COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

August 17, 2026

The Honorable Ron Wyden
Ranking Member, Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Submitted electronically to drugs@finance.senate.gov

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

Dear Ranking Member Wyden:

On behalf of the Council for Affordable Health Coverage (CAHC), thank you for the opportunity to respond to the June 16, 2026 Request for Information, *Commonsense Policy Options to Lower Drug Prices for Patients* (RFI), issued by your office together with Senators Cortez Masto, Welch, Gallego, Kelly, Baldwin, Hassan, Merkley, Van Hollen, Duckworth, and Blumenthal. CAHC is a broad-based coalition of patients, employers, manufacturers, providers, technology companies, and other stakeholders working toward affordable, high-quality health coverage for all Americans. We share the Committee's interest in directly lowering what patients pay at the pharmacy counter and in correcting the perverse incentives across the drug supply chain that keep costs high even where list-price competition exists.

This letter concentrates on Section II (Enhancing Prescription Drug Affordability) and Section III (Bolstering Biopharmaceutical Innovation in the United States), including several issues examined in depth at a Medicare Part D roundtable CAHC convened on July 29, 2026, with experts concerned that the Part D market is unstable and increasingly unaffordable. Before turning to those two sections, we offer brief, preliminary comments on four related questions posed in Section I, because each bears directly on the affordability and market stability recommendations that follow.

Section I: Lowering Drug Prices

Inflation-adjusted net prices for brand drugs have fallen for the eighth consecutive year, but those savings are often captured by pharmacy benefit managers (PBMs) and other middlemen instead of reaching patients.[1] Considering 92 percent of Americans have some form of coverage, we encourage your efforts there as it has more potential to drive affordability for patients. CAHC opposes expanding price control mechanisms in Medicare and new price control measures in other markets because it will lead to reduced patient access and innovation. Applying the policies outlined in Section I would also work against the biopharmaceutical innovation goals outlined in Section III.

Congress should not incorporate international reference pricing into Medicare's negotiation framework.
The tradeoff between better affordability through price controls is reduced innovation, fewer therapies and less patient access. These models are primarily designed to help *governments* pay for public benefits versus *patients* and *consumers* benefiting from lower costs.

[1] Drug Channels: U.S. Brand-Name Drug Prices Fell in 2025 as the Net Pricing Drug Channel Emerges

The evidence on international price controls is overwhelming and negative. For example: of 545 novel active substances, the US had 58 percent availability (the highest of any market studied), Japan 55 percent, and European Union (EU) countries ranged from 52 percent down to 2 percent. US approval-to-availability was roughly 0.4–0.5 years faster than the EU average and 1.3–2.8 years faster than Japan. 25 of 27 EU countries had longer median delays to availability than the US, and 22 of 27 had a median time-to-availability of a year or longer.[2] Following Canada's 2017–2021 Patented Medicine Prices Review Board (PMPRB) reform proposals, the two-year launch rate for new patented medicines in Canada fell from 45.0 percent to 30.8 percent, while the comparable US rate held stable at roughly 81–82 percent. For high-therapeutic-benefit drugs specifically, Canada's launch rate fell from 45.8 to 31.3 percent while the US rate rose to 100 percent.[3]

Europe spent the early 2000s tightening drug price controls, and it cost the continent its position as the world's pharmaceutical innovation hub. As Sally Pipes documents in her Pacific Research Institute book *The World's Medicine Chest*, Europe was the center of pharmaceutical R&D through the 1970s, but by 2004 every European nation had adopted some form of drug price control, and the innovation base shifted to the US.[4] Roughly two-thirds of new drugs brought to market over the last decade originated in the US, compared with about 22 percent from Europe. University of Connecticut economist Joseph Golec's estimates that the US would have lost more than 100 new medicines between 1986 and 2004 had it imposed European-style price controls over that period.[5]

In addition, reference countries are often not comparable to the United States. Their pricing reflects different budgets, values, and health-system tradeoffs. In current international reference pricing (IRP) models proposed by the Administration, the reference benchmark is a moving target built on other benchmarks: 14 of the 19 designated reference countries set prices using data from 35 additional countries that do not meet the Center for Medicare and Medicaid Innovation (CMMI) models' own selection criteria.[6] The Office of Health Economics found 18 of 19 reference countries use Quality-Adjusted Life Years (QALYs) formally or informally, while a Copenhagen Economics analysis found all 19 do.[7]

US patients place a premium on rapid access and on the autonomy to weigh physical, emotional, and financial tradeoffs themselves, rather than deferring to a government health-technology board. QALY-based pricing discriminates intentionally by undervaluing treatments for people who are elderly, terminally ill, or living with a disability, which is why the National Council on Disability opposes their use. And Congress has already drawn this line twice. Both the Affordable Care Act (ACA) and the Inflation Reduction Act (IRA) restrict QALY use in federal programs. A mandatory

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[2] IQVIA Institute, "Assessing Availability of New Drugs in Europe, Japan, and the U.S.," Dec. 11, 2024, Assessing Availability of New Drugs in Europe, Japan, and the U.S. | IQVIA

[3] Zhang, Grootendorst, Hollis, Anis, and Sun, "The Impact of Proposed Price Regulations on New Patented Medicine Launches in Canada: A Retrospective Cohort Study," CMAJ 196, no. 20 (2024): E691. [PDF] The impact of proposed price regulations on new patented medicine launches in Canada: a retrospective cohort study | Semantic Scholar

[4] Sally Pipes, *The World's Medicine Chest: How America Achieved Pharmaceutical Supremacy—and How to Keep It* (Pacific Research Institute, Feb. 2025).

[5] Golec and Vernon, "Financial Effects of Pharmaceutical Price Regulation on R&D Spending by EU versus US Firms," *PharmacoEconomics* 28, no. 8 (2010): 615–628, https://pubmed.ncbi.nlm.nih.gov/20617857/

[6] National Pharmaceutical Council: *How Mandatory International Reference Pricing Uses Prices From Countries That Don't Meet Stated Criteria* (2026), https://www.npcnow.org/resources/mandatory-irp-uses-prices-fact-sheet

[7] How Widely Are QALYs Used in OECD Countries? A Snapshot of International Practices - OHE

incorporation of international prices in Medicare is a back door way to adopt QALY-like policies by reference.

We agree with the Committee that America disproportionately bears the costs of global pharmaceutical development. The United States accounts for roughly 62 percent of pharmaceutical sales among OECD countries despite representing only about 24 percent of volume[8], a disparity that reflects other countries' administered price controls and delayed patient access mechanisms, rather than a benchmark Congress should import wholesale into Medicare. Those controls also make the underlying data unreliable: Germany, one of the countries under consideration for a US reference basket, changed its law in January 2025, specifically, to keep most rebates and other price concessions confidential so it could negotiate deeper, hidden discounts[9], meaning a US reference-pricing system built on reported foreign prices would rest on figures our trading partners are actively working to understate.

Medicare's existing negotiation authority already directs the Secretary to weigh US-specific factors, research and development costs, unit costs of production, federal financial support for discovery, and evidence on alternative treatments, in setting a maximum fair price. That is a more transparent and more tailored basis for a negotiated price than an imported foreign ceiling.

Rather than international reference pricing, Congress should end foreign governments free-riding on American innovation. The *USTRx Act* (S. 5265), introduced in the Senate by Tim Sheehy[10], would create a Chief Pharmaceutical Trade Negotiator at the Office of the United States Trade Representative (USTR), require annual reporting on foreign drug price-control practices, mandate a 30-day USTR response plan, and authorize Section 301 trade investigations against wealthy countries that refuse to pay their fair share.

Congress can avoid repeating Europe's mistakes by using trade tools to raise what other countries pay, preserving the incentive structure that made America the world's medicine chest in the first place.

1. Subscription models can expand access to population-health drugs — and Congress already has a bipartisan vehicle to build on in the *MVP Act.*

CAHC supports subscription-style payment arrangements for high-volume, population-health therapies such as GLP-1s and believes revising structural barriers to these models is preferred to therapeutic specific interventions. Rather than building an entirely new legal framework from scratch, we encourage the Committee to start from the bipartisan MVP Act (S. 1637/H.R. 7871, 119th Congress, introduced by Senators Mullin, Hassan, and Scott of South Carolina), which already establishes tools directly relevant to subscription-style arrangements: (1) authority for manufacturers to report multiple best-price points tied to value-based purchasing arrangements, (2) adjusted

[8] U.S. Department of Health and Human Services, Assistant Secretary for Planning and Evaluation (ASPE), International Prescription Drug Price Comparisons: Estimates Using 2022 Data (Feb. 2024), https://aspe.hhs.gov/sites/default/files/documents/8e057b0a094e6f9b9d01171fce6698f4/international-price-comparisons.pdf

[9] Brendan Melck, "All Change in Germany – Confidential Pricing In, IRP Out," Pharmaceutical Technology (Jan. 31, 2025), https://www.pharmaceutical-technology.com/analyst-comment/all-change-germany-confidential-pricing-irp/

[10] Sheehy Introduces the Use Sovereignty to Reduce Rx Act

average-manufacturer-price calculations when payment is made in installments or tied to patient outcomes, and (3) a new anti-kickback safe harbor covering arrangements where a patient does not achieve an intended outcome.

The MVP Act's framework could be directly applied to Part D and commercial-markets, extending comparable multiple-best-price and anti-kickback protections, so manufacturers and plans have the legal certainty to negotiate capped-utilization, subscription-style arrangements for population-health drugs without running afoul of Medicaid best-price rules. Plans could incorporate these models directly into benefit designs and bid pricing.

Expanding Coverage for Obesity

As one of the lead Committee staff who negotiated the section of the Part D law that may exclude drugs when used for anorexia, weight loss or weight gain, I recommend simply eliminating the confusion around whether obesity related products may be covered by Part D plans. At the time the law was drafted, the causes and factors related to metabolic diseases, generally, and obesity, specifically, were not well understood. Therapeutic products were limited and not as effective as current therapies. Our intent was to exclude products simply used for weight loss or lifestyle based on then-current Medicaid standards. During the initial regulations for the program, CMS clearly defines our intent:

> *Drugs that are excluded from coverage under Part D when used as agents for certain conditions may be considered covered when used to treat other conditions not specifically excluded by section 1927(d) (2) of the Act, provided they otherwise meet the requirements of section 1860D–2(e)(1) of the Act and are not otherwise excluded under section 1860D–2(e)(2)(B) of the Act. To the extent this is the case, and a drug is dispensed for a 'medically accepted indication' as described in the statute, weight loss agents may be covered for the treatment of morbid obesity…*[11]

Since then, the science has advanced, and new innovative products are changing the economics of disease. CAHC believes CMS' recent re-interpretation[12] is incorrect in that anti-obesity medications (AOMs) that receive FDA approval for an additional indication such as diabetes or cardiovascular disease may be covered for that specific use. The statute and CMS' 2005 regulation are clear: obesity may be covered by Part D. Congress should clear up the confusion in implementing the law by clearing stating that GLP-1s and other products may be covered by Part D plans for treatment of obesity.

We also believe the Congressional Budget Office (CBO) is vastly underestimating service cost reductions associated with GLP-1 coverage. Incorporating GLP-1s into standard Part D coverage for their approved indications, including obesity, diabetes, and cardiovascular disease will, in our estimation, significantly lower costs associated with hospitalizations, emergency room visits, and associated comorbidities.

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[11] CMS, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,194, 4,230 (Jan. 28, 2005, https://www.govinfo.gov/content/pkg/FR-2005-01- 28/pdf/05-1321.pdf

[12] CMS, HPMS E-Mail, Part D Coverage of Anti-Obesity Medications with Medically Accepted Indications (March 20, 2024), https://www.cms.gov/aboutcms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-march-18-22

Section II: Enhancing Prescription Drug Affordability

CAHC's July 29, 2026 roundtable brought together plans, manufacturers, former regulators, and policy experts to examine growing instability in the Medicare Part D market following the Inflation Reduction Act's redesign. That work, together with our coalition's longstanding focus on the perverse incentives that run through the drug supply chain, informs the recommendations below.

Considering 92 percent of Americans have some form of coverage[13], the Committee is right to focus on what is actually broken: most Americans pay an insurance set price for prescription drugs, and increasingly insurers are increasing costs for patients. Reforms to Medicare, Medicaid and commercial markets will do more to lower drug costs than any price control on drugs.

A. Lowering Patient Out-of-Pocket Costs

Patient smoothing, made genuinely usable, is a more direct answer to high per-script costs than new blanket caps.

A tradeoff in layering across-the-board out-of-pocket caps onto more classes of chronic-care drugs that benefit discrete patient subpopulations is increased premiums for the entire beneficiary pool. Congress should first fix the tool the IRA already created for this purpose: the Medicare Prescription Payment Plan (MPPP), or "smoothing," which lets beneficiaries spread high point-of-sale costs across the plan year. The program is barely used. Data from early 2025 showed only about 0.4 percent of beneficiaries enrolled in the initial months[14], a rate that had risen to only about 1 percent of non-low-income-subsidy, non-employer-group-waiver-plan beneficiaries by the end of 2025[15]. Of the roughly 5.4 million beneficiaries who reached the catastrophic phase in 2025, and who stood to benefit most from smoothing, only about 3.8 percent were enrolled. Beneficiary awareness appears to be the central barrier: a 2025 survey found that nearly three-quarters of seniors had heard little or nothing about the program[16].

CAHC's July 29 roundtable participants recommended making MPPP enrollment available directly during plan selection and through a simple opt-in at the pharmacy counter or point of service, rather than the current after-the-fact application process. We support that approach, along with using Medicare.gov and 1-800-MEDICARE as a single point of entry, rather than relying on individual plan sponsors that bear the cost of beneficiary non-payment and therefore have limited incentives to promote enrollment. Allowing beneficiaries who elect smoothing to have payments deducted directly from Social Security benefits, as is already done for Part B and Part D premiums; and simplifying the underlying formula to the beneficiary's annual out-of-pocket maximum divided by the number of months remaining in the plan year at enrollment would also improve the program. Made genuinely

[13] U.S. Census Bureau: Health Insurance Coverage in the United States: 2024
[14] Milliman, MedIntel Insights: Early Look at Medicare Prescription Payment Plan Enrollment (Apr. 2025), https://www.milliman.com/en/insight/medintel-insights-early-look-m3p-enrollment.
[15] Avalere Health, New Analysis Highlights Opportunities to Improve MPPP Uptake (July 2026), https://advisory.avalerehealth.com/insights/new-analysis-highlights-opportunities-to-improve-mppp-uptake.
[16] Partnership to Fight Chronic Disease, New Poll: Majority of Seniors with Medicare Prescription Drug Coverage Remain Unaware of New Payment Options (Apr. 2025), https://www.fightchronicdisease.org/post/new-poll-majority-of-seniors-with-medicare-prescription-drug-coverage-remain-unaware-of-new-payment.

usable, patient smoothing is a more targeted, more administrable answer to high per-script costs than a new blanket cap that would raise premiums for beneficiaries who never approach the out-of-pocket maximum.

Basing cost-sharing on net price, and extending delinking beyond Part D, will stop patients from paying more than plans actually pay.

Patients whose cost-sharing is calculated under a deductible or as coinsurance are typically charged based on a drug's undiscounted list price, not the discounted net price a plan or PBM actually pays after rebates. The Government Accountability Office found that across 79 of the top 100 highly rebated drugs in Medicare Part D, total costs borne by beneficiaries exceeded total net costs to plan sponsors by nearly 400 percent, $21 billion compared with $5.3 billion.[17] A JAMA Network Open analysis similarly found that rebate growth in Part D was associated with an average $13 increase in beneficiary cost-sharing per prescription between 2014 and 2018, even as rebates in the program grew 162 percent over that same period.[18]

Congress has already taken the first step toward fixing this by delinking PBM compensation in Medicare Part D from a drug's list price, in the Consolidated Appropriations Act, 2026.[19] CAHC supports extending that same delinking principle, and basing patient cost-sharing on net price rather than list price, across the commercial market as well as Part D.

Patients should keep the benefit of the lowest available price: cash-pay and direct purchase prices should count toward deductibles and out-of-pocket maximums.

Today, a patient who finds a lower cash-pay, discount-card, or direct manufacturer purchase price for a covered medicine typically cannot apply that spending toward their deductible or annual out-of-pocket maximum, because the purchase falls outside the plan's own network and pricing structure. That gap penalizes patients for choosing the option that actually costs them, and the system, less. CAHC's July 29 roundtable specifically recommended ensuring that lower cash or discount-card prices count toward beneficiary out-of-pocket obligations whenever the price is below the plan-negotiated amount.

We believe the HHS Inspector General erred in treating direct purchase programs and TrumpRx as copay assistance programs. These are voluntary price concessions available to any patient, regardless of coverage in any market. When a consumer finds a lower priced option, it should be rewarded. This would create pressure on insurers to reduce gross-to-net pricing distortions and seek out better prices from manufacturers. The Committee should consider linking Part D reimbursement to plans to a “lesser of price”. CAHC estimates that by allowing payment of the lowest transparent

[17] U.S. Government Accountability Office, Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending, GAO-23-105270 (Sept. 2023), https://www.gao.gov/assets/gao-23-105270.pdf.
[18] Kai Yeung et al., "Association of Branded Prescription Drug Rebate Size and Patient Out-of-Pocket Costs in a Nationally Representative Sample, 2007-2018," JAMA Network Open 4, no. 6 (2021): e2113393.
[19] Consolidated Appropriations Act, 2026, H.R. 7148, 119th Cong. (enacted Feb. 2026).

direct-to-consumer price for eligible brand and generic drugs could save Medicare $10 to $18 billion annually, $8.5 billion of which is from generics alone.[20]

We recommend the Committee: (1) recognize CMS-certified direct-to-patient and comparable transparent cash-pay purchases of covered drugs as counting toward a Part D beneficiary's annual out-of-pocket threshold, and toward deductibles and out-of-pocket maximums in commercial coverage; (2) require plans and PBMs to apply the lowest publicly disclosed price for a covered medicine to a patient's cost-sharing calculation wherever that information is reasonably accessible, and allow patients to invoke a lower price directly at the point of sale; and (3) adopt a guardrail making clear that the existence of a lower-cost direct-purchase option cannot itself be used to justify narrowing a drug's formulary status or shifting additional costs onto patients elsewhere in the benefit design, so that plans cannot respond to (1) and (2) by simply dropping the drug from coverage.

Stabilizing the Part D market: reform the NAMBA calculation, protect LIS benchmark access, and fix risk adjustment.

The core mechanism of Part D plan market destabilization was the substantial and rapid shift of catastrophic-phase risk onto plans: Medicare's reinsurance share of catastrophic-phase drug costs fell from about 80 percent to about 20 percent, while plan liability rose roughly threefold, from 20 percent to 60 percent, on a benefit that is also more generous. The catastrophic attachment point fell from roughly $7,400 to about $2,000, so plans reach liability far earlier and less predictably than before.

Plan bids reflect that shift starkly. The national average monthly bid amount (NAMBA) rose from $34.71 in 2023 to a projected $296.05 in 2027, a cumulative increase of roughly 753 percent over four years, while the base beneficiary premium has stayed comparatively flat by statutory design, a gap increasingly absorbed by a federal direct subsidy rather than reflected in what beneficiaries see. Plan availability has contracted accordingly: the number of nationwide standalone prescription drug plans (PDPs) fell from 709 in 2024 to 360 in 2026, a third consecutive year of decline and less than a fifth of the 2007 peak of 1,909, while the number of PDPs available to the average beneficiary fell from 30 in 2021 to 11 in 2026, and the number of parent organizations offering PDPs per region fell from 7 to 5 over the same two-year span.[21] Deductibles and coinsurance have also grown markedly more common in the standalone PDP market specifically: average PDP deductibles rose from $340 in 2020 to $491 in 2025, while the share of PDPs using coinsurance on Tier 3 preferred brands rose from 9.9 percent in 2020 to 84.1 percent in 2025.[22] CMS's own response to date, the Premium Stabilization Demonstration, is a temporary subsidy rather than a structural fix: MedPAC estimates it will cost Medicare roughly $9 billion combined across 2025 and 2026, and the IRA's separate 6 percent base-beneficiary-premium growth cap alone added an estimated $20 billion in direct-subsidy cost in 2026[23], masking rather than resolving the underlying bid pressure ahead of both mechanisms' expiration after 2029.

[20] This is an unpublished estimate from CAHC based on our model and previous research and prices from Cost Plus Drugs and GoodRx across the most commonly used therapeutic agents in Part D. We are happy to make the estimate available to the Committee.
[21] *https://www.kff.org/medicare/a-current-snapshot-of-the-medicare-part-d-prescription-drug-benefit/*
[22] *https://mann.usc.edu/news/most-medicare-beneficiaries-may-pay-more-for-drugs-under-the-ira/*
[23] https://www.medpac.gov/wp-content/uploads/2026/03/Mar26_Ch13_MedPAC_Report_To_Congress_SEC.pdf

We encourage the committee to adopt several changes to improve risk dynamics for plans and to help ensure standalone PDPs continue to be available as an option to Medicare Advantage plans:

- Create a reinsurance based high-risk pool for beneficiaries with exceptionally high drug costs to reduce unpredictable plan exposure and support participation by smaller plans. Similarly designed reinsurance models have helped states stabilize their ACA markets, encouraging plans to reenter states they had exited, while decreasing premiums and taxpayer subsidies.
- Improving the accuracy of the Prescription Drug Hierarchical Condition Category (RxHCC) risk-adjustment model: the model tends to underpredict costs for PDP beneficiaries and overpredict costs for Medicare Advantage Prescription Drug plan (MA-PD) beneficiaries, and is calibrated on a multi-year data lag that leaves it out of step with actual post-IRA utilization patterns. Congress should also consider allowing PDPs to use timely Parts A and B data, and diagnostic information obtained through prior authorization, for risk-adjustment purposes, with appropriate privacy safeguards.
- Rebalancing catastrophic-phase risk sharing to reduce plan liability above the threshold while adjusting risk corridors so plans are not exposed to catastrophic liability as quickly or as unpredictably as they are today.
- Revisit the out-of-pocket cap. Options included retaining a clean $2,000 cap with correct true out-of-pocket (TrOOP) accumulation, or raising it to more than $3,000. We also suggest pairing modest ongoing coinsurance with a maximum monthly copay in the catastrophic phase to encourage appropriate utilization.

With respect to the Committee's questions on NAMBA and low-income subsidy (LIS) reform, CAHC recommends:

- Congress should require calculation of the NAMBA separately for standalone PDPs and MA-PDs, or on a regional basis, and include Special Needs Plans (SNPs) in that calculation. SNP enrollment grew from 1.3 million beneficiaries in 2010 to 8.2 million in 2026 and accounted for 85 percent of the net increase in Medicare Advantage enrollment from 2025 to 2026[24], yet SNP bids are still excluded from the NAMBA calculation that helps set the base beneficiary premium for the entire Part D market.
- Using only standalone PDP bids, not blended PDP and MA-PD bids, to calculate the low-income subsidy (LIS) benchmark, so that lower MA-PD bids do not artificially depress the number of PDPs that qualify as premium-free benchmark plans for LIS beneficiaries. The number of premium-free standalone plans available to LIS beneficiaries has fallen by more than half since the IRA's enactment, and beneficiaries in 21 states and Washington, D.C. now have two or fewer benchmark plans to choose from.

B. Addressing Perverse Dynamics in the Supply Chain

Ending vertical-integration abuses, strengthening the Medical Loss Ratio, and prohibiting insurer-PBM-pharmacy conglomerate ownership in Part D.

[24] KFF, Medicare Advantage in 2026: Enrollment Update and Key Trends (June 2026), https://www.kff.org/medicare/medicare-advantage-in-2026-enrollment-update-and-key-trends/.

As I testified to the Senate Permanent Investigations Subcommittee in December[25], the prescription drug supply chain has become heavily vertically integrated. The three largest PBMs, CVS Caremark, Express Scripts, and OptumRx, control roughly 80 percent of prescriptions dispensed nationally and are each affiliated with one of the three largest health insurers, with their own specialty and mail-order pharmacies, and, increasingly, with provider groups. The consequences for patients are measurable. One recent analysis found that 86 percent of oral oncology and 92 percent of immunology patients who attempted to fill a brand prescription at a non-PBM-affiliated pharmacy were initially rejected, compared with 58 percent and 71 percent respectively at PBM-affiliated pharmacies, with correspondingly longer average coverage delays at non-affiliated pharmacies.[26] A recent National Bureau of Economic Research study found that vertically integrated Part D insurers increased prices at their affiliated pharmacies by 9.5 percent per claim relative to non-affiliated pharmacies following the introduction of MLR regulation, adding an estimated $1.2 billion to gross Part D drug spending from 2014 to 2016[27], and a Health Affairs study found UnitedHealthcare reimburses its affiliated Optum providers at rates 17 percent higher than its competitors on average, a gap that widens to 61 percent in markets where UnitedHealthcare holds at least a 25 percent market share.[28]

These vertically integrated entities are driving up costs for patients and consumers. CAHC recommends the Committee address this at its structural root: prohibit any entity providing PBM services in Medicare Part D from also owning, controlling, or holding a beneficial interest in a health plan, a retail, specialty, or mail-order pharmacy, or an entity that commercializes a prescription drug (including PBM-owned private-label generics and biosimilars) operating in that same market. A structural separation requirement is a more durable fix than narrower conduct rules, such as a cost-plus pricing mandate applied only to PBM-owned private-label biosimilars, layered onto a supply chain whose underlying incentive to self-deal remains intact.

Short of full structural separation, and as a complementary near-term step, CAHC supports strengthening Medicare Part D and commercial Medical Loss Ratio (MLR) requirements so that inflated reimbursement to affiliated pharmacies and providers can no longer count as patient-care spending for MLR purposes. Specifically, the MLR calculation should exclude the payments to affiliated entities to the extent they exceed the actual cost of delivering care measured by reimbursement an unaffiliated provider would receive for the same item or service in the same market. Congress should require mandatory reporting of reimbursements paid to owned or affiliated entities as part of the MLR calculation and make those reports subject to False Claims Act penalties since they affect taxpayer subsidies. We suggest applying MLR at the entity level to capture corporate-wide activity.

Finally, we suggest restricting PBMs from denying consumers access to any specialty pharmacy to access their medicines. We are concerned that changes to PBM requirements included in the

[25] Testimony of Joel White to the Permanent Subcommittee on Investigations Committee on Homeland Security and Governmental Affairs, December 10, 2025 available at: Defining Our Healthcare Problem, and Principles We Should Follow to Solve it - Committee on Homeland Security & Governmental Affairs
[26] Ehrenberg R., Copley K., and Johnson P., How PBMs' Vertically Affiliated Pharmacies Shape Access Pathways for Oncology and Autoimmune Patients, IQVIA (Mar. 2026).
[27] Kakani P. et al., "Profit Regulation and Strategic Transfer Pricing by Vertically Integrated Firms: Evidence from Health Care," National Bureau of Economic Research Working Paper No. 35043 (Apr. 2026).
[28] Arnold D. and Fulton B., "UnitedHealthcare Pays Optum Providers More Than Non-Optum Providers," Health Affairs (Nov. 2025).

Consolidated Appropriations law will cause PBMs to seek additional revenue streams through higher fees on plan sponsors or employers, or by restricting access to affiliated specialty pharmacies. CAHC encourages the Committee to apply a "lower cost pharmacy" principle similar to our proposal on direct purchase programs: if a consumer finds a pharmacy that costs less, they should be allowed to access their prescription from that venue.

Prohibiting PBM gag clauses and exclusive-negotiator arrangements, following the logic of the Healthy Competition for Better Care Act.

The RFI describes PBM contract terms that may make a PBM the "exclusive negotiator" of drug prices for its plan-sponsor clients, and separate "non-solicitation"-style terms that prohibit manufacturers from offering discounts directly to health plans or employers. These clauses can gag stakeholders from communicating with each other and foreclose exactly the kind of creative, direct-contracting arrangements that could otherwise lower costs. Congress has intervened against comparable gag clauses before: the 2018 Patient Right to Know Drug Prices Act banned PBM contract terms that prohibited pharmacists from telling patients about lower-cost ways to obtain their medicine.[29] CAHC recommends the Committee apply that same anti-gag-clause, anti-exclusivity logic here and prohibit exclusive-negotiator and non-solicitation clauses in PBM contracts with manufacturers, employers, and Part D plan sponsors.

We note that the specific model the Committee should draw on here, the bipartisan Healthy Competition for Better Care Act (S. 4027/H.R. 6248, 119th Congress, led by Senator Husted and Representatives Arrington, Allen, Davis, and Edwards)[30], currently targets a different part of the health care system, banning all-or-nothing clauses, anti-steering and anti-tiering clauses, most-favored-nation clauses, and gag clauses in hospital-insurer contracting.[31] We raise it here as a model to extend, not a bill that already reaches PBM contracts. The same anticompetitive dynamics, all-or-nothing terms, exclusivity, and confidentiality provisions that suppress price competition between hospitals and insurers, are present in PBM contracting with manufacturers and plan sponsors, and Congress should apply a parallel prohibition in that context.

Ensuring wide pharmacy access, fair minimum dispensing fees, and support for any willing pharmacy where prices are lower.

Pharmacy dispensing fees in Medicare Part D are, by some analyses, often less than a dollar, even though survey data from pharmacies put the actual cost of dispensing a prescription at $11 to $13. That shortfall pushes pharmacies to rely on margin, the spread between acquisition cost and reimbursement, as a substitute form of compensation, which in turn increases drug costs for patients and the system.[32]

CAHC recommends Congress establish an any-willing-pharmacy standard requiring Part D plans and their PBMs to allow any pharmacy that meets reasonable network terms and can offer equal or lower

[29] Patient Right to Know Drug Prices Act, Pub. L. No. 115-263 (2018).
[30] Text - S.4027 - 119th Congress (2025-2026): Healthy Competition for Better Care Act | Congress.gov | Library of Congress
[31] CAHC Endorsement Letter for H.R. 6248 available at CAHC-endorsement-letter-2025-HCBC.pdf
[32] Abt Associates, Cost of Dispensing Study (Jan. 2020), https://www.nacds.org/pdfs/pharmacy/2020/NACDS-NASP-NCPA-COD-Report-01-31-2020-Final.pdf

net cost to participate in the network, rather than steering volume to PBM-affiliated pharmacies through narrower networks or preferential terms.

Wide pharmacy access is also about the scope of care a patient can receive once they get there. The bipartisan Main Street Pharmacy Act (H.R. 3164/S. 2426, 119th Congress, led by Representative Adrian Smith) would formally recognize pharmacists as Medicare providers for testing and treatment of certain common respiratory illnesses, including flu, strep throat, and RSV, in states that already authorize pharmacists to provide that care, without preempting existing state scope-of-practice law.[33] CAHC supports that legislation as a complement to our any-willing-pharmacy recommendations: patients benefit from wide pharmacy access both in the sense of being able to fill a prescription at the pharmacy of their choice, and in the sense of being able to receive more of their routine care at that same community pharmacy.

Constraining utilization management tools to improve patient access.

Part D plans and PBMs may face incentives to use prior authorization, formulary exclusions, and step therapy as cost-control tools that go well beyond legitimate clinical safeguards, particularly when prescriber judgment, pharmacist review, and existing risk mitigation programs already ensure patient safety. The RFI's own review of HHS Office of Inspector General data found that 73 percent of Part D prior authorization rejections appealed by beneficiaries were ultimately overturned[34], and a 2025 IQVIA study found that beneficiaries who were initially denied a prescription and ultimately overcame the denial waited an average of 14 to 24 days for treatment, with 10 to 19 percent of these patients delayed five weeks or longer[35]. A rejection rate that high, and an overturn rate that high, are strong evidence that utilization management is too often functioning as a cost lever rather than a clinical safeguard.

CAHC recommends Congress: require plans to provide patients and providers with specific, standardized denial rationales, distinguishing incomplete documentation from a medical-necessity determination or another administrative issue; direct CMS to require plan-level and geographically disaggregated public reporting of prior authorization and point-of-sale rejection rates, appeal and overturn rates, and time-to-decision; establish a new Part D Star Rating measure tied to utilization-management performance, so that plans have a direct, quality-bonus-linked incentive to reduce inappropriate rejections; and surface plan-level denial performance on the Medicare Plan Finder so beneficiaries can compare plans on this basis during enrollment. We also encourage the Committee to examine whether broker and agent compensation can be structured to reward beneficiaries' enrollment in plans with better utilization-management track records, so brokers are not incentivized to steer beneficiaries toward plans with poor access records.

Section III: Bolstering Biopharmaceutical Innovation in the United States

[33] Main Street Pharmacy Act, H.R. 3164/S. 2426, 119th Cong. (2025-2026).
[34] Suzanne Murrin, "Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs," Office of Inspector General, U.S. Department of Health and Human Services (Sept. 18, 2019).
[35] IQVIA Institute, The Impact of Formulary Controls on Medicare Patients in Five Chronic Therapeutic Areas (June 16, 2025).

CAHC agrees that a successful affordability agenda must be paired with policies that keep biopharmaceutical research, development, and manufacturing anchored in the United States, with robust incentives to produce better and more therapies. We note that as more products come to market within therapeutic classes, brand prices typically fall significantly. We also see that more products that cure or treat illnesses better can reduce service costs. Ideally, we believe a shift in the health spending pie, with more spent on drugs, and less on hospital services, can both improve health and reduce the total spent on health care. In short, incentives to bring more products to market can reduce costs.

Incentivizing domestic manufacturing.

As the National Security Commission on Emerging Biotechnology (NSCEB)[36] has noted, reducing domestic barriers and expanding investments in US medical innovation, drug development, manufacturing, and jobs requires favorable policies to keep America in the lead. A roadblock to domestic production is proving that products and processes can scale. NSECB states, "Researchers are generating new products faster than manufacturing capacity is increasing. Building new facilities is expensive and time-consuming. Precommercial facilities can cost $100-200 million—while facilities for commercial scale can take two to five years to build and prepare and cost up to $2 billion."

CAHC recommends the Committee pair the affordability reforms described above with direct incentives for domestic production, alongside recommendations from the NSCEB to accelerate innovation in biopharmaceuticals. This could include: a 25 percent investment tax credit for qualified domestic biopharmaceutical manufacturing facilities under a new Internal Revenue Code Section 48F; authorize Defense Production Act financial assistance for essential-medicines manufacturing facilities, designated as critical infrastructure; require HHS to publish and annually update an Essential Medicines List and maintain a six-month strategic stockpile of active pharmaceutical ingredients for priority medicines, alongside an early-warning system for drug shortages.

Regulatory agencies should create simple pathways to market and exempt familiar products from unnecessary regulation. Congress and the FDA could also deregulate and standardize the product submission process while eliminating multiple submission requirements through a single point of entry for applications. Congress should also codify and expand the use of priority review vouchers, including the National Priority Review Voucher, which is explicitly tied to national security. Changes to the FDA approval process will accelerate new products on market that creates competition that lowers prices. Faster Medicare coverage will promote investment in new therapies as clearer, standard pathways help ensure more and larger investments as programs are de-risked. Congress could also authorize an add-on payment through Medicare reimbursement to allow preference for Made in America products. Finally, prioritizing DOD, VA, and HHS procurement policy for Made in USA with multi-year contracts to ensure predictable demand will help accelerate domestic production.

Another idea is to create targeted domestic production enterprise zones for biopharmaceuticals that provide tax incentives, revised environment and labor laws, and accelerated FDA approval for new

[36] https://www.biotech.senate.gov/

products meeting pricing goals. This is consistent with the President's Executive Order on Regulatory Relief to Promote Domestic Manufacturing of Medicines.[37]

Counteracting the China Threat

The RFI documents a rapid shift in global biopharmaceutical leadership. China now accounts for nearly one-third of the global pharmaceutical R&D pipeline, and since 2020 the number of pipeline assets, patents, and clinical trials held by the most innovative Chinese biopharmaceutical companies has grown 100 percent, 450 percent, and 110 percent respectively.[38] That growth is the product of deliberate, well-funded industrial policy, not organic market competition, including direct funding, low- or no-interest loans, discounted land and utilities, and cash rebates for new manufacturing facilities.

To stay ahead of China, the US needs smart policies to remain competitive. As the NSCEB has suggested, the Chinese Communist Party (CCP) employs "…a strategy that experts have called 'brute force economics,' a set of policies designed to increase China's dominance in strategically important sectors, including biotechnology".

The NSCEB has suggested, "In the face of China's aggressive efforts to dominate the biotechnology industry, the US government must fight back, taking targeted steps to unleash American innovation, capital, and manufacturing capacity." Track single points of supply chain vulnerability located in foreign countries of concern.[39] A strong, secure global supply chain will reduce dependency on foreign adversaries and keep America first. To keep drug prices lower and the supply chains stable, only impose punitive tariff taxes on military adversaries such as communist China rather than on allies. Increase protections for US intellectual property and ensure fair access to markets for American products and services.

Drug development is among the most expensive and time-intensive scientific pursuits, with early-stage R&D costing upwards of $2.5 billion. China is outpacing the US on cost efficiency and investment incentives, offering policy-forward environments that accelerate regulatory review and extend patent life, while translating into billions in additional return on investment.

To remain competitive, the US must rethink its innovation infrastructure. Artificial intelligence (AI) offers a powerful lever to reduce costs and speed up discovery by identifying drug targets, designing molecules, and optimizing clinical trials through real-time data analysis. But AI's potential is throttled by limited access to high-quality, diverse datasets. Existing databases are siloed, proprietary, and often lack interoperability.

A publicly funded NIH data repository could transform this landscape by aggregating deidentified claims, clinical, biologic, and other data to fuel AI model training and drug discovery, research, and development. With enabling legislation, drug companies could access this resource to conduct R&D and initiate clinical trials. This would create a virtuous cycle of public investment, private innovation, and improved patient therapies.

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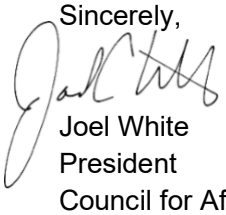
[37] President's Executive Order on Regulatory Relief to Promote Domestic Manufacturing of Medicines
[38] RFI at 39, citing Ian Lloyd, "Pharma R&D Annual Review 2025," Citeline (Mar. 2025), and "Mainland China Biopharma Innovation 2.0," Clarivate (Dec. 8, 2025).
[39] https://www.biotech.senate.gov/

We encourage the Committee to draw on this framework as it considers how to keep pace with China's centrally coordinated investment in biopharmaceutical manufacturing and research capacity.

Conclusion

CAHC appreciates the Committee's continued attention to prescription drug affordability, and we hope the recommendations above, grounded both in our own Part D roundtable work and in the broader public record, are useful as the Committee moves from this Request for Information toward legislative text. We would welcome the opportunity to discuss any of these recommendations in more detail, and we look forward to continuing to work with the Committee on these issues.

Sincerely,



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