This executive summary outlines PhRMA's key recommendations in response to Senator Wyden's Request for Information on "Commonsense Policy Options to Lower Drug Prices for Patients." The recommendations below are intended to provide a concise overview of PhRMA's policy positions; readers should refer to PhRMA's full comment letter for additional context, supporting evidence and detailed discussion of each recommendation.

Section I: Lowering Drug Prices

Factoring International Pricing into the MDPNP

- PhRMA urges the Committee to reject proposals that incorporate MFN pricing or other international reference pricing into the MDPNP.
- The Committee should not import foreign price controls or valuation methods—many of which rely on discriminatory tools such as QALYs.

Negotiating Lower Prices on More Drugs & Earlier in the Lifecycle

- PhRMA strongly opposes proposals that would shorten the statutory eligibility timeline for Medicare drug price setting.
- PhRMA also strongly opposes proposals that would expand the number of drugs subject to the MDPNP.
- The Committee should advance solutions that preserve incentives for post-approval research, additional indications, small molecule innovation and biologics development.

Generic and Biosimilar Competition

- PhRMA supports preserving incentives for generic and biosimilar market entry.
- The Committee should address IRA-related biosimilar barriers by simplifying the Special Rule process, allowing quicker exit from price setting after biosimilar approval and marketing and eliminating CMS' "bona fide marketing" standard.
- The Committee should explore policies that reform PBM incentives that disadvantage biosimilars, including self-preferencing of private-label biosimilars over lower cost options.

Eliminating the Orphan Cures Act (OCA)

- PhRMA strongly disagrees that a replacement framework for the Orphan Cures Act is needed.
- Instead, the Committee should preserve orphan drug incentives included in the Orphan Drug Act, as well as the OCA's corrections to the IRA's narrow orphan drug exclusion. These protections are immensely important for facilitating research to meet the needs of patients with rare diseases.

Modifying and Extending Medicare Inflation Rebates

PhRMA strongly opposes proposals to:

- Re-base Part B and Part D inflation rebate benchmark dates to an earlier year.
- Extend Medicare inflation rebates to the commercial market.
- Extend the Part B inflation rebate program to Medicare Advantage units.

Subscription Models

- To advance the objectives of the RFI, the Committee should explore policy actions to reduce regulatory barriers to market-based negotiations that can limit wider adoption of innovative contracting arrangements, such as subscription models that support expanded GLP-1 access.
- Any new payment model should be explored on a voluntary basis, and should not impose a mandatory subscription framework, which could disrupt competition and patient access.

Section II: Enhancing Prescription Drug Affordability

Out-of-Pocket Caps

- The Committee should reimagine Medicare Prescription Payment Plan (MPPP) administration through a centralized contractor rather than Part D plan sponsors.
- The Committee should consider and start to lay the groundwork for enrollment through real-time point-of-sale election, formula simplification, rolling 12-month smoothing, targeted auto-enrollment with opt-out and stronger plan incentives.
- Consider allowing beneficiaries to elect Social Security deductions for smoothed payments.

Improvements to Medicare Low-Income Assistance Programs

- Ensure eligible beneficiaries can access existing affordability programs.
- Consider options such as targeted outreach to LIS beneficiaries paying premiums to ensure they know about premium-free options, broker incentives to help LIS-eligible beneficiaries access the subsidy and improved messaging on Medicare.gov and Plan Finder for beneficiaries to elect more information/personal outreach.

Distortions in Coinsurance & Deductibles

- Require PBMs and plans to pass manufacturer rebates and discounts directly to patients at the pharmacy counter.
- Ensure patients in deductibles or coinsurance benefit from negotiated net prices across Medicare Part D and the commercial market.

Direct Purchase Programs

- Clarify that a medication's inclusion in a direct purchase programs (DPP) cannot be used to justify narrowing covered benefits or shifting additional costs onto patients.
- Require DPP purchases of covered medicines to count toward deductibles and out-of-pocket limits.
- Consider requiring plans to base patient cost sharing on lower public market prices, such as those available on DPPs.

Part D Market Impact

- Improve Part D risk adjustment accuracy by addressing RxHCC data lag and reliance on medical diagnoses rather than prescription drug utilization.
- Improve payment accuracy through separate MA-PD/PDP NAMBA calculations, SNP inclusion, separate application of the IRA six percent premium cap and comparable PDP stabilization support.

- Use only PDP bids to calculate LIS benchmarks or consider requiring MA-PD sponsors to offer at least one PDP in each region to address shrinking LIS plan offerings.

"Games & Abuses Due To Vertical Integration"

- Ban PBM GPO ownership or control by entities providing PBM services.
- Prohibit pharmacy steering to PBM-affiliated pharmacies, require transparency for affiliated-pharmacy transactions and explore whether further structural remedies related to pharmacy ownership could address pharmacy steering challenges.
- Reform MLR calculations and affiliated-entity reporting to prevent profit shifting from counting as patient care spending.

PBM Private Label Drugs

- Prohibit PBM ownership or control of entities that commercialize prescription drugs.

PBM Gag Clauses

- Prohibit PBM non-solicitation, exclusivity and gag clauses that block lower cost or non-traditional access models.

Increasing PBM Accountability for Rising Drug Costs

- Avoid PBM trend- or inflation-based caps that could discourage coverage of innovative therapies.
- Strengthen and enforce Part D MLR requirements to address profit shifting and improve PBM accountability.

Addressing Price-Linked Compensation

- Preserve the ASP-plus add-on reimbursement framework for Part B medicines.
- Avoid additional cuts, caps or tiered add-on payments that could undermine independent physician practices and patient access to community-based care.

Inappropriate Pharmacy Rejections

- Require payers to provide specific prior authorization (PA) denial reasons to patients and providers and report standardized denial rationales to CMS.
- Publicly report plan-level denial, appeal, overturn, time-to-decision and point-of-sale rejection metrics, disaggregated where feasible.
- Link denial-related performance to accountability tools, including Star Ratings, Medicare Plan Finder and Exchange flags, and financial, enrollment or broker incentives.

Section III: Bolstering Biopharmaceutical Innovation in the United States

Bolstering Funding for Basic Research in the United States

- PhRMA does not believe that a sector-specific assessment on the biopharmaceutical industry to fund NIH research is warranted.
- Congress should fund NIH through predictable appropriations and preserve incentives that attract private investment, including Bayh-Dole licensing, patent certainty and voluntary technology-transfer models that do not attach pricing conditions to federally funded science.

Increasing the Rigor of NIH funded Basic Research

- Congress should codify preregistration and pre-analysis plans as scored NIH grant review criteria.
- Congress should also amend the annual NIH appropriations law or the Public Health Service Act to explicitly support rigor in scientific research.
- Congress should direct NIH in statute to collect and report annually to the authorizing and appropriations committees of jurisdiction on a defined set of accountability indicators. .
- The Committee should direct the President and Congress to jointly establish a National Biomedical Enterprise Research Advisory Body with coordinating authority to galvanize national leadership and establish scientific rigor standards across federal funders.
- Advance legislation that would improve the quality of important pre-clinical research through pre-grant review support.

Improving Domestic Investments in Translational Research

Congress should:

- Reauthorize NCATS to de-risk translational research for qualified private sector, academic and nonprofit partners through voluntary co-investment.
- Grant NCATS its own Other Transaction Authority to enable flexible, milestone-based agreements at a scale sufficient to attract a meaningful level of co-investment.
- Remove or substantially modify the restriction on NCATS funding of clinical trials beyond Phase II in defined market-failure circumstances.
- Establish by statute a National Translational Science Investment Fund administered jointly by NCATS and a public-private governance board address translational bottlenecks.
- Strengthen the CTSA hubs as a national delivery and learning network.

Boosting Domestic Clinical Trials

- Reform IND and IRB frameworks, including predictable FDA feedback and a national IRB network, to improve early-phase clinical research.
- Integrate clinical research into routine care through point-of-care trial platforms, decentralized models and regulatory-grade real-world data standards.
- Reduce participation barriers by excluding reasonable trial supports from taxable income and means-tested benefit calculations and clarifying AKS protections.
- Clarify use of local providers in decentralized trials and reimburse clinical research coordination under Medicare and Medicaid.

Preserving the FDA Approval Framework That Drives Innovation

- Reaffirm and protect the premarket-approval framework as the reliable pathway for establishing broad commercial access to safe and effective medicines.
- Address illegal mass compounding of unapproved copies through enforcement, not expanded availability.

Scientific Talent and the Biomedical Workforce

- Create a national biomedical service corps focused on research and manufacturing expertise.
- Fund reciprocal biotech professional exchanges across government, industry and academia.

- Retain critical biomedical talent through targeted tax, loan, housing, apprenticeship and high-skilled immigration policies.
- Build responsible AI fluency into STEM education and biomedical workforce development.

Lessons from the Inflation Reduction Act and CHIPS and Science Act

- Avoid IRA-style price controls and investment disincentives that reduce early-stage capital, clinical trial activity and small molecule innovation.
- Preserve the U.S. innovation ecosystem through strong IP, regulatory predictability, globally integrated supply chains, public-private research and market-based incentives.