Executive Summary
Comment Letter to HHS on Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

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The Pharmaceutical Research and Manufacturers of America (PhRMA) submitted comprehensive comments to the Department of Health and Human Services (HHS) request for information (RFI), *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*. We commend the Administration for examining key factors that influence spending on medicines and identifying areas where improvements are needed. We are committed to advancing policies that address misaligned incentives in the biopharmaceutical supply chain and lower out-of-pocket costs for patients.

The Administration's Drug Pricing Blueprint and RFI include an expansive series of proposals that could realign incentives and fundamentally change how patients access medicines. It is important we assess each proposal on its individual merits and enact policies that would improve how the system operates today. While some of the changes in the RFI could make improvements to the system, others would be a step backward for patients.

Key Issue Areas

PhRMA provided in-depth feedback on a myriad of issues addressed in the RFI. Individualized summaries on several of those core issues follow. To review the entire PhRMA submission, please click here.

Rebates: The biopharmaceutical industry is taking a bold new stance on how payments work in the supply chain. How we pay for medicines has evolved into a complex system of list prices and rebates that move through an opaque supply chain that often results in uncertainty and frustration for patients and payers alike. Pharmacy benefit managers (PBMs) and other entities in the supply chain have incentives to favor medicines with high list prices and rebates. This hurts patients and increases costs, and we believe it must change. We recommend the following policies in our RFI comments:

- *Delink supply chain payments from list price:* The current system should shift to one where PBMs and other entities in the supply chain no longer have their fees calculated based on a percent of the list price of a medicine.
- *Empower payers:* Payers should have greater visibility into PBM compensation arrangements.
- *Make sure patients benefit from rebates:* Rebates and other price concessions that payers receive from biopharmaceutical companies should be used to lower cost sharing for medicines.

Medicare Part D: Changes are needed to improve affordability and predictability in the Medicare Part D program. But some of the proposals in the RFI would be a step backward for patients. In our comments, we urge the following policies to protect Medicare patients:

- *Strengthen out-of-pocket protections:* We support lowering out-of-pocket costs for seniors by requiring that patients receive a share of negotiated rebates at the pharmacy and establishing an annual maximum out-of-pocket spending limit on medicines. Research shows these reforms will provide immediate financial relief to patients facing high out-of-pocket costs at the pharmacy.
- *Maintain current formulary protections:* The current six protected classes and two drugs per class requirements are core patient protections in Part D and should be maintained. Insurers currently have ample opportunities under these protections to manage formularies and use prior authorization and step therapy to steer patients to lower cost medicines. Weakening these protections could jeopardize patient care and result in additional paperwork and red tape for physicians due to an increase in appeals requests to access appropriate off-formulary medicines.
- *Continue current treatment of coverage gap discounts in the calculation of true out-of-pocket (TrOOP) spending:* Ignoring coverage gap discounts when calculating TrOOP would exacerbate beneficiary affordability challenges and undermine the Administration's goal of reducing out-of-pocket costs. This change would prolong the amount of time patients spend in the coverage gap and increase out-of-pocket spending by hundreds of dollars for some patients.

Global free-riding: America's biopharmaceutical sector has witnessed a surge in the number of trading partners that mandate price controls and other harmful trade practices to artificially depress the market value of innovative medicines. These practices stifle global research and development and the flow of new medicines that lead to greater competition and savings. The result is that Americans are increasingly shouldering the burden of global investment in discovering new medicines. We propose four actions to end the most unfair and discriminatory trade practices:

- *Secure strong trade commitments:* Global, regional and bilateral negotiations (including the ongoing NAFTA renegotiations) provide opportunities to secure commitments necessary to drive and sustain 21st century biopharmaceutical innovation.
- *Enforce existing trade commitments:* The Administration should use all available tools to ensure America's trading partners live up to their obligations in trade agreements, such as those negotiated with South Korea and Australia.
- *Ensure foreign government pricing and reimbursement policies are transparent, non-discriminatory and appropriately value innovation:* The U.S. government can play a critical role in ensuring transparency and due process of pricing and reimbursement policies, as well as in highlighting the global benefits to patients that result from a reduction in trade barriers.
- *Leverage all available trade tools to combat abuse of compulsory licensing:* Where specific and credible threats of compulsory licensing arise, the U.S. government must defend American innovators and engage relevant authorities abroad.

340B Drug Pricing Program: PhRMA supports the goals of the 340B program, but increasing evidence from the Government Accountability Office (GAO) and the HHS Office of Inspector General (OIG) and recent journal articles is proving many hospitals are taking advantage of the program. Even as independent watchdogs have raised concerns about patients not benefiting from the program, 340B has continued to grow exponentially, and economists have raised concerns that the program's growth is likely increasing overall spending on medicines. We urge the Administration to revisit current 340B policies and make changes to strengthen the program, including:

- *Issue a clearer patient definition:* The GAO and the OIG have both raised concerns that the current guidance on which patients qualify for 340B discounts is overly vague and is not interpreted consistently. HHS should develop clearer standards for who is a 340B patient and ensure the definition is aligned with the statute.
- *Update eligibility standards for hospitals' outpatient sites:* Current eligibility rules increase incentives for provider consolidation, driving up costs for consumers.
- *Revisit contract pharmacy guidance:* A new GAO report found hospitals often do not pass along 340B discounts and large pharmacy chains are profiting off the program.

Value-based contracts: The biopharmaceutical industry is working with health plans and others to develop new contracting approaches that tie payment more closely to value – as evidenced by the 19 biopharmaceutical companies that publicly announced these arrangements from 2009 to Q1 2018. These value-based contracts can support lower costs and better outcomes while improving patient affordability and access. Recent data show value-based contracts may have lowered patients' copays by 28 percent. It is essential that value-based contracts be based on negotiations between private entities, as government price setting based on centralized determinations of value would harm patient access to medicines. To encourage voluntary value-based contracts, we suggest the following policy changes:

- *Address regulatory barriers:* The Food and Drug Administration recently issued two final guidance documents helping to address one of the key regulatory barriers to value-based contracts. We encourage the Administration to continue this momentum and issue an Anti-Kickback Statute safe harbor for value-based arrangements and clarify the rules for the reporting of Medicaid best price.

Medicare Part B: The Medicare Part B program provides vulnerable Medicare patients with a range of complex conditions access to medicines that are generally administered by providers. Part B relies on a market-based system that has succeeded in keeping spending trends below medical inflation. As changes are considered to this program, it is critical to preserve patients' ability to obtain timely access to the full range of treatment options. It will be important that the Administration:

- *Refrain from moving coverage of medicines from Part B to Part D:* Shifting medicines from Part B into Part D would increase costs for most patients. Also, introducing closed formularies into Part B would limit patient access to medicines where patients typically are not able to switch between therapies.
- *Avoid the implementation of a competitive acquisition program (CAP) that would undermine strengths of the current system:* We have concerns that a CAP program would restrict patient access, increase patient costs or undermine the market-based Average Sales Price system. Any CAP program should be voluntary for physicians and should reduce their administrative burden and support quality patient care.

Medicaid: Spending on medicines represents a small share (7 percent on average) of total state Medicaid budgets. At the same time, biopharmaceutical companies' Medicaid rebate liability and tax obligations have increased dramatically with the implementation of the Affordable Care Act. The expansion of Medicaid rebates, along with the pharma tax, may have placed pressure on list prices, forcing companies to raise prices overall in the market. To avoid further market distortions, the Administration should:

- *Maintain the cap on Medicaid rebates:* This cap is a common-sense policy that prevents further cost shifting – while still ensuring Medicaid can obtain many medicines for free after rebates are received. Removing this cap could backfire on the Administration's goal and contribute to higher launch prices.

Direct-to-Consumer (DTC) advertising: The disclosure of list prices in DTC ads would not benefit patients and could be confusing given the significant negotiations occurring in the marketplace. List prices are often not the prices insurers pay and are generally not a good indicator of what patients will pay at the pharmacy counter since their insurer may charge a flat copayment or patients may have reached their out-of-pocket maximums. In addition, price comparison websites already exist to help consumers compare prices charged for medicines at different pharmacies. Moreover, any such requirement would raise significant legal issues, including First Amendment concerns.