

Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy

Executive Summary

President Biden’s Executive Order 14036, “Promoting Competition in the American Economy” (the Competition Executive Order), identifies a lack of competition as a key driver for problems across economic sectors. This Report presents the principles for equitable drug pricing reform through competition, innovation, and transparency; describes promising legislative approaches; and summarizes actions already underway or under consideration across the Department of Health and Human Services (HHS). In the course of preparing the Report, Secretary Xavier Becerra, other HHS officials, and HHS staff held listening sessions with consumer groups, staff from the Medicare Payment Advisory Commission (MedPAC), independent experts and researchers, and stakeholders from across the health care system.

Americans spend more than \$1,500 per person on prescription drugs and pay prices that are far higher than any comparable nation. Prices for brand name drugs are rising faster than inflation. Many Americans do not take medications as prescribed because of their cost, with resulting harm to their health care and health. Lack of competition is a key factor in these high drug costs.

The Report identifies three guiding principles for the Drug Pricing Plan:

- 1) **Make drug prices more affordable and equitable for all consumers and throughout the health care system** - Support drug price negotiation with manufacturers and stop unreasonable price increases to ensure access to drugs that can improve health for all Americans
- 2) **Improve and promote competition throughout the prescription drug industry** - Support market changes that strengthen supply chains, promote biosimilars and generics, and increase transparency
- 3) **Foster scientific innovation to promote better health care and improve health** - Support public and private research and make sure that market incentives promote discovery of valuable and accessible new treatments, not market gaming

Support for Bold Legislative Action. The Report highlights potential legislative policies Congress could pursue to advance the principles described above, including:

- Drug price negotiation in Medicare Parts B and D, with those negotiated prices also available to commercial plans (including the Marketplace) and employers who want to participate
- Medicare Part D reform, including a cap on catastrophic spending to protect beneficiaries from unaffordable out-of-pocket costs
- Legislation to slow price increases over time on existing drugs

- Legislation to speed the entry of biosimilar and generic drugs, including shortening the period of exclusivity, and policies in Medicare Part B to increase the prescribing of biosimilars by clinicians
- Prohibition on “pay-for-delay” agreements and other anti-competitive practices by drug manufacturers
- Investment in basic and translational research to foster innovation, including President Biden’s proposal to create the Advanced Research Projects Agency for Health (ARPA-H)

Administrative Actions. There are also many administrative tools HHS can use to promote competition and reduce drug prices to advance the Administration’s principles, including:

- Testing models using value-based payments in Medicare Part B, in which payment for drugs is directly linked to the clinical value they provide patients
- Testing models providing additional cost-sharing support to Medicare Part D Low-Income Subsidy Beneficiaries for using biosimilars and generics
- Testing total cost of care models in Medicare to determine whether they produce changes in drug utilization, reductions in total spending, and improvements in patient outcomes
- Data collection from insurers and Pharmacy Benefit Managers (PBMs) to improve transparency about prices, rebates, and out-of-pocket spending on prescription medications
- Continuing to implement the Food and Drug Administration’s Biosimilars Action Plan and Drug Competition Action Plan, and clarifying the approval framework for generic drugs to encourage a more transparent and efficient process
- Work with states and Indian Tribes to develop drug importation programs that reduce costs to consumers without increasing risks to safety

The overall goal of the Biden-Harris Administration is to foster innovation, increase competition, and improve the market environment, all in pursuit of reduced drug spending for consumers and throughout the health care system. Most importantly, these actions will protect patients and improve their access to affordable prescription drugs, ultimately helping to keep Americans healthier and more financially secure.