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August 17, 2026

The Honorable Ron Wyden
United States Senator
Ranking Member, Committee on Finance

Dear Ranking Member Wyden,

The Academy of Managed Care Pharmacy (AMCP) thanks the Senate Finance Committee Minority Staff for the opportunity to provide comments in response to the request for information titled Commonsense Policy Options to Lower Drug Prices for Patients.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 300 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.[1]

Section I. Bolstering Medicare's Ability to Negotiate Lower Drug Prices

AMCP welcomes the opportunity to provide feedback on policies to improve prescription drug affordability for America's seniors. Managed care pharmacists design and implement prescription drug coverage for nearly 55 million seniors enrolled in plans that offer the Part D benefit.[2] Our members leverage their expertise in analyzing clinical and scientific evidence to encourage the appropriate use of medications to enhance patient and population health outcomes while optimizing the use of limited health care resources.[3] Managed care pharmacists working within Medicare Part D plans and pharmacy benefit

[1] Academy of Managed Care Pharmacy. *About AMCP.* Available at https://www.amcp.org/about,
[2] Cubanski, J., & Damico, A. (2025, July 16). *Key facts about Medicare Part D enrollment, premiums, and cost sharing in 2025*. KFF. https://www.kff.org/medicare/key-facts-about-medicare-part-d-enrollment-premiums-and-cost-sharing-in-2025/
[3] Happe LE, Edgar BS. A primer on managed care pharmacy. J Manag Care Spec Pharm. 2023 Dec;29(12):1371-1376. doi: 10.18553/jmcp.2023.29.12.1371.

managers (PBMs) leverage formulary design and utilization management tools, such as prior authorization and quantity limits, to reduce plan costs by negotiating lower net prices and encouraging beneficiaries to use high-value treatments. Our members ensure that seniors have access to the medications they need to treat their conditions.

The Medicare Drug Price Negotiation Program (MDPNP), along with inflation rebates, capping out-of-pocket costs for beneficiaries in Part D, and other reforms in the *Inflation Reduction Act (IRA)*, is delivering savings to the federal government and patients. As the RFI notes, the Maximum Fair Prices (MFPs) for the first 25 drugs selected under the MDPNP would have saved the federal government roughly $18 billion had they been in effect during the applicable look-back period.[4,5] There are several issues with CMS's calculation that may overstate MFP savings. For instance, CMS compares MFPs to the list prices of selected drugs, which ignores the discounts negotiated by Part D plans.[6] The $18 billion in savings relies on the assumption that net prices for the selected drugs remain constant, whereas research indicates that net prices decline each year a brand product is on the market.[7] Finally, selected drugs are not subject to the Manufacturer Discount Program (MDP), which means that liability shifts from manufacturers to Part D plans (and the federal government through increased Part D bids).[8] More research is needed to understand how the IRA's changes to Medicare Parts B and D impact beneficiary and total costs.

Factoring International Pricing into Negotiation

Prescription drugs are the fastest-growing component of health care spending in the US, driven by increased prices for and utilization of specialty drugs.[9] There are several factors that explain why Americans pay higher prices: manufacturers are allowed to set list prices for brand drugs, often increasing prices after launch;[10] compared to other developed

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[4] Centers for Medicare & Medicaid Services. 2024. *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026*. Fact sheet. https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf.

[5] Centers for Medicare & Medicaid Services. 2025. *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027.* Fact sheet. https://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf.

[6] Klaisner, J., Holcomb, K., & Simenc, D. (2026, January 12). *Medicare drug price negotiation: Navigating the next wave of maximum fair prices*. Milliman. https://www.milliman.com/en/insight/medicare-drug-negotiation-next-maximum-fair-prices.

[7] Lin CH, Campbell JD, Motyka J, Cohen JT. US Drug Pricing Patterns Before Loss of Exclusivity. Value Health. 2025 Jun;28(6):907-914. doi: 10.1016/j.jval.2025.03.008.

[8] Klaisner, J., Holcomb, K., & Simenc, D. (2026, January 12). *Medicare drug price negotiation: Navigating the next wave of maximum fair prices*. Milliman. https://www.milliman.com/en/insight/medicare-drug-negotiation-next-maximum-fair-prices.

[9] Niu S, Happe LE, Abuloha S, Svensson M. Concentration of spending and share of specialty drug spending in Medicare Part D over a 10-year period. J Manag Care Spec Pharm. 2024 Dec;30(12):1355-1363. https://doi.org/10.18553/jmcp.2024.30.12.1355.

[10] Bosworth, A., Sheingold, S., Finegold, K., Sayed, B. A., De Lew, N., & Sommers, B. D. (2023, October 6). Changes in the list prices of prescription drugs, 2017-2023 (HP-2023-25). Office of the Assistant Secretary for Planning and Evaluation, U.S.

countries, manufacturers in the US benefit from longer exclusivity windows and can prevent competition using patent thickets and other strategies to maintain monopoly pricing for longer;[11] and, unlike many peer nations, manufacturers and hospitals negotiate coverage and reimbursement with many payers, which reduces payer negotiating power and may increase net spending.[12,13] As the RFI notes, the US pays 3 to 4 times more on average for brand drugs than peer nations.

It is understandable that policymakers would seek to leverage external reference pricing to reduce US drug costs. The MDPNP has substantially reduced prices for selected drugs, but net costs remain significantly higher than in other high-income countries. A recent article published in the Journal of Managed Care & Specialty Pharmacy assessed how the MFPs for the IPAY 2027 selected drugs compare with prices in most-favored-nation reference countries. The researchers found that MFPs were nearly 40% lower than estimated US net prices but remained more than double the average list price in reference countries for the Global Benchmark for Efficient Drug Pricing (GLOBE) and Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Models.[14] This estimate likely understates the disparity between MFPs and international prices because the authors did not account for price concessions that manufacturers of selected drugs offer to comparator countries, which are often confidential. Moreover, many reference countries determine pricing and reimbursement based on the findings of health technology assessment (HTA) bodies that evaluate both clinical and economic evidence.[15] HTA bodies often perform cost-effectiveness analyses (CEA) that use metrics such as quality-adjusted life years (QALYs) or disability-adjusted life years (DALYs) to assess the added value of new pharmaceuticals and to guide health care decisions.[16] AMCP supports the use of quality metrics and CEAs to guide coverage and

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Department of Health and Human Services. https://aspe.hhs.gov/sites/default/files/documents/e24f630a33f0a0585337c65745904487/aspe-drug-price-tracking-brief.pdf.

[11] American Economic Liberties Project & Initiative for Medicines, Access, & Knowledge (I-MAK). (2023, May). The costs of pharma cheating. American Economic Liberties Project. https://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf.

[12] U.S. Government Accountability Office. (2023, September 5). Medicare Part D: CMS should monitor effects of rebates on plan formularies and beneficiary spending (GAO-23-105270). U.S. Government Accountability Office. https://www.gao.gov/assets/gao-23-105270.pdf.

[13] Feldman WB, Rome BN, Brown BL, Kesselheim AS. Payer-Specific Negotiated Prices for Prescription Drugs at Top-Performing US Hospitals. JAMA Intern Med. 2022 Jan 1;182(1):83-86. https://doi.org/10.1001/jamainternmed.2021.6445.

[14] Gabriel, Nico, Kristi Martin, Emma M. Cousin, Kevin H. Li, Jens Grueger, and Sean D. Sullivan. 2026. "Assessment of IPAY 2027 Medicare Drug Price Negotiation Maximum Fair Prices With Prices in Most-Favored Nation Reference Countries." *Journal of Managed Care & Specialty Pharmacy* 32 (5): 530–539. https://doi.org/10.18553/jmcp.2026.32.5.530.

[15] European Commission, Directorate-General for Health and Food Safety. (2017). Mapping of HTA national organisations, programmes and processes in EU and Norway. Publications Office of the European Union. https://doi.org/10.2875/5065.

[16] Willke, R. J., Pizzi, L. T., Rand, L. Z., & Neumann, P. (2024). The value of the quality-adjusted life years. Value in Health, 27(6), 702-705. https://doi.org/10.1016/j.jval.2024.03.022.

pricing decisions; however, this practice has drawn scrutiny in the US from members of Congress and patient advocacy organizations.

There are compelling reasons why the US *should* spend more than other countries. One important consideration is patient access. Manufacturers often delay market entry in countries that use external reference pricing, leaving patients waiting a year or more to access treatments available in the US.[17,18] Delays in market entry impact patients with rare diseases the most, given that they often lack alternative treatment options. Another important consideration is the impact of lower US prices on drug innovation. Global financing of pharmaceutical innovation is heavily reliant on the US—one analysis found that our market accounts for almost 80% of revenues for recently launched single-source drug products.[19] If the US significantly reduces drug spending without offsetting increases across peer nations, there will be fewer new cures in the future. Finally, operational hurdles may prevent accurate measurement of international net prices. Many countries prohibit manufacturers from disclosing price concessions, which means that CMS would either have to rely on gross prices or estimate net prices in reference countries. In light of these important tradeoffs, AMCP recommends that the committee take a cautious approach when considering policies to inject international reference prices into Medicare negotiations.

AMCP suggests that Congress amend Section 1194(e)(1) of the IRA to enable the Secretary to consider international prices for selected drugs as a negotiation factor, collected as part of the manufacturer-specific data. This would give the government flexibility to negotiate aggressively when US prices are unjustifiably higher than in comparator countries, while also balancing priorities such as maintaining US-based innovation and patient access to selected drugs and their therapeutic alternatives.

Negotiating Lower Prices on More Drugs

AMCP agrees that HHS should be given flexibility to select more qualifying single-source drugs (QSSDs) for negotiation rather than increasing the set number of drugs required under the IRA. Based on the statute and CMS guidance, the agency develops a list of 50 Part B and 50 Part D negotiation-eligible products and then ranks each product based on

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[17] Maini, Luca, and Fabio Pammolli. 2023. "Reference Pricing as a Deterrent to Entry: Evidence from the European Pharmaceutical Market." American Economic Journal: Microeconomics 15 (2): 345–83. https://doi.org/10.1257/mic.20210053.
[18] Fu M, Ghosh R, Taherifard E, Ramachandran R, Ross JS. Novel Drug Launches in Most-Favored-Nation Countries and Medicare Pricing Benchmarks. *JAMA Health Forum.* 2026;7(7):e262340. https://doi.org/10.1001/jamahealthforum.2026.2340.
[19] Murphy, S. (2026, June 23). Measuring the pull-side innovation burden for pharmaceutical drugs by OECD country. U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE). https://aspe.hhs.gov/reports/innovation-burden-pharmaceutical-drugs.

its total combined expenditures. The drugs selected for negotiation are simply the 20 products with the greatest total combined expenditures. Congress should consider how this system impacts incentives for Part D plans, providers that bill for administering drugs under Part B, and manufacturers of both selected and nonselected products before expanding the MDPNP:

- **Part D plans:** The MDPNP and Part D redesign may impact patient access to selected drugs or other products that treat the same condition due to changes in plan design. The statute requires Part D plans to cover selected drugs, though the law and subsequent CMS guidance do not dictate how plans place them on their formularies or manage their utilization through tools such as prior authorization or step therapy.[20] Selected drugs are exempt from the Manufacturer Discount Program, meaning Part D plans assume a greater share of financial risk in the catastrophic phase. For certain high-cost therapies where even the lower MFP would cause a beneficiary to reach the out-of-pocket maximum, Part D plans may design their benefits to encourage the use of therapeutic alternatives. Meanwhile, the MFP serves as a public price benchmark that may be lower than the net prices Part D plans currently pay for therapeutic alternatives. Plans may favor selected drugs over competitors with higher net prices, forcing patients to switch to a different therapy or navigate the exception process. CMS has indicated that it is using its routine oversight of Part D plan formularies to ensure adequate patient access to selected drugs.[21]
- **Providers:** The MDPNP may encourage providers to favor drugs that do not have an active MFP, particularly in fee-for-service. Under Medicare Part B, providers are reimbursed for administered drugs and biologics based on the product's Average Sales Price (ASP) plus a 6% add-on payment Once the MDPNP expands in 2028, CMS intends to reimburse providers based on MFP rather than ASP, lowering both the base and add-on payment. This could significantly reduce the margins providers receive for administering selected drugs, potentially shifting utilization to higher-

[20] Centers for Medicare & Medicaid Services. (2025, September 30). *Medicare Drug Price Negotiation Program: Final guidance, implementation of sections 1191–1198 of the Social Security Act for initial price applicability year 2028 and manufacturer effectuation of the maximum fair price in 2026, 2027, and 2028*. U.S. Department of Health and Human Services. https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.

[21] It may be too early to determine how negotiation affected benefit design and patient access to the first 25 selected drugs and their competitors. AMCP recommends that the committee obtain insight from CMS on how formulary access may have changed in coverage years 2026 and 2027.

priced nonselected alternatives.[22] Medicare Advantage plans may mitigate this incentive by using preferred drug lists or step therapy to ensure that selected drugs are administered rather than higher-cost alternatives.

- **Manufacturers:** Manufacturers of nonselected products are incentivized to increase the amount of price concessions they offer to Part D plans to maintain preferred formulary placement.[23] This may benefit plan sponsors, who can offset the plan's financial risk associated with increased liability in the catastrophic phase. However, beneficiaries may face greater out-of-pocket costs due to increased coinsurance and additional barriers to accessing selected products.

AMCP recommends that Congress give CMS the flexibility to negotiate prices for additional QSSDs to ensure access to the most appropriate and cost-effective medications for Medicare beneficiaries. CMS should be allowed to select additional negotiation-eligible QSSDs that are therapeutic alternatives to 1) negotiation-eligible products that must be selected in the same negotiation cycle based on being in the top 20 combined expenditures during the benchmark period, or 2) products that have an active MFP due to being selected in a previous negotiation cycle. This would require CMS to make a qualitative judgment about which products are therapeutic alternatives before negotiations begin and may necessitate gathering stakeholder input earlier in the negotiation process.

Delivering Lower Negotiated Drug Prices to Patients Faster

AMCP appreciates the committee's interest in accelerating the schedule for when drugs become eligible for negotiation under the MDPNP. AMCP is concerned that shortening the time before biologics or small-molecule drugs enter negotiations may have the unintended consequence of crowding out generic competition. This issue is most pressing in the specialty category, where Medicare spending grew an average of nearly 24% annually over the past decade.[24] Biologic competition can bring down net prices for high-cost treatments

[22] Sachs, R., & Frank, R. G. (2025, April 1). Analyzing the expansion of the Medicare drug price negotiation program to Part B. Brookings Institution. https://www.brookings.edu/articles/analyzing-the-expansion-of-the-medicare-drug-price-negotiation-program-to-part-b/.

[23] Simenc, D., & Huang, P. (2025, December 8). Adapting to the IRA: 5 manufacturer considerations for Part D formulary access negotiations. Milliman. https://www.milliman.com/en/insight/ira-manufacturer-considerations-part-d-formulary-negotiations.

[24] Niu, S., Happe, L. E., Abuloha, S., & Svensson, M. (2024). Concentration of spending and share of specialty drug spending in Medicare Part D over a 10-year period. Journal of Managed Care & Specialty Pharmacy, 30(12), 1355–1363. https://doi.org/10.18553/jmcp.2024.30.12.1355.

by up to 70%.[25] AMCP is concerned that negotiating prices for reference products earlier could dissuade biosimilar manufacturers from developing alternatives. AMCP recommends several market-based approaches to reducing drug prices.

AMCP believes that promoting biologic competition is the most effective way to reduce drug prices. The Hatch-Waxman framework has led to tangible savings for patients and payers in the small-molecule space over the past four decades. Managed care pharmacists have played a key role in this process, applying formulary design principles to encourage patients and providers to use lower-cost generics while maintaining safety and quality standards.[26] Allowing Medicare to set drug prices earlier in their life cycles could disrupt the market-based mechanisms that reduce prices for patients and payers in the long run. When Congress passed the Biologics Price Competition and Innovation Act (PBCIA) in 2010, there was hope that the framework would encourage manufacturers to develop innovative biologics and, over time, help control prices through a robust market for biosimilars. Biosimilars are helping reduce drug spending, with more than $56 billion saved since the first biosimilar was licensed in 2015, but significant work remains to ensure they realize their full potential.[27] The market for biosimilars has been slower to develop due to a variety of factors, including higher research & development costs compared to generics, barriers at the state level that prevent substitution, litigation by reference product patent holders that delay biosimilar market entry, and pricing dynamics in medical and pharmacy benefits that favor the reference product.

Congress should take the following steps to improve biologic competition:

1. **Remove excessive clinical trial requirements that increase the costs of biosimilar development:** Biosimilar development is a costly and time-consuming process, with average development costing $100 million to $250 million and taking 5-8 years before FDA approval.[28] Achieving interchangeability requires conducting additional comparative effectiveness studies, which can take 1-3 years and cost

[25] Myshko, D. (2026, August 4). Biosimilars are driving down costs and increasing access to biologics. Managed Healthcare Executive. https://www.managedhealthcareexecutive.com/view/biosimilars-are-driving-down-costs-and-increasing-access-to-biologics.

[26] Academy of Managed Care Pharmacy. (2025). Access, affordability, and outcomes: The value of managed care pharmacy. https://www.amcp.org/aaoreport-2025.

[27] Association for Accessible Medicines. (2025, September). The U.S. generic & biosimilar medicines savings report. Association for Accessible Medicines. https://accessiblemeds.org/wp-content/uploads/2025/09/AAM-2025-Generic-Biosimilar-Medicines-Savings-Report-WEB.pdf.

[28] Makary MA, Yim S, Ünlü M, Ricci MS. FDA's Regulatory Reforms to Unlock Competition and Lower Drug Costs: Breaking the Biosimilar Bottleneck. JAMA. 2026;335(17):1473–1474. https://doi.org/10.1001/jama.2026.3088.

more than $20 million.[29] The FDA has recently updated guidance on the use of comparative effectiveness[30] and switching studies[31] to demonstrate biosimilarity and interchangeability, respectively. These policies could cut the time and cost required to develop a biosimilar in half. AMCP supports these initiatives and encourages Congress to codify the FDA's guidance, which will provide biosimilar manufacturers with the certainty they need to invest in the US market.

2. **Curb anticompetitive behavior by reference product manufacturers:** Brand manufacturers leverage strategies like patent thickets, pay-for-delay, and sham petitions to delay competition. AMCP supports legislation such as the Eliminating Thickets to Increase Competition Act (S. 2276), the Preserve Access to Affordable Generics and Biosimilars Act (S. 1096), and the Stop STALLING Act (S. 1095), which would limit these behaviors and enable patients to access lower-cost alternatives more quickly. AMCP also supports efforts to streamline patent dispute resolution by adding a "use it or lose it" clause to Hatch-Waxman and limiting damages in lawsuits involving follow-on patents.[32]
3. **Enable pharmacists to substitute biosimilars at the pharmacy counter:** In recent years, the FDA and international regulatory bodies have updated their policies to indicate that switching studies are not necessary to demonstrate interchangeability in most cases. The FDA has consistently affirmed that there is no scientific difference between biosimilars and interchangeable biologics and has recommended that Congress remove the outdated distinction.[33] AMCP believes that Congress should enact the Biosimilar Red Tape Elimination Act (S. 1954), which would ensure that all biosimilars are deemed interchangeable with their reference product. Many states limit pharmacists' substitution authority to interchangeable biologics. This bill will enable pharmacists operating within state law to provide patients with broader access to more affordable treatments for their conditions.

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[29] Ibid.

[30] U.S. Food and Drug Administration. (2025, October). *Scientific considerations in demonstrating biosimilarity to a reference product: Updated recommendations for assessing the need for comparative efficacy studies* (Draft guidance for industry). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/scientific-considerations-demonstrating-biosimilarity-reference-product-updated-recommendations.

[31] U.S. Food and Drug Administration. (2024, June). *Considerations in demonstrating interchangeability with a reference product: Update*. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-demonstrating-interchangeability-reference-product-update.

[32] https://www.capparx.org/the-issue.

[33] Padula, A. (2026, April 22). *FDA releases congressional justification for FY 2027 budget, including proposal regarding interchangeability of biosimilars*. Big Molecule Watch. https://www.bigmoleculewatch.com/2026/04/22/fda-releases-congressional-justification-for-fy-2027-budget-including-proposal-regarding-interchangeability-of-biosimilars/.

AMCP supports removing the orphan drug carve-out to the MDPNP that was included in H.R. 1. The CBO estimates that the Orphan Cures Act will cost Medicare more than $8 billion.[34] This measure delays or forestalls negotiation for several products for which Medicare spends over $1 billion annually. New research indicates that nearly every orphan-designated drug that would otherwise be eligible for negotiation recoups its development costs before negotiated prices would come online.[35] This measure requires patients and taxpayers to pay inflated prices for drugs that have been on the market for a decade or more, without meaningfully supporting orphan drug development.

Developing a Subscription Model to Help Facilitate Access and Lower Pricing on Certain Drugs Utilized by Broad Populations, Including GLP-1s

AMCP thanks the committee for highlighting alternative payment models for prescription drugs. Subscription models may provide payers with greater predictability in deciding whether to cover products such as anti-obesity medications (AOMs). Commercial health plans and large employers are already negotiating innovative contracts to provide their members with access to AOMs. However, AMCP would encourage the committee to consider other alternative payment models that would shift payment for population health drugs from fee-for-service to value-based payment. Our members have helped design and implement value- and outcomes-based payment arrangements (VBPs) that tie payment for a drug to a patient meeting certain agreed-upon benchmarks. Under a VBP, a manufacturer of an AOM may agree to accept a lower upfront payment and receive episodic payments based on treatment durability.[36] This arrangement would enable broader patient access, with the manufacturer and payer sharing long-term savings due to improved population health outcomes.

AMCP encourages the committee to remove barriers to VBPs and enable Medicaid and other payers to adopt innovative approaches to covering AOMs. The Medicaid VBPs for Patients Act (S. 1637) would enable manufacturers to report multiple best prices under the Medicaid Drug Rebate Program. The bill would allow manufacturers and state Medicaid programs to choose between the traditional fee-for-service best price and a

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[34] Silverman, E. (2025, October 20). CBO says revised cost of orphan drug exemptions will add $3.9 billion to Medicare. STAT. https://www.statnews.com/pharmalot/2025/10/20/medicare-orphan-keytruda-rare-disease-darzalex-jnj/.

[35] Chen, J. C., Madsen, C., & Kaltenboeck, A. (2026). The economics of orphan blockbuster drug development. Health Affairs. Advance online publication. https://doi.org/10.1377/hlthaff.2026.00209.

[36] Sexton Ward, A., Trish, E., Goldman, D., & Lakdawalla, D. (2025). *Proposal for a value-based agreement to reimburse anti-obesity medicines in traditional Medicare* [Preprint]. *medRxiv*. https://doi.org/10.1101/2025.07.10.25331289.

"value-based" price for covered outpatient drugs. The bill would exempt sales made under a VBP from the calculation of ASP and Average Manufacturer Price, providing manufacturers with clarity on how these contracts interact with Medicare and Medicaid price benchmarks.

Other Improvements to the Medicare Drug Price Negotiation Program

AMCP encourages the committee to make two additional improvements to the MDPNP beyond those outlined in the RFI.

Direct CMS to select drugs with the highest net spending in Parts B and D, rather than gross spending. Congress should amend section 1191(c)(5) of the IRA to define the term "total expenditures" to mean the total net covered prescription drug costs. Under the Final IPAY 2028 Program Guidance, CMS will identify 50 negotiation-eligible QSSDs based on the highest spending in each of Medicare Parts B and D.[37] CMS will base the list of negotiation-eligible QSSDs in Part D on total gross spending, while the corresponding list in Part B will consider both Part B fee-for-service claims data and Medicare Advantage encounter data. This means that CMS will consider the net prices secured by MA plans for clinician-administered drugs but will not account for discounts negotiated by Part D plans. Without this important context, AMCP is concerned that selections will not reflect the products that have the greatest real cost to the government and beneficiaries.

Selecting drugs that are already heavily rebated may benefit enrollees whose out-of-pocket costs are based on list price. The Part D redesign addresses this concern for many Medicare beneficiaries who are prescribed high-cost medications. Congress should focus the MDPNP on securing the largest discount relative to existing net prices, which will help stabilize the Part D market and benefit all Medicare Part D enrollees by lowering premiums.

Adjust the ceiling price for high-cost QSSDs based on the Manufacturer Discount Program. Currently, manufacturers are exempt from paying the discounts required under the Manufacturer Discount Program for any selected drug with an active MFP. This is designed to provide relief to manufacturers of selected drugs, but mounting evidence suggests the exemption leaves potential savings on the table.[38] The MDP requires

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[37] Centers for Medicare & Medicaid Services. (2025, September 30). *Medicare Drug Price Negotiation Program: Final guidance, implementation of sections 1191–1198 of the Social Security Act for initial price applicability year 2028 and manufacturer effectuation of the maximum fair price in 2026, 2027, and 2028*. U.S. Department of Health and Human Services. https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.

[38] Jeon, Y. K., Martin, K., & Sullivan, S. (2026) "The Interaction Between The Manufacturer Discount Program And Medicare Drug Price Negotiation," Health Affairs Forefront, May 29, 2026. https://doi.org/10.1377/forefront.20260526.802745.

manufacturers to provide discounts on applicable drugs in the Initial Coverage (10%) and Catastrophic Coverage (20%) phases of the Part D benefit. The MDP, which replaced the Coverage Gap Discount Program in 2025, has led to higher mandatory rebates to Medicare, particularly for high-priced medications. One analysis of Part D spending in 2022 found that manufacturer discounts would have more than doubled if the MDP had been in place instead of the Coverage Gap Discount Program, with drugs in the highest-price quartile seeing the greatest increase in discounts.[39] Another study found that the uncapped MDP discounts may outweigh negotiated savings for high-cost drugs. For products like Imbruvica, which has a roughly $180,000 total gross cost per beneficiary, the government's 10% "selected drug subsidy" for Part D plans offsets a significant amount of savings tied to the MFP. Put another way, *manufacturers of certain high-cost therapies may come out ahead by being selected for negotiations rather than paying an open-ended discount under the MDP.* Congress should act to ensure that the MDPNP does not encourage manufacturers to raise list prices of specialty drugs to maximize the benefit of the MDP exemption.

This fix is critical given that high-cost medications make up a growing share of the prescription drug market. New drug launches signal that pressures will only increase. According to the Institute for Clinical and Economic Review (ICER), median annual launch list prices grew by 25% between 2022 and 2024, while median annual launch estimated net prices grew at an even faster rate (33%) after adjusting for drug characteristics and inflation.[40] Medicare faces challenges in managing specialty drug spend given recent changes to the Part D benefit. According to the Medicare Payment Advisory Commission (MedPAC), in 2024, the first year of the Part D redesign, Part D plans experienced a 24% increase in the specialty trend among beneficiaries without low-income subsidies (LIS).[41] Higher specialty utilization and rising net prices have driven Part D spending, which the government is temporarily controlling through the premium stabilization demonstration, at a price tag of $9.8 billion in 2025 alone.[42] Congress can promote sustainable, affordable

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[39] Rome, B. N., Garrett, K. R., & Maini, L. (2025). *Medicare Part D savings under the Manufacturer Discount Program vs coverage gap discounts*. JAMA Network Open, 8(9), e2530778. https://doi.org/10.1001/jamanetworkopen.2025.30778.

[40] Agboola, F., Lin, G. A., Lee, W., Wright, A., Phillips, M., Lee, M., Koola Fisher, C., & Emond, S. K. (2025, October 23). *Launch price and access report*. Institute for Clinical and Economic Review. https://icer.org/wp-content/uploads/2025/10/ICER_2025_Launch-Price-and-Access-Final-Report_For-Publication.pdf

[41] Medicare Payment Advisory Commission. (2026, March). *The Medicare prescription drug program (Part D): Status report* (Chapter 13). In *Report to the Congress: Medicare payment policy*. Medicare Payment Advisory Commission. https://www.medpac.gov/wp-content/uploads/2026/03/Mar26_Ch13_MedPAC_Report_To_Congress_SEC.pdf

[42] U.S. Government Accountability Office. (2026, February 26). *Medicare Part D: Implementation of beneficiary premium stabilization demonstration* (GAO-26-107935). https://www.gao.gov/products/gao-26-107935.

access to selected drugs by reducing the statutory ceiling price based on manufacturer discounts that would otherwise be paid under the MDPNP.

Section II. Enhancing Prescription Drug Affordability

AMCP appreciates Senate Democrats' attention to the affordability of prescription drugs and shares the commitment to improving patient access. Affordable prescription drugs are essential for improving patient care and outcomes. AMCP is concerned that many of the suggestions contained in the RFI will likely not have the effect of lowering overall costs. In general, they propose to regulate plan behavior without necessarily lowering the list price of drugs or adjusting employer incentives. These proposals are likely to substantially increase plan liability while simultaneously limiting their ability to fund care. As a result, these policies risk further destabilization in the Part D and commercial markets, possibly leading plan sponsors to withdraw from the market and leaving patients with few options for coverage.

Lowering Patient Out-of-Pocket Costs

The RFI proposes several ideas for reducing patient out-of-pocket spending:

- Applying out-of-pocket caps to more chronic care drugs in Medicare beyond insulin.
- Determining whether cost-sharing under the deductible and when coinsurance applies should be based on net drug prices or if there are other mechanisms for holding Pharmaceutical Benefit Managers (PBMs) and plans accountable when they prefer high-list price products over lower priced alternatives.
- Expanding eligibility for Part D Low-Income Subsidies (LIS).
- Containing Part D premiums.
- Addressing generic drug price markups.

Out-of-Pocket Costs

Imposing out-of-pocket caps without reducing the list price of drugs increases the risk that premiums will become unaffordable for patients, resulting in more uninsured seniors who would not benefit from caps. Out-of-pocket caps seek to reduce patient spending by imposing limits on how much health plans and PBMs can charge in cost-sharing for a prescription drug, such as co-pays or co-insurance. A study of Utah's 2021 co-pay cap for insulin determined that patient out-of-pocket costs decreased at the point of sale, but plan costs for insulin increased because Utah's law did not affect the list

or wholesale acquisition cost (WAC) prices.[43] Co-pay caps have been described by some as "squeezing the balloon;" only the distribution of the air inside the balloon changes, not the total amount. Because of the underlying cost dynamics, Congress would be more likely to achieve its goal of improved affordability through policies that target the growth of list price.

The Committee should carefully consider whether it is comfortable increasing premiums across all plan enrollees in exchange for lower point-of-sale costs. Despite the public perception, cost-sharing is not based on list price. Instead, cost-sharing is usually calculated in Part D based on the "negotiated price" reported on the prescription drug event—the final, adjudicated Part D claim. This can be very close to WAC but is also often a discounted-WAC benchmark. Because plans and PBMs are prohibited from negotiating upfront discounts on drugs, the net cost of the drug to the plan or PBM is not known at the point of sale. Only after rebate amounts have been retrospectively determined is the true net cost known. This results in higher patient spending at the point of sale but lower premiums. Under the approach favored by the RFI, some high-utilization patients would almost certainly realize overall savings.[44] Low-utilization patients, however, would see their premiums increase without substantial offsets at the pharmacy counter.

A further risk to patient spending of a net-cost approach is that the rebate amount can easily be calculated based on cost-sharing burdens if the cost sharing is not based on aggregated rebates because Part D cost-sharing percentages are publicly reported. In some cases, publicly known figures can produce greater overall savings, but it can also mean many plan sponsors lose negotiating power and costs increase.

Prioritizing savings in one type of spending over another is a legitimate policy decision, but we should be clear-eyed about the downstream impacts of such a decision. If a net-cost model is adopted, it must use aggregated rebate amounts to protect sensitive information regarding rebate negotiation.

AMCP supports expanded eligibility for the Part D LIS.

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[43] Li N, Panchal R, Giannouchos T, Pan RJ, Nguyen D, Nohavec R, Britton L, Chaiyakunapruk N, Biskupiak J, Wilson A, Brixner D. The impact of a statewide insulin copay cap policy for insured patients with diabetes in Utah. J Manag Care Spec Pharm. 2024 Feb 3;30(2):112-117. doi: 10.18553/jmcp.2024.30.2.112. PMID: 38308630; PMCID: PMC10839465. Accessed June 26, 2026. https://pmc.ncbi.nlm.nih.gov/articles/PMC10839465/

[44] Trish, E., Kaiser, K., & Joyce, G. (2020, March). *How would sharing rebates at the point-of-sale affect beneficiary cost-sharing in Medicare Part D?* USC Leonard D. Schaeffer Center for Health Policy & Economics. https://schaeffer.usc.edu/wp-content/uploads/2024/10/Sharing_Rebates_at_POS__Beneficiary_Cost-Sharing_Medicare_PartD_WhitePaper-1.pdf

Generic Drugs

The RFI misses key details regarding the nature of generic drug coverage and reimbursement. As a result, many of the proposed solutions would not benefit patients and in some cases run contrary to other stated goals in the RFI.

The RFI proposes to move pharmacy reimbursement to a cost-plus or NADAC-based model for generic drugs. In practice, many generic effective rates are already tied to NADAC, and the RFI relies too heavily on comparisons to loss leader cash prices on select drugs in its analysis of generic drug pricing.

PBMs do not typically negotiate reimbursement on a drug-by-drug basis, especially for generics. In some cases, there may be a list of maximum allowable cost (MAC) prices in place. MAC price is "the unit price at which a pharmacy benefit manager (PBM) or payer will pay a pharmacy for a generic drug and branded drugs that have generic versions available (multi-source drugs)."[45] Unlike a NADAC-based model, MAC prices are not directly tied to acquisition costs. Because generic drugs are interchangeable and sourced from multiple manufacturers, PBMs will set a MAC price across all generic versions.[46] This promotes the use of drugs with lower acquisition costs. One risk of mandating a cost-plus model is that it may be ineffective in promoting drugs with lower acquisition costs, raising patient out-of-pocket expenses and premium rates. Additionally, NADAC-plus fails to address concerns about pharmacy reimbursement based on drug margin. Because NADAC is an average of all ingredient prices, it presents opportunities for pharmacies to purchase lower than average priced products and receive both margin and an increased dispensing fee.

In other cases, plans will negotiate for overall generic reimbursement through the generic effective rate (GER). This is usually benchmarked as something like "Average Wholesale Price minus 90%," but sometimes other prices like NADAC are used instead. Under GER arrangements, pharmacies may charge more or less than the benchmark for an individual drug, but the total reimbursement amount inclusive of all dispensed generics must equal the benchmark.

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[45] IPD Analytics. (2021, December 15). *Understanding generic drug pricing*. IPD Analytics. https://www.ipdanalytics.com/post/understanding-generic-drug-pricing

[46] Hung A, Dickson S. A primer on prescription drug pricing benchmarks in the United States. J Manag Care Spec Pharm. 2025 Dec;31(12):1326-1335. doi: 10.18553/jmcp.2025.31.12.1326. PMID: 41296316; PMCID: PMC12653627. Accessed July 7, 2026. https://pubmed.ncbi.nlm.nih.gov/41296316/

The RFI highlights Costco's list of 184 drugs that are cheaper in cash than through Part D benefits. This is an example of a loss leader strategy common in grocery store pharmacies. Grocery stores willingly take a loss on certain low-cost drugs in order to attract shoppers into their store. Other examples include Walmart's "$4 Drug List" or Wegman's 2013 promotion of free generic Lipitor. [47,48] These prices are not necessarily set with the primary goal of a sustainable pharmacy business and are limited to only the cheapest generic drugs. Further, these cash prices can create "usual and customary" reimbursement amounts, where the Part D sponsor will pay the cash price plus a dispensing fee. The Costco analysis includes dispensing fees in its calculation of overpayments by Medicare, which likely account for all or nearly all of the overpayment. Pharmacies intentionally do not collect dispensing fees directly from patients under loss leader models. The RFI proposes elsewhere to increase dispensing fees to pharmacies, *which would result in even more "overpayment" as defined in the Costco study.*

The RFI states that "it is a profound market failure that health insurers are not providing affordable access to lower-cost, commoditized generics" and that "many Medicare beneficiaries and patients with other forms of coverage are not even using the insurance they pay" for, pointing to the research indicating that 10 percent of generic prescriptions are dispensed through cash pay options. In fact, this is an example of the market self-regulating and demonstrates that a patient's benefits produce savings at least 90 percent of the time. As Dr. T. Joseph Mattingly testified to the House Judiciary Subcommittee on the Administrative State, Regulatory Reform, and Antitrust in 2024, the price of some generics can be so low that it makes little market sense to incur the administrative costs of using benefits.[49] Additionally, the RFI does not reflect that the 10 percent cash pay figure includes uninsured patients. While cash pay patients utilize substantially fewer prescriptions than insured patients, it does mean that the rate of insured patients who elect to pay cash is something less than 10 percent.

Selecting cash pay when the price of a drug is sufficiently low promotes competition and results in lower premiums because that reimbursement is no longer factored into rate calculations. As a result, comparisons of pharmacy loss leaders to the costs paid

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[47] Freadenheum M. Side effects at the pharmacy. The New York Times. Nov. 30, 2006. Accessed July 7, 2026. https://www.nytimes.com/2006/11/30/business/30pharmacy.html

[48] Fein A. What generic Lipitor says about pharmacy's future. Drug Channels Institute. March 14, 2013. Accessed July 7, 2026. https://www.drugchannels.net/2013/03/what-free-generic-lipitor-says-about.html

[49] House Judiciary Committee Republicans. (2024, September 11). *The role of pharmacy benefit managers*. https://judiciary.house.gov/committee-activity/hearings/role-pharmacy-benefit-managers-0. Accessed July 30, 2026.

through insurance benefits do a poor job of capturing the full scope of the value of prescription drug benefits.

However, AMCP agrees that greater insight into NADAC would enhance price transparency for patients and believes that the Medicaid NADAC survey should be mandatory for pharmacies.

Addressing Perverse Dynamics in the Supply Chain

The RFI identifies several areas of potential perverse dynamics in the supply chain. AMCP agrees that the supply chain contains many misalignments that may promote higher drug costs than could otherwise be achieved. However, the RFI's proposals largely target areas where there is little evidence that certain practices result in higher costs. The RFI suggests:

- Moving to a cost-plus/NADAC-based reimbursement model for generic medicine ingredient costs.
- Addressing inflated prices on PBM-owned private label drugs.
- Prohibiting or putting guardrails around PBMs' ability to limit direct contracting between manufacturers, health plans, and other entities in Medicare Part D and other markets.
- Addressing potential Medicare program abuses that occur through vertical integration.
- Helping pharmacies become less reliant on drug margin as a form of compensation by ensuring reasonable dispensing fees in Medicare Part D.
- Building on Part D delinking by addressing additional forms of price-linked compensation in the supply chain, including physician add-on payments in Part B.
- Holding health insurance plans and PBMs accountable for inappropriate pharmacy rejections in Part D.

<u>Pharmacy Reimbursement</u>

The desire to move from margin-based pharmacy reimbursement to fee-based reimbursement is understandable. This promotes the use of drugs with lower acquisition costs. One risk of mandating a cost-plus model is that it may be ineffective in promoting drugs with lower acquisition costs, raising patient out-of-pocket expenses and premium rates. Additionally, NADAC-plus fails to address concerns about pharmacy reimbursement based on drug margin.

AMCP does not take a position on whether Congress should shift pharmacy compensation away from drug margin and towards dispensing fees. However, it is essential for

policymakers to understand that there will be winners and losers under such a change. Shifting to dispensing fee-only approaches will drive up the cost of some drugs, such as very low-cost generics, while reducing the cost of others. Further, some of the proposals contained within this RFI, including NADAC-plus reimbursement, would continue to incentivize drug margin as compensation. The Senate Finance Committee should carefully consider the potential downstream impacts of such a change and whether they are willing to raise costs in one area to reduce costs in another.

Sole-negotiator Clauses

Contractual exclusivity for negotiating drug benefits prices is an important tool for promoting cost-effective care and premium stability. The RFI claims that such contract terms "may interfere with drug supply chain stakeholder business decisions" but does not cite any examples of actual interference or negative outcomes for clients. The RFI also notes that PBMs have stated that "exclusive negotiator" clauses are "important to preserving the confidentiality of the PBM's pricing information and leverage in negotiations." Both points are true, but there are other factors that support allowing PBMs and employers to voluntarily enter such arrangements.

One important factor is the actuarial impact of decentralizing price negotiation. By spreading negotiation across multiple entities, PBMs will be less able to predict the costs of administering care, raising potential plan liability and driving up premium rates. Direct-to-employer models of drug purchasing pose similar risks to employer finances and patient access. Health plans and employers contracting with PBMs are not required to enter into contracts with terms they find unacceptable. **In the absence of evidence demonstrating that plans and employers experience negative outcomes due to sole negotiator clauses, it would be premature to impose policies that would certainly destabilize actuarial predictions and result in higher premiums**.

Vertical Integration

The RFI does not identify any specific examples of abuse due to vertical integration occurring. Contrary to the RFI's position, **an OIG report from 2026 found that vertically integrated Part D plans reimbursed unaffiliated pharmacies at higher net rates than affiliated pharmacies.**[50]

[50] U.S. Department of Health and Human Services, Office of Inspector General. (2026, May 15). *Impacts of vertical integration in Medicare Part D on sponsors' drug costs, pharmacy reimbursement, and enrollee cost sharing* (OEI-BL-24-00240). Office of Inspector General. https://oig.hhs.gov/documents/evaluation/11667/OEI-BL-24-00240.pdf

The possibility of abuse is a legitimate concern, and preventive measures can be reasonable. However, those measures should be narrowly-tailored guardrails focused on the most significant risks, rather than large-scale changes that could destabilize pharmacy access. In the absence of specific examples of abuse, Congress should not take action at this time. Given OIG's finding that unaffiliated pharmacies receive higher payments, changes to the law may result in unintended consequences that reduce pharmacy revenue.

Utilization Management

Prior authorization is a frequently cited frustration among patients, and plans and PBMs have a responsibility to reduce friction as much as possible. However, the RFI takes for granted that inappropriate rejections are the fault of insurers rather than providers. The RFI notes that Part D sponsors "rejected millions of prescriptions . . . often due to prior authorization rules" and cites a 2019 report from the HHS Office of the Inspector General.[51] The RFI does not acknowledge that **OIG determined the majority of denials were because the prescribed drugs were not on formulary** or that Part D plans were required to offer real-time benefit tools for prescribers starting in 2021.[52] The most useful measures—largely absent from the OIG report—for determining whether an overturned denial was inappropriate are the reason for the initial decision, what changed before approval, and whether the patient experienced a treatment delay.

According to the Office of the National Coordinator for Health Information Technology (ONC), only 55% of hospitals report integrating real-time benefit information for all or nearly all plans as of 2025.[53] Further, nearly half of all prior authorization requests across all markets are submitted by prescribers via fax machine.[54] Requests may also be submitted to the wrong benefit (e.g., medical vs. pharmacy). These factors substantially increase the risk of an initial denial.

A 2024 report by the Massachusetts Health Policy Commission found that 80% of medical benefit denials in the state that year were due to incomplete claims, coding errors,

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[51] Senate Finance Committee Minority Staff. Request for information: commonsense policy options to lower drug prices for patients. June 16, 2026. https://www.finance.senate.gov/imo/media/doc/061626_sfc_drug_pricing_rfi.pdf
[52] Department of Health and Human Services, Centers for Medicare & Medicaid Services. Medicare and Medicaid programs; contract year 2022 policy and technical changes to the Medicare Advantage program, Medicare prescription drug benefit program, Medicaid program, Medicare cost plan program, and programs of all-inclusive care for the elderly. January 19, 2021. Accessed July 2, 2026. https://www.federalregister.gov/documents/2021/01/19/2021-00538/medicare-and-medicaid-programs-contract-year-2022-policy-and-technical-changes-to-the-medicare
[53] Office of the National Coordinator for Health Information Technology. 'Hospital Adoption of Real-Time Benefit Tools,' Health IT Quick Stat #67. Accessed July 2, 2026. https://healthit.gov/data/quickstats/hospital-adoption-real-time-benefit-tools/
[54] AHIP. Improving Prior Authorization for Patients & Providers. Accessed July 2, 2026. https://ahiporg-production.s3.amazonaws.com/documents/202506_AHIP_Report_Prior_Authorization.pdf

duplicate claims or coverage, or other administrative errors.[55] When prescribers do not include essential details such as CPT/ICD codes or patient information, plans must request additional information and wait to receive it. OIG observes that Part D regulations require "sponsors to issue a determination within 24-72 hours of receiving a drug coverage request."[56] While an incomplete claim can typically be amended without filing an appeal, these regulations force Part D plans to issue a denial due to incomplete information if they do not receive a response from the prescriber within that window. What portion of total denials and successful appeals are attributable to the mandated timeline is not mentioned.

Unfortunately, the blame for these errors is placed entirely on insurers. Insurers have taken steps to simplify prior authorization requests to reduce errors, such as standardizing codes across payers and implementing bundled prior authorizations in 2027.[57]

The 2019 OIG report found that 35% of drug coverage requests were denied, and that 26% of denials were appealed (i.e., 9% of all denials are appealed). Of those appeals, 73% were overturned. This means that about 6.6% of all denials are overturned. Importantly, **OIG notes that "overturned denials do not necessarily mean that sponsors' initial denials were inappropriate."** Worth considering is that the denials appealed are the ones most likely to succeed. The RFI operates from the assumption that the high rate of successful appeals indicates more broadly that denials are generally inappropriate without accounting for the role of selection bias in which denials are appealed or the other factors described above.

The proposals in the RFI related to the creation of Star Rating metrics and public reporting of "inappropriate" denial rates—while potentially valuable—are not likely to significantly improve patient outcomes. AMCP recommends policies that focus on modernizing the tools used by prescribers and health systems as the best opportunity to reduce patient friction related to utilization management. These policies could include:

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[55] Massachusetts Health Policy Commission. Issue 33: Evidence of administrative complexity: Health insurance claim denials in Massachusetts. Accessed July 2, 2026. https://masshpc.gov/publications/datapoints-series/issue-33-evidence-administrative-complexity-health-insurance-claim

[56] Department of Health and Human Services, Centers for Medicare & Medicaid Services. Medicare and Medicaid programs; contract year 2022 policy and technical changes to the Medicare Advantage program, Medicare prescription drug benefit program, Medicaid program, Medicare cost plan program, and programs of all-inclusive care for the elderly. January 19, 2021. Accessed July 2, 2026. https://www.federalregister.gov/documents/2021/01/19/2021-00538/medicare-and-medicaid-programs-contract-year-2022-policy-and-technical-changes-to-the-medicare

[57] AHIP. Health plans take next step to streamline and simplify prior authorization for patients and providers. April 24, 2026. Accessed July 2, 2026. https://www.ahip.org/news/articles/health-plans-take-next-step-to-streamline-and-simplify-prior-authorization-for-patients-and-providers

1. Prohibiting the use of fax machines in most circumstances, with exceptions for necessity;
2. Mandating the adoption and use of real-time benefit tools by prescribers and imposing penalties for non-compliance;
3. Adopting enhanced electronic prescribing forms that provide pharmacies with information relevant to a prior authorization request, such as diagnosis; and
4. Extending the decision window for Part D claims if the sponsor has indicated a request for additional information for processing.

Delays in medically necessary care due to inefficiencies in the prior authorization process are serious and must be eliminated. While errors occur on the plan side, the most effective way to reduce friction is to implement policies that govern the systems and behaviors of prescribers, the entities with the most control over request submissions. In addition to the market-led streamlining, plan sponsors are already substantially regulated in this area, reflected in the modest suggestions in the RFI. There is much more opportunity to reduce delays by modernizing the technology used by prescribers.

Section III. Bolstering Pharmaceutical Innovation in the United States

AMCP welcomes the opportunity to provide feedback on bolstering biopharmaceutical innovation in the United States. The research partnership that exists between the federal government and external stakeholders, including academic institutions, nonprofit organizations, and private enterprise, is paramount to maintaining American dominance in the biopharmaceutical space. AMCP is proud to support domestic biopharmaceutical innovation through several channels. In 2024, AMCP launched the AMCP Research Institute (ARI), a research-based resource that conducts and facilitates projects important to the mission of managed care pharmacy. The ARI incorporates the existing Biologics and Biosimilars Collective Intelligence Consortium (BBCIC), which carries a mission to generate reliable real-world evidence on the safety and effectiveness of biologics and biosimilar therapies. The BBCIC has published over 4 research reports, 18 manuscripts, and 54 posters to date, with dozens of additional projects now ongoing in conjunction with the ARI. BBCIC research is partially supported through FDA grant funding, intended to generate evidence on the use and interchangeability of biosimilars.[58] AMCP also supports biopharmaceutical innovation by investing in future-focused research through its 501(c)(3) affiliate, the AMCP Foundation. Research supported by the AMCP Foundation centers on

[58] AMCP Research Institute. Accessed Aug. 5, 2026. https://www.amcp.org/Research-Institute

four guiding pillars: real-world evidence to inform managed care pharmacy decision making; value-based models to address the total cost of care; the impact of benefit design or utilization management strategies on patient outcomes; and the impact of direct patient care services provided by managed care pharmacy on patient outcomes.[59] AMCP publishes research manuscripts and subject reviews, through its official publication, the Journal of Managed Care and Specialty Pharmacy (JMCP). JMCP is the premier, peer-reviewed research journal for managed care pharmacy thought leadership and research, and is read by over 14,000 health system leaders, 7,100 health plan professionals, and 4,200 managed care executives.[60] AMCP's comprehensive suite of research-minded affiliates guides the organization's positioning on opportunities to improve domestic biopharmaceutical investment.

Enhancing Investments in Drug Research and Development

Basic and Translational Research

The RFI seeks feedback on ways to bolster funding for basic and translational research conducted in the United States, including strategies to increase the amount of extramural research conducted in partnership with academic institutions. As alluded to in the RFI, the Trump administration's termination and/or freezing of roughly 3,800 previously approved NIH research grants in 2025—amounting to roughly $3 billion in total funding cuts—has drastically reduced domestic basic and translational research capabilities and threatens the United States' position as the preeminent global hub for biopharmaceutical innovation.[61] While many of these initial cuts were abandoned, scaled back, or overturned in federal court, continued uncertainty around and unreliability of federal research funding under the current administration poses a significant threat to the public-private partnership that fosters countless breakthrough biopharmaceutical innovations in the U.S. The Trump administration's FY 2027 HHS budget request now seeks $41.4 billion in funding for NIH, equating to a roughly $5 billion cut from FY 2026 enacted levels.[62] AMCP encourages Congress to reestablish confidence in the reliability of NIH's grantmaking process by appropriating a 5% ($2.37 billion) increase in agency funding from FY 2026 enacted levels, appropriating $49.86 billion in total for FY 2027. This 5% increase would offset stagnation in

[59] Research Agenda. AMCP Foundation. Accessed Aug. 5, 2026. https://amcpfoundation.org/reports-research/research-agenda
[60] About JMCP. Journal of Managed Care and Specialty Pharmacy. Accessed Aug. 5, 2026. https://www.jmcp.org/about-jmcp
[61] Krass M, Grawert A. The Cost of the Trump Administration's Attack on Research Funding. Brennan Center for Justice. May 14, 2026. https://www.brennancenter.org/our-work/research-reports/cost-trump-administrations-attacks-research-funding
[62] Budget in Brief Fiscal Year 2027. US Department of Health and Human Services. April 3, 2026. https://www.hhs.gov/sites/default/files/fy-2027-budget-in-brief.pdf

annual agency funding increases since FY 2024, further demonstrating the federal government's willingness to foster science, innovation, and drug development through grant-funded research conducted at academic institutions.[63]

The RFI also seeks proposals that would create additional funding streams for basic and translational research enabled by NIH grants, through a new assessment on the pharmaceutical industry. The collection of fees, assessments, or charges is commonplace for goods and services offered by the federal government and has a proven track record of bolstering government capacity while simultaneously benefiting private stakeholders. This is no more apparent than through the imposition of user fees on entities seeking FDA approval for medical products, including prescription drugs, biologics, generics, and devices. User fees collected by the FDA have supported higher agency staffing levels and more comprehensive training, leading to speedier review processes for novel therapies and devices. This increased capacity correlates to net benefits for consumers and manufacturers, including exponential returns on manufacturer investments and expedited consumer access to safe, cost-effective treatments.[64] However, AMCP urges Congress to exercise caution and refrain from implementing policies that unduly burden biopharmaceutical research and development with additional, unnecessary costs. From 2000 – 2018, the mean expected capitalized cost of developing a new drug in the United States topped out at $879.3 million.[65] While the RFI's assertion that the pharmaceutical industry stands as the primary financial beneficiary of basic and translational research enabled by NIH holds validity, it is also true that pharmaceutical manufacturers invest significant capital into later stages of the drug development cycle, including clinical trials, real-world evidence generation, and post-market drug safety monitoring. A study on the costs incurred for basic or applied research related to 354 of the 356 drugs approved by the FDA from 2010-2019 demonstrates that the amount NIH invests per approved drug roughly equates the total amount invested by the biopharmaceutical industry.[66] The imposition of additional user fees onto biopharmaceutical manufacturers would upset this

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[63] National Institutes of Health (NIH) Funding: FY1996-FY2026. May 18, 2026. https://www.congress.gov/crs-product/R43341

[64] Parasrampuria S, Beleche T. FDA User Fees: Examining Changes in Medical Product Development and Economic Benefits: Issue Brief. Office of the Assistant Secretary for Planning and Evaluation (ASPE); March 2023. https://www.ncbi.nlm.nih.gov/books/NBK603243/

[65] Aylin S, Beleche T, Jessup A. Cost of Drug Development and Research and Development Intensity in the US, 2000-2018. JAMA Network Open. June 28, 2024. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2820562

[66] Galkina Cleary E, Jackson MJ, Zhou EW, Ledley FD. Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019. JAMA Health Forum. April 7, 2023. https://pmc.ncbi.nlm.nih.gov/articles/PMC10148199/

careful balance of public-private partnership and threaten American dominance in biomedical research as manufacturers seek less restrictive regulatory regimes abroad. The value of this partnership is no more apparent than in the biopharmaceutical accelerators alluded to in the RFI. AMCP supports the use of biopharmaceutical accelerators as a means for expanding and improving domestic biopharmaceutical research capacity. Should Congress implement a statutory definition of such programs, AMCP encourages the use of a broader definition of "therapeutic accelerator," that acknowledges and advances the development of innovative, effective, nonbiologic treatments such as prescription digital therapeutics, in additional to the biopharmaceuticals.[67]

Clinical Trials

AMCP supports Senate Finance Democrats' intent to reduce drug prices by investing in new therapies for conditions considered high risk for drug development. The RFI specifically alludes to current investment risks for new cell and gene therapies (CGTs), such as high manufacturing costs and commercial unpredictability. Many of these concerns revolve around the fact that CGTs now constitute the world's most expensive drugs, with some carrying price tags upwards of $4.25 million per dose.[68] And while many CGTS treat rare diseases and may be curative, outcomes are often highly individualized. A CGT that cures a condition for one patient may show little to no improvement for another.

This risk is especially tenuous for CGTs reimbursed under the Medicaid Drug Rebate Program, which requires manufacturers to pay rebates that are the greater of 23.1% of the average manufacturer price (AMP) or the difference between AMP and the "best," or lowest price available to any wholesaler, retailer, or provider, excluding certain government programs. While manufacturers with value-based arrangements are permitted to report varying "best price" points for drugs through the existing Multiple Best Price Rule, many remain concerned that reporting a value-based price for CGTs could set the "best price" to zero if a full refund is offered for an ineffective treatment under a value-based arrangement. AMCP encourages Congress to assuage these fears and incentivize CGT development by codifying the Multiple Best Price Rule, amending Section 1927(c)(1)(C)(ii) of the Social Security Act to permit the inclusion of multiple best price points for a single dosage form and strength of a drug subject to a VBP, provided the manufacturer offers the

[67] Prescription Digital Therapeutics. AMCP Legislative and Regulatory Position Statement. AMCP. April 26 2024. https://www.amcp.org/legislative-regulatory-position/prescription-digital-therapeutics
[68] Smith G. World's Most Expensive Drug is Now $4.25 Million Gene Therapy. March 20, 2024. https://www.bloomberg.com/news/articles/2024-03-20/world-s-most-expensive-drug-is-now-4-25-million-gene-therapy

arrangement to all states. This change would provide regulatory certainty for manufacturers, including the small biotech firms that constitute a significant portion of active CGT manufacturers, by clarifying that the voluntary value-based price reported by a manufacturer under the Medicaid Drug Rebate Program represents the net price paid, provided that a patient meets all agreed-upon clinical benchmarks. AMCP also urges Congress to amend Section 1847A(c)(3) of the Social Security Act and exclude VBPs from the ASP calculation for drugs reimbursed under Medicare Part B. These proposals are also included in the Medicaid VBPs for Patients Act (S. 1637) and would partially alleviate many of the risk factors CGT manufacturers experience in bringing new therapies to market.[69] Greater regulatory certainty would help spur the development of new CGTs—which show promise in treating or even curing debilitating conditions such as sickle cell disease, Parkinson's disease, or Duchenne muscular dystrophy—and expand access for America's most vulnerable patient populations.[70]

Addressing Competition from China

Boosting Clinical Trials

AMCP welcomes the opportunity to comment on enhancing clinical trials in the United States. AMCP has long recognized the value of optimizing clinical trial data to bringing safer, more effective medications to America's patients. In 2022, AMCP celebrated passage of the Pre-Approval Information Exchange Act as part of the Consolidated Appropriations Act, 2023.[71] AMCP worked alongside House Energy and Commerce Committee leaders in the 117th Congress to advance this policy—first conceived during an AMCP Partnership Forum event in 2016—which authorizes pharmaceutical manufacturers to proactively share certain economic and scientific information about medical products with health payers ahead of FDA approval.[72] While pre-approval information exchange is already reducing the amount of time it takes for patients to receive new FDA-approved therapies, AMCP believes that real-world evidence (RWE) generation will further optimize clinical trials, improve the domestic drug development process, and expedite patient access to lower-cost therapies. RWE includes pharmacological and health outcomes data generated outside

[69] S.1637 - 119th Congress (2025-2026): MVP Act. May 7, 2025. https://www.congress.gov/bill/119th-congress/senate-bill/1637
[70] Conditions Treated with Cell + Gene Therapy. American Society of Gene + Cell Therapy. Accessed Aug. 8, 2026. https://patienteducation.asgct.org/understanding-cell-gene-therapy/conditions-treated
[71] H.R.7008 - 117th Congress (2021-2022): Pre-approval Information Exchange Act of 2022. March 10, 2022. https://www.congress.gov/bill/117th-congress/house-bill/7008
[72] AMCP Partnership Forum: Enabling the Exchange of Clinical Economic Information Pre-FDA Approval. Journal of Managed Care & Specialty Pharmacy, Volume 23, Number 1. Dec. 22, 2016. https://www.jmcp.org/doi/10.18553/jmcp.2016.16366

of controlled clinical trials, such as electronic health records, insurance claims, and patient-reported outcomes.[73] RWE generation will likely never supplant randomized control trials (RCTs) as the gold standard for clinical evidence, but it can yield impactful data when RCTs are not feasible. This includes instances where the creation of an RCT warrants excessive costs; situations where use of a placebo is considered unethical; and for rare diseases with small or inaccessible patient populations.[74]

Congress acknowledges the value of RWE generation, as evidenced by the 21st Century Cures Act. The law, a momentous step in accelerating domestic medical product development, mandated that the FDA establish a framework for evaluating the potential use of RWE to support the approval of new drug indications for previously approved therapies or to help satisfy post-approval study requirements. While the law benefited new indication approvals and post-market safety monitoring, the ARI identified an additional gap in guidance for incorporating RWE into health care payer coverage and reimbursement decisions. In a July 2024 survey of 36 managed care executives, the ARI found that only 18% of respondents reported regularly using RWE as part of their decision process, while 80% of respondents expressed interest in utilizing RWE.[75] Given the lack of federal input on best practices, AMCP urges Congress to amend Section 505F of the Federal Food, Drug, and Cosmetic Act and expand upon FDA's existing RWE framework by directing the agency to promulgate additional guidance on RWE standards for payer information sharing, including:

1. A customized checklist of relevant criteria for RWE study design, assessment, and decision-making processes specifically to address payer needs; and
2. An outline to describe RWE study types and US payer-specific endpoints at different facets of the product life cycle.

AMCP stands as a willing partner to HHS in developing the expanded program framework in accordance with the consultation requirements of Section 505F.[76] The ARI project on real-world evidence standards offers 29 RWE study design criteria across six categories

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[73] Real World Evidence (RWE) Initiative. AMCP. Accessed Aug. 4, 2026. https://www.amcp.org/RWE
[74] Beaulieu-Jones, B. K., Finlayson, S. G., Yuan, W., Altman, R. B., Kohane, I. S., Prasad, V., & Yu, K. H. (2020). Examining the Use of Real-World Evidence in the Regulatory Process. Clinical Pharmacology and Therapeutics, 107(4), 843–852. https://doi.org/10.1002/cpt.1658
[75] Lockhart, C. M., Powers, E., Sweet, B., Gleason, P. P., & Brixner, D. AMCP real-world evidence standards: Overcoming barriers to using real-world evidence in US payer decision-making. Journal of Managed Care & Specialty Pharmacy, 31(12), 1230-1236. Sept 18, 2025. https://doi.org/10.18553/jmcp.2025.25108
[76] Federal Food Drug, and Cosmetic Act 21 U.S.C. § 355g https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section355g&num=0&edition=prelim

(General Study Questions, Data Source, Outcomes Measured, Analytics, Results, and Limitations) along with an outline of study types and endpoints for use during the four stages of the drug life cycle (preapproval, approval, postapproval, and expansion into new indications).[77] This enhanced framework would alleviate one of the primary flaws with RCT data; evidence driven by RCTs may not reflect diverse beneficiary populations or outcomes monitored in clinical settings. Generally, RWE studies are less costly, less time consuming, and carry far fewer inclusion or exclusion criteria when compared to RCTs, allowing for a broader population of participants to be monitored, along with the generation of effectiveness data for a drug across varying populations. The authorization of a comprehensive RWE framework would supplement, but not supplant, government-sponsored clinical trials in justifying FDA approval for new drugs. Researchers, manufacturers, payers, and patients would benefit not only from more comprehensive evidence on the safety and efficacy of novel therapies, but from data on the *real-world effectiveness* of prescription drugs developed in the United States.[78] The inclusion of RWE, in addition to RCT data, allows for a more comprehensive body of evidence to justify whether a new product is approved by the FDA, covered by insurance, and trusted by patients or providers.

Scientific Talent

As China looks to the future by bolstering its scientific talent pool, the Unted States has taken significant steps backwards in reducing domestic research capacity and recruitment. Last year, the One Big Beautiful Bill Act eliminated the federal Direct PLUS Loan Program, while simultaneously capping the amount that professional graduate students may borrow at $50,000 annually, up to $200,000 over a lifetime.[79] AMCP published a statement opposing this provision on May 22, 2025, and continues to believe that such changes will significantly disadvantage the professional students who rely on these programs to finance their education and launch their careers. The professional borrowing cap is especially alarming for the practitioners responsible for maintaining America's biopharmaceutical dominance, including the physicians and pharmacists who conduct cutting edge-research at the nation's preeminent research hubs. AMCP fears that these actions will direct professional graduate students towards either predatory private lenders or away from the

[77] Lockhart, Powers, Sweet, Gleason and Brixner. AMCP real-world evidence standards. https://doi.org/10.18553/jmcp.2025.25108
[78] Chodankar D. (2021). Introduction to real-world evidence studies. *Perspectives in clinical research*, *12*(3), 171–174. https://doi.org/10.4103/picr.picr_62_21
[79] Text - H.R.1 - 119th Congress (2025-2026): An act to provide for reconciliation pursuant to title II of H. Con. Res. 14. July 4, 2025. https://www.congress.gov/bill/119th-congress/house-bill/1/text

medical profession altogether. According to the American Association of Colleges of Pharmacy and the National Center for Education Statistics, roughly 80% of student pharmacists utilized federal graduate student loans to fund their education, prior to the elimination of such opportunities in 2025.[80] AMCP recommends that Congress repeal Section 81001 of the One Big Beautiful Bill Act, reinstitute federal Direct PLUS loan offerings to professional students studying in American universities, and permit professional graduate students to borrow up to the full cost of attendance for their professional education. By reinstating the pre-H.R. 1 federal student loan offerings for professional graduate students, Congress will reiterate the importance of fostering a future workforce that is well-prepared to tackle the public health challenges of tomorrow.

Conclusion

AMCP thanks the Committee for the opportunity to provide feedback on policy options to lower the prices that drug manufacturers charge for treatments, reduce out-of-pocket costs, and bolster biopharmaceutical research. We look forward to working together to improve access to prescription drugs. If you have any questions regarding AMCP's comments or would like further information, please contact me at acolborn@amcp.org or (703) 684-2627.

Sincerely,

Adam Colborn, JD
Vice President, Government Affairs

[80] Graduating Student Survey–2024 National Summary Report. American Association of Colleges of Pharmacy. Aug. 2024. https://www.aacp.org/sites/default/files/2024-08/2024-gss-national-summary-report.pdf?mf_ct_campaign=yahoo-synd-feed&utm_content=syndication