

Client Alert

White House Looks to CMMI to Test New Ways to Lower Drug Prices

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President Biden signs Executive Order directing HHS to “consider additional actions to further drive down prescription drug costs”

On October 14, 2022, President Biden signed an Executive Order (EO) directing the Secretary of the Department of Health and Human Services (HHS) to consider new healthcare payment and delivery models the Center for Medicare & Medicaid Innovation (CMMI)—part of the Centers for Medicare & Medicaid Services (CMS) and created by the Affordable Care Act—can test to lower drug costs and promote access to innovative drug therapies for Medicare and Medicaid beneficiaries. The EO specifies the HHS Secretary should include models that may lead to lower cost-sharing for commonly used drugs and support value-based payment initiatives that promote high-quality care. The Secretary’s report, describing any models selected, must be submitted within 90 days of the EO’s issuance.

The EO comes two months after the president signed the Inflation Reduction Act (IRA) which aims to lower the cost of prescription drugs for many Medicare beneficiaries. In summary, the IRA will:

- Phase in an annual cap for out of pocket expenses at the pharmacy
- Establish a \$35 monthly cap per prescription of insulin
- Allow beneficiaries to pay \$0 out of pocket for recommended adult vaccines covered under Medicare Part D plans
- Require drug manufacturers who raise prices faster than inflation to pay Medicare a rebate
- Lower beneficiary costs for certain single-source drugs accessed at the pharmacy and physician administered drugs by requiring HHS to negotiate lower drug prices with drug manufacturers

CMMI has broad statutory authority not only to test, design, and implement health care payment and delivery models for Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP) but in certain instances, can implement such models without Congressional action. Generally, as long as HHS determines that a model improves the quality of patient care without increasing spending, CMMI may expand its models through rulemaking. Since CMMI’s creation, four models have met the statutory criteria for expansion. They include the Medicare Diabetes Program (aimed to prevent onset type 2 diabetes among beneficiaries with an indication of prediabetes), the Home Health Value-Based Purchasing program, the Medicare Prior to Authorization Model for Repetitive Scheduled Non-Emergent Ambulance Transport, and the Pioneer Accountable Care Organization (ACO) Model.

Previous administrations attempted to lower drug prices using CMMI models with limited success

This is not the first time that the White House will try to leverage CMMI's testing authority to create models that would lower drug costs in Medicare. CMMI attempted to test nationwide models to fundamentally change Medicare Part B drug payment policy under the Obama and Trump administrations but pressure from Congress, various stakeholders, and legal challenges voided the models before they could be tested.

In 2016, the Obama administration attempted to use CMMI to test the Medicare Part B Drug Payment Model Demonstration ("Part B Demo") which would have created incentives for patients and physicians to select lower-cost, therapeutically equivalent drugs. Phase one of the model would have evaluated whether reducing the cost of the add-on fee for Part B drugs from the statutorily-required Average Sales Price (ASP) + 6% to ASP + 2.5% plus a flat fee of \$16.80 would disincentivize providers to prescribe higher-cost drugs. Phase two would have tested the use of value-based purchasing tools used by commercial health plans, hospitals and pharmacies. Because of its mandatory and far-reaching scope, nearly 200 Members of Congress signed a letter to CMS asking to "cease all current and future planned mandatory initiatives with CMMI" and that "future CMMI models fully comply with current law...and seeking Congressional approval if expansion of test models require changes to underlying statutes." Stakeholders worried that the Part B Demo would limit patient access to certain drugs and threaten the economic viability of small physician practices. Succumbing to Congressional and broad stakeholder pressure, CMS withdrew the payment model.

In late 2020, the Trump administration proposed the Most Favored Nation Model (MFN), also to be tested by CMMI, which would have assessed whether 1) more closely aligning payment for 50 Medicare Part B drugs with international prices and 2) removing incentives to use higher-cost drugs could control growth in Medicare Part B spending without adversely affecting quality of care for beneficiaries. In other words, Medicare would pay no more for high-cost drugs and biologicals than the lowest price that drug manufacturers receive in other similar countries, resulting in lower out of pocket costs for beneficiaries. Met with several court challenges, the MFN's implementation was halted when the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction pending the completion of notice and comment process under the Administrative Procedure Act's (APA) requirements. Health care stakeholders such as health systems, drug manufacturers, patient advocacy groups, and physician groups expressed concerns about the potential for beneficiaries to lose access to drugs, the financial hardship and administrative burden on hospitals/practices, and the potential for the model to exacerbate practice struggles during the COVID-19 pandemic. The Biden administration formally rescinded the MFN model in 2021.

Potential directions CMMI may take to lower drug costs

CMMI has already telegraphed new models aimed at lowering drug costs for Medicare and Medicaid beneficiaries. We expect that HHS's response to the October 14 EO will rely upon prior issuances and statements from government officials. Posted last August, CMMI issued a [Strategic Refresh](#) white paper proposing to address affordability directly through models that "focus on moderating drug prices," or indirectly through models that "target low-value care and sources of waste that drive up patient costs." Earlier this year, CMMI director Liz Fowler voiced the Center's commitment to beneficiary goals such as reducing out-of-pocket costs on

drugs by lowering program spending and increasing biosimilar/generic drug utilization. As outlined in the Strategic Refresh, CMMI will consider models that test innovative payment approaches for Medicare Part B drugs such as shared savings and bundled payment models or total cost of care models that include Part B and Part D drugs. CMMI is already testing a Part D Senior Savings Model which offers beneficiaries the choice of Part D plans with lower out-of-pocket costs on insulin.

Last September, in response to President Biden's EO on Promoting Competition in the American Economy, the HHS Secretary issued a Comprehensive Plan for Addressing High Drug Prices that included several plans to incorporate CMMI models as a part of the administration's actions to reduce drug prices. According to the Plan, HHS also contemplated using CMMI to test:

- Innovative payment models that link payment for prescription drugs to factors like improved patient outcomes, reduction in health disparities, and overall lower costs. Models in this category include incentives for use of high-value therapies and outcome-based arrangements with manufactures.
- Shared savings models in which savings from utilization of biosimilars and generics are shared between providers and the government benefiting beneficiaries with lower premiums and lower out-of-pocket costs.
- Bundled payment models that focus on episodes of care that include drugs and biologics and include incentives for use of biosimilar and general drugs.
- Total Cost of Care Models, like the Enhanced Oncology Model – the next generation Oncology Care Model – which will continue test whether comprehensive payment and service delivery reform results in changes to drug utilization, spending, and patient outcomes.

Mid-January, HHS Secretary Becerra will send a report to the White House with a list of models CMMI could test to lower drug costs and promote access to innovative drug therapies. HHS and CMMI have identified several models that have the potential to lower drug costs for millions of Medicare and Medicaid beneficiaries, but history suggests the Biden administration's reliance on CMMI to change the trajectory of drug costs may be limited without significant support from Congress.

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