-congress/house-bill/3521
[220] FDA's "reduce the incentive" statement — FDA's March 2019 503B bulk-substances evaluation, plus 84 Fed. Reg. 7384.
[221] Thalidomide — Abigail Alliance, 495 F.3d 695 (D.C. Cir. 2007), citing Teff & Munro.
[222] E-Ferol — United States v. Hiland, 909 F.2d 1114 (8th Cir. 1990).
[223] $2.6 billion / 10 years — Lilly Key Facts and Deloitte (2026).
[224] Attrition (90% preclinical; 43.6% / 51.4% / 41%) — Pammolli (2020), Sun (2022), and Schuhmacher (2025).
[225] Marketing application, user fee ($4.70 million), and ~10% non-approval — 21 U.S.C. 355(a)/42 U.S.C. 262(a)/21 C.F.R. 314.50, FDA FY2025–26 user-fee rates, and BIO's 2011–2020 success-rates report.

risk because the FDCA preserves the incentive to do so, and allowing unapproved compounded copies to compete with approved medicines erodes that incentive directly.

These concerns are not theoretical. Compounded products are not reviewed for safety, effectiveness or quality before they reach patients, are not produced under the current good manufacturing practice requirements that apply to approved drugs, and in many states are not subject to full USP sterile-compounding standards, despite the fact that the sector has a documented history of serious quality failures, from the 2012 New England Compounding Center meningitis outbreak that caused more than 60 deaths and 750 infections[226] to the more than 75,000 units of compounded GLP-1 products recalled since 2022.[227] The appropriate pathway for an unapproved substance with genuine therapeutic promise is the investigational new drug process, with its informed-consent, institutional-review, adverse-event-reporting and FDA-oversight protections, not mass compounding that subjects patients to what amounts to uncontrolled and unconsented experimentation. ***PhRMA therefore urges Congress to reaffirm and protect the premarket-approval framework and to address the proliferation of illegal mass compounding through enforcement rather than expanded availability. The unregulated mass manufacturing of unapproved copies of innovative medicines is both a serious patient-safety concern and a direct threat to the innovation this Committee seeks to bolster.***

Boosting Domestic Clinical Trials

The United States faces a structural challenge in conducting clinical trials efficiently. China, by contrast, has spent the past decade building out Phase 1 trial infrastructure at scale, with purpose-built trial units, streamlined regulatory pathways and centralized site networks that reduce trial times and lower costs. Rebuilding and modernizing U.S. clinical trial capacity is therefore not merely an administrative reform priority; it is a patient-access, national security and economic competitiveness imperative critical to public health and resilience. Congress should pair any new HHS and FDA initiatives with measurable actions that improve the research infrastructures and reduce trial start-up timelines, harmonize and centralize IRB processes, expand decentralized and community-based trial infrastructure, ensure broad participation of representative populations without imposing rigid quotas and preserve FDA's science-based evidentiary standards. PhRMA applauds HHS' recent announcement under "Operation TrialBlazer" of a set of new HHS and FDA initiatives to accelerate and modernize clinical research.[228]

PhRMA supports comprehensive reforms of the IND and IRB frameworks as foundational elements of maintaining U.S. competitiveness in early-phase clinical research, including predictable FDA feedback timelines, clear standards for first-in-human packages, broader reliance on central IRBs and policies that reduce duplicative site-level reviews without weakening human-subject protections. [229] In particular, PhRMA looks forward to commenting on the proposed FDA pilot intended to shorten the time from drug discovery to first-in-human studies and reduce early-stage development timelines by six to twelve months, as well as sharing other ideas for how FDA can work to remove barriers to conducting clinical trials in the U.S. while maintaining the high level of human subject protection underpinning the IND and IRB regulations. We also note FDA's legislative proposal to advance a "Expedited IND pathway in statute," and support Congress considering statutory changes in combination with a public process to more comprehensively reform the IND/IRB regulations through rulemaking.

[226] NECC outbreak — CDC.
[227] GLP-1 recalls — FDA recall data.
[228] HHS. (2026). Operation TrialBlazer: HHS Roadmap to Maintaining U.S. Leadership in Early Clinical Research and Development. Available at: https://www.hhs.gov/sites/default/files/operation-trialblazer.pdf
[229] *Ibid.*

PhRMA supports the establishment of a national IRB network to share best practices, establish consistency benchmarks, standardize training requirements and pre-qualify clinical trial sites. Such a network would reduce site-by-site startup friction and create a more efficient and predictable review environment for multi-site and first-in-human studies.

PhRMA also supports efforts to integrate clinical research into routine health care. By establishing reusable, point-of-care clinical trial platform networks as a part of the broader expansion of decentralized clinical trials, the U.S. could create a scalable infrastructure that reduces per-trial costs, accelerates enrollment timelines and expands participation beyond large academic medical centers to community health care settings. PhRMA believes that a cross-agency structure—integrating FDA, NIH, ARPA-H, CMS, and the Office of the National Coordinator for Health Information Technology (ONC)—would ensure that platform data standards align with federal interoperability requirements. This would also help real-world data generated through these networks meet the evidentiary bar for regulatory submissions, while preserving patient privacy, cybersecurity, data quality and FDA's independent role in determining whether evidence is fit for regulatory decision-making. Congress should ensure that interoperability policies facilitate research use of high-quality data without creating mandatory data-sharing obligations that compromise proprietary information, trade secrets or patient trust. This would support a more efficient pathway from clinical research to product approval and patient access.[230] This effort should be appropriately resourced and structured to avoid imposing an unnecessary burden on the clinical trial infrastructure through excessive bureaucratic processes. In addition, Congress and FDA should advance the use of digital health technologies (including wearables, sensors and electronic patient-reported outcome tools) that complement the decentralization of clinical trials through remote data capture. For a patient in a rural community, these tools can be the difference between having a trial option and having none. Hybrid and fully remote trial designs that draw on local health care providers, laboratories, imaging centers and electronic health record data sharing allow patients to participate from their own communities rather than traveling hours to a distant site, taking unpaid time away from work or arranging extended caregiving. Advancing these tools alongside point-of-care platforms would expand the geographic and demographic reach of U.S. clinical research while lowering the practical burden that trial participation places on patients and their families.

PhRMA supports several critical reforms that would reduce barriers to participation in clinical trials. To ensure appropriate compensation for participation does not penalize volunteers, Congress should amend the Internal Revenue Code so that trial participation stipends and per-diems, travel support, lodging, meals, digital health technologies, translation services, childcare and caregiver support provided by sponsors are not considered taxable income and are not counted against income limits for programs such as Medicaid, subject to guardrails that preserve informed consent and prevent coercion.[231] In addition, Congress should expressly permit sponsor support for travel, parking, food, lodging, copays, digital health technologies and other types of support for clinical trial participants under anti-kickback statutes to facilitate clinical trial participation, removing legal uncertainty that may deter sponsors from offering support and enabling decentralized trial models that reduce geographic barriers.[232] Congress

[230] Alignment with CMS/ONC data standards should seek to facilitate interoperability but should not conflate FDA's regulatory evidentiary standards with payer coverage or quality-measure evidence needs, nor create mandatory data requirements outside FDA's statutory role.

[231] *See:* Clinical Trial Modernization Act (S. 4440, H.R. 3521)

[232] This could be achieved legislatively by amending relevant ant-kickback statutes to include appropriate exceptions for clinical trial supports that pose low risk of fraud and abuse, such as the federal Anti-Kickback Statute at 42 U.S.C. § 1320a-7b(b)(3), or administratively by adding new regulatory safe harbors under HHS' authority at 42 C.F.R. 1001.952. The HHS OIG recently published a Request for Information seeking feedback on issuing such a new regulatory safe harbor under HHS' department-wide initiative "Operation TrialBlazer." HHS Office of Inspector General, *Medicare and State Health Care Programs: Fraud and*

should also require FDA to address barriers to using local health care providers (HCPs) in decentralized clinical trials (DCTs), by clarifying that local health care providers need not be directly nor significantly supervised by trial investigators when they perform activities within the scope of their routine area of clinical practice to support a decentralized clinical trial, and exempt such HCPs from financial disclosure requirements. And finally, Congress should authorize clinical research coordination as a reimbursable care management activity for participating sites under Medicare and Medicaid (as included in H.R. 3521).

Scientific Talent and the Biomedical Workforce

The innovative biopharmaceutical sector is a major economic strength of the United States, supporting millions of well-paying U.S. jobs. The industry grew its U.S. workforce by 30.8 percent from 2015 to 2022—far outpacing overall U.S. manufacturing (3.8 percent) and overall U.S. private sector (8.8 percent) employment growth over the same period.[233] As the biopharmaceutical industry seeks to tackle increasingly complex diseases and expand its domestic R&D and manufacturing footprint, STEM workforce needs are growing to match. The Bureau of Labor Statistics estimates that the U.S. will need an additional one million jobs in production occupations each year from 2025 to 2034.[234] During that period, the biopharma sector alone is expected to require 30,000 biomanufacturing workers annually, of which close to half are in skill-based roles that can be created through investments in re-skilling the existing adult workforce.[235] PhRMA member companies have backed that demand with direct investment: biopharmaceutical companies and their foundations have contributed $180 million to STEM education, reaching 111 million students and nearly 183,000 teachers through 37 industry-initiated programs.[236] Our industry has shown that public-private partnerships are a valuable pathway to successfully recruit and retain scientific talent, and should be promoted and supported

PhRMA supports policies that strengthen and support the STEM workforce and urges the Committee to consider the following actions to cultivate domestic scientific talent that is more collaborative, efficient, and effective:

- Create a national biomedical service corps focused on research and manufacturing expertise and provide financial incentives in exchange for working in designated roles or locations for a set period (included in H.R.2756; S.1387 National Biotechnology Initiative Act of 2025).
- Authorize and fund a reciprocal biotech professional exchange program that rotates biotech experts across government, industry and academia to improve coordination, policy quality and innovation outcomes (included in H.R.2756; S.1387 National Biotechnology Initiative Act of 2025).
- Explore incentives for early-career scientists, clinical research professionals, biostatisticians, regulatory scientists, process engineers, advanced-manufacturing technicians and data science talent to remain in or relocate to the U.S., including targeted tax incentives, loan repayment,

Abuse; Request for Information Regarding the Federal Anti-Kickback Statute and Beneficiary Inducements CMP, 91 Fed. Reg. 37902 (June 24, 2026).

[233] TEConomy Partners. (May 2024). The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. Available at: https://cdn.aglty.io/phrma/policy-issues/research-ecosystem/economy/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.

[234] Farrell R., Ice L. (May 2026). Producing the goods of the future: Job opportunities in manufacturing. *U.S. Bureau of Labor Statistics.* Available at: https://www.bls.gov/careeroutlook/2026/article/manufacturing.htm

[235] TEConomy Partners. (June 2026). Beyond Bricks and Mortar: The Workforce Skilling Investments Behind the Biopharmaceutical Industry's U.S. Manufacturing Expansion. Available at: https://www.teconomypartners.com/wp-content/uploads/2026/06/TEConomy-PhRMA-Workforce-Skilling-Report-vFinal2.pdf

[236] *Ibid*.

housing support in high-cost research hubs, apprenticeships and modernized high-skilled immigration pathways for individuals trained in strategically important biomedical fields.
- Build AI fluency into the education of future STEM talent as an overarching imperative to remain competitive on the global stage, ensuring that the future STEM workforce is able to implement and use AI tools to accelerate biomedical research through responsible and ethical application.

Lessons from the Inflation Reduction Act and CHIPS and Science Act

PhRMA submits that the IRA's impact illustrates what policymakers should seek to avoid when designing policies to help start-ups and other early-stage companies innovate and grow.

- Rather than demonstrating positive lessons learned, analysis shows that the law's drug pricing provisions have led to a nearly 70 percent decline in early-stage asset investment since the law was introduced.[237]
- Empirical evidence shows that the IRA is associated with a contraction in industry clinical development activity, which is antithetical to innovation and growth.
- Studies have observed a 25 percent decline in clinical trials testing new small molecule medicines since the IRA's passage, a 30 percent decline in post-approval trials on those medicines, and an even steeper drop—over 47 percent—in post-approval small molecule drug trials in cancer.[238,239]
- Looking forward, economists estimate that investments in R&D for small molecule medicines are expected to decrease by approximately $232 billion over the next 20 years, resulting in an estimated 188 fewer small molecule advances.[240]

Far from being weakened by international competition, the innovative biopharmaceutical industry in the United States is strengthened by its ability to leverage global resources and has demonstrated sustained growth, stability and economic resilience over many years, making the industry a key driver of the U.S. economy. These advantages did not arise by accident; they are the product of a policy environment built over decades around strong intellectual property rights, predictable patent and regulatory data-protection rules, competitive R&D tax treatment, a best-in-class regulatory system, a robust public-private research ecosystem, globally integrated supply chains and a market-based system that incentivizes and rewards biopharmaceutical innovation. PhRMA believes that the consequential question for U.S. policymakers is whether the United States is doing everything it can to remain the world's best place to discover, develop and manufacture new medicines.

Ultimately, the Committee should treat biopharmaceutical innovation policy as an integrated competitiveness agenda. Congress should avoid government price controls and pricing conditions that reduce expected returns on high-risk research, preserve strong patent and regulatory data-protection rules, modernize FDA and clinical-trial infrastructure, support voluntary public-private partnerships that respect

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[237] Schulthess D.G. et al. (April 2025). The Inflation Reduction Act's Impact Upon Early-Stage Venture Capital Investments. *Ther. Innov Reg Sci*. Available at: https://link.springer.com/article/10.1007/s43441-025-00773-3

[238] Long G. (March 2026). Trends in Industry-Sponsored Clinical Trial Activity Since Passage of the Inflation Reduction Act. *Journal of Medical Economics.* Available at: https://www.tandfonline.com/doi/full/10.1080/13696998.2026.2646075#abstract

[239] Zheng H., Patterson J., Campbell J. (April 2025). The Inflation Reduction Act and Drug Development: Potential Early Signals of Impact on Post-Approval Clinical Trials. *Ther Innov Reg. Sci*. Available at: https://link.springer.com/article/10.1007/s43441-025-00774-2?utm_source=costcurve.beehiiv.com&utm_medium=newsletter&utm_campaign=more-evidence-that-the-ira-s-warped-incentives-are-reducing-research&_bhlid=17385a256db5ceff61373dd14a44c4b7af27a4ef

[240] Philipson T., Ling Y., Chang R. (October 2023). The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act. *The University of Chicago*. Available at: https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2023/10/Small-Molecule-Paper-Final-Oct-5-2023.pdf

IP and ensure the United States remains open to global scientific collaboration while strengthening domestic discovery, development and manufacturing capacity.

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PhRMA appreciates the opportunity to provide comments on the proposals to lower drug prices for patients outlined in the request for information and looks forward to working with Congress and other key stakeholders to continue to advance innovative medicines for patients. Please feel free to contact Elizabeth Carpenter (ECarpenter@phrma.org) and Michael Woody (MWoody@phrma.org) with any questions.

Sincerely,

/s/

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Elizabeth Carpenter

Executive Vice President, Policy and Research

/s/

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Michael Woody

Senior Vice President, Federal A