

Lowering Prescription Drug Costs for Americans, Response to President Biden’s Executive Order

Prescription drug prices in the United States are higher than in other comparable countries.¹ The elevated prices result in affordability and access challenges for millions of Americans. In the past year, 3 in 10 American adults reported not taking their medications as prescribed due to cost.² The underlying causes of high prescription drug prices are well documented and include market failures, such as lack of price and data transparency, and misaligned financial incentives for providers and others in the drug supply chain, which allow the growth of prescription drug prices to outpace inflation.³ These high prices can force Americans to make difficult choices between paying their household expenses and rationing their medication doses or, worse yet, not filling their prescriptions at all. Medication non-adherence is strongly correlated with poor health outcomes and preventable medical costs.⁴

Enactment of the Inflation Reduction Act of 2022 (IRA) (P.L. 117-169) brought sweeping changes to help address rising prescription drug prices in Medicare Parts B and D. These changes include, but are not limited to, caps on beneficiary out-of-pocket spending, access to certain vaccines at no cost to the beneficiary, drug inflation rebates, and a provision that requires the Secretary of Health and Human Services (HHS) to negotiate the prices of certain drugs.

The selected models will help lower the high cost of drugs and promote accessibility to life-changing drug therapies while maintaining and/or improving quality of care and beneficiary experience.



To build on the IRA, on October 14, 2022, President Biden issued Executive Order 14087, “**Lowering Prescription Drug Costs for Americans**,” to further address prescription drug affordability through the work of the Centers for Medicare & Medicaid Services’ (CMS) Center for Medicare and Medicaid Innovation (the Innovation Center).⁵ The Innovation Center tests innovative payment and service delivery models designed to reduce program expenditures while preserving or enhancing the quality of care furnished to its beneficiaries.⁶




The executive order directs the Secretary of HHS to “consider whether to select for testing by the Innovation Center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs, including models that may lead to lower cost-sharing for commonly used drugs and support value-based payment that promotes high-quality care.”⁷ It further directs the Secretary to submit a report to the White House’s Assistant to the President for Domestic Policy no later than 90 days from the date of the executive order “enumerating and describing any models that the Secretary has selected,” including “the Secretary’s plan and timeline to test any such models,” and to “take appropriate actions to test any health care payment and delivery models discussed in the report.”

To develop and prioritize model options for consideration by the Secretary, the Innovation Center used specific criteria consistent with the Center’s strategic priorities, notably, affordability, accessibility, and feasibility of implementation.⁸ To help identify model options, the Innovation Center solicited input from experts within CMS, other federal agencies, and over 40 external stakeholders, including but not limited to beneficiary and caregiver advocacy groups; trade associations representing manufacturers; payers and pharmacy benefit managers; independent consultants; academic research institutions; hospital systems; provider groups; and data vendors.

The report, in response to the President’s executive order, describes three models the Secretary has selected for testing by the Innovation Center that will complement the prescription drug provisions contained in the IRA. The Secretary believes the selected models will help lower the high cost of drugs and promote accessibility to life-changing drug therapies while maintaining and/or improving quality of care and beneficiary experience. In addition to the selected models, the Secretary identifies three areas for additional research.

The Innovation Center will work with interested parties to continue research into the design and feasibility of these ideas, while ensuring that it is first able to move forward with the three selected models.

Table 1. The Secretary’s Selected Drug Affordability & Accessibility Models

Area	Model	Test Question	Design
Medicare Part D	Medicare High-Value Drug List 	What is the impact of standardizing the Part D benefit for high-value generic drugs on beneficiary affordability, access, health outcomes, and Medicare spending?	Part D plans would be encouraged to offer a low, fixed co-payment across all cost-sharing phases of the Part D drug benefit for a standardized Medicare list of generic drugs.
Medicaid	Cell & Gene Therapy Access 	Does a CMS-led approach to administering outcomes-based agreements for certain cell and gene therapies improve beneficiary access and equity and reduce health care costs?	State Medicaid agencies would assign CMS to coordinate and administer multi-state outcomes-based agreements with manufacturers for certain cell and gene therapies.
Medicare Part B	Accelerating Clinical Evidence 	Do targeted adjustments in Part B fee-for-service payments for drugs approved by the Food and Drug Administration (FDA) under the accelerated approval pathway improve timely confirmatory trial completion and reduce Medicare spending, while maintaining or improving quality of care?	CMS would develop payment methods for drugs approved under accelerated approval, in consultation with FDA, to encourage timely confirmatory trial completion and improve access to post-market safety and efficacy data.

Endnotes

¹ RAND Corporation. (2021). International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies (RR-2956-ASPEC). <https://doi.org/10.7249/RR2956>

² Kaiser Family Foundation. (2022, October 20). Public Opinion on Prescription Drugs and Their Prices. <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>

³ Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy. September 2021. <https://aspe.hhs.gov/reports/comprehensive-plan-addressing-high-drug-prices>

⁴ Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Report to Congress on the Affordability of Insulin. December 16, 2022. <https://aspe.hhs.gov/reports/insulin-affordability-rtc>

⁵ Executive Order No. 14087, 87 Fed. Reg. 63399 (October 14, 2022)

⁶ Sec. 1115A. [42 U.S. Code § 1315a] - Center for Medicare and Medicaid Innovation

⁷ Executive Order No. 14087, 87 Fed. Reg. 63399 (October 14, 2022)

⁸ Center for Medicare and Medicaid Innovation. (2021). Driving Health System Transformation - A Strategy for the CMS Innovation Center’s Second Decade. <https://innovation.cms.gov/strategic-direction>

