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Insight Alert

Drug Pricing Déjà Vu: The Biden-Harris Administration's Fiscal Year 2024 Budget Doubles Down on Inflation Reduction Act Reforms; CMMI and MedPAC Also Weigh In

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Are Accelerated Approval Drugs a New Target for Cost Reductions?

As outlined in our prior analysis, the Inflation Reduction Act (IRA) included sweeping drug pricing reforms for the Medicare program and the Biden-Harris administration has made clear that they are "full steam ahead" with implementing these provisions. The IRA's provisions may significantly impact the future of pharmaceutical innovation, patent litigation and market entry. However, the recent release of the President's Fiscal Year (FY) 2024 Budget clearly signaled that the Biden-Harris administration also sees an expansion of the IRA's drug pricing provisions as the path to Medicare savings. While it is unlikely that these budget proposals will get very much traction in the current era of divided government, it is worth taking stock of this development, especially as stakeholders continue to grapple with implementation of the existing reforms enacted last year and other recent drug pricing actions by the Biden-Harris administration and Medicare Payment Advisory Committee (MedPAC). This policy alert outlines the drug pricing reforms included in the FY 2024 budget proposal, the drug pricing models recently released by the Center for Medicare and Medicaid Innovation (CMMI) and continued consideration of novel and potentially disruptive drug pricing proposals by MedPAC.

Fiscal Year 2024 Budget Proposes More Drug Pricing Reforms

The Biden-Harris FY 2024 Budget seeks to double down on the foundational elements of the IRA drug pricing provisions by proposing to:

- Expand the Medicare Drug Price Negotiation Program ("Negotiation Program") to apply to more Part B and Part D drugs.
- Require the Negotiation Program to apply to drugs sooner.
- Apply the inflation rebate requirements to commercial health insurance.
- Extend the cap for patient cost-sharing to insulin products in the commercial markets.

The FY 2024 Budget also proposes additional reforms to:

- Give the Department of Health and Human Services (HHS) the authority to negotiate additional, supplemental, Medicaid drug rebates on behalf of states.
- Extend existing Medicaid drug requirements to states that operate their Children's Health Insurance Programs separately from Medicaid.
- Cap Part D cost-sharing on certain generic drugs to $2 per prescription per month.

It is noteworthy that the Biden-Harris administration put forward these proposed changes as the Centers for Medicare and Medicaid Services (CMS) is concurrently seeking feedback from stakeholders on the implementation of various parts of the IRA drug pricing provisions enacted last year. Proposing further changes in this nascent stage of implementation adds additional uncertainty and complexity to the implementation of the Negotiation Program and inflation rebates. There are already many questions and areas of uncertainty regarding how CMS will ultimately implement the IRA's drug pricing provisions, and proposing further changes at this stage of implementation casts further uncertainty into the process, outcomes and requirements manufacturers will be subject to going forward. Stakeholders seeking to submit comment on the implementation of the IRA drug pricing provisions may want to contemplate how further programmatic changes along the lines of what the Biden-Harris administration's budget proposals would factor into their feedback to CMS on IRA implementation.

CMMI Moves Ahead with Drug Pricing Models, Additional Areas of Research

The Biden-Harris administration has also been leveraging CMMI in its drug pricing work. On October 14, 2022, President Biden signed Executive Order (EO) 14087 on "Lowering Prescription Drug Costs for Americans." The EO called for additional actions to "complement the IRA" in lowering drug costs and directs CMMI within CMS to submit a report to The White House on potential payment and delivery models that would lower drug costs and promote access to innovative drugs within 90 days. On February 14, 2023, the HHS released this much anticipated report, revealing three models CMMI intends to pursue and three areas of continued research focus. In many ways the release of this report offered a preview of the proposals that were included in the FY 2024 Budget and raises more fundamental questions about the role CMMI will play in drug pricing.

CMMI's Proposed Models

- The Medicare High-Value Drug List Model – The test question for this model is **what is the impact of standardizing the Part D benefit for high-value generic drugs on beneficiary affordability, access, health outcomes, and Medicare spending**? The design for this model is for Part D plans 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.
- The Cell & Gene Therapy Access Model – The test question for this model is **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**? The design for this model is for State Medicaid agencies to assign CMS to coordinate and administer multi-state outcomes-based agreements with manufacturers for certain cell and gene therapies.
- The Accelerating Clinical Evidence Model – The test question for this model is **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 has expressed its concern about the "the high cost and lack of confirmed effectiveness of drugs receiving accelerated approval." As a result, the stated goal of this model is to "reduce Medicare spending on drugs that have no confirmed clinical benefit." The design

for this model is for CMS to 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. A group of Republican senators have already written to HHS Secretary Xavier Becerra and CMS Administrator Chiquita Brooks-LaSure asking that the administration not pursue this model any further, arguing that it is contrary to FDA's role and the purpose of accelerated approval.

The report also includes discussion of additional areas for research, noting that the Secretary of HHS has called on CMMI to continue to evaluate potential models in the areas of accelerating biosimilar adoption, data access changes to support price transparency, and cell and gene therapy access in Medicare Fee-For-Service.

MedPAC Dives into Drug Pricing

Drug pricing proposals also continue to be a key area of focus for the Medicare Payment Advisory Commission (MedPAC). Earlier this month, MedPAC convened a meeting to consider three policy proposals that would change how Medicare pays for Part B drugs.

- **Applying a Cap on the Payment of Accelerated Approval Drugs** – As outlined by the MedPAC meeting materials, under this first policy proposal which aligns with the CMMI model on accelerated approval, payment caps would be put in place until "a manufacturer verifies a drug's clinical benefit." The Secretary could set the payment cap based on the clinical benefit and cost of the drug relative to the standard of care. The Secretary could operationalize the cap using a rebate under which manufacturers pay Medicare the difference between the otherwise applicable Average Sale Price (ASP)-based payment amount and the cap based on use of the drug for the accelerated approval diagnosis.
- **Price competition among drugs with similar health effects** – As outlined by the MedPAC meeting materials, this second policy envisions extending reference pricing to product with "similar health effects" is premised on the concern that there is insufficient competition for single-source drugs, biologics and biosimilars with therapeutic alternatives because each is paid according to their own ASP. Under the proposal, each product could remain in its own billing code and payment would be based on the volume-weighted ASPs of all products in a reference group. To define reference groups, the Secretary could consider various factors, including organizing reference groups by clinical indications and drug classification and ease of implementation. Exactly how "similar health effects" might be defined remains to be seen. One proposed reference grouping approach includes branded products, their generic equivalents and related products approved under the 505(b)(2) pathway.
- **Improving financial incentives associated with Part B drug add-on payment** – As outlined by the MedPAC meeting materials, this third proposal outlines a three-part approach to restructuring the ASP add-on payments. As the example provided ASP add-on would equal the lesser of 6%, 3% plus $24, $220 per drug per day. Under the proposal, the add-on would be eliminated for drugs paid based on Wholesale Acquisition Cost (WAC). The proposal also raised the prospect of CMS assessing the separate drug administration payment rates in implementing the reduced add-on in addition to CMS monitoring utilization patterns among providers.

Takeaway

Stakeholders continue to navigate a rapidly evolving drug pricing landscape, and now must consider how to factor in the precedent of, and additional uncertainty related to, the release of these various proposals and continued developments on Capitol Hill. Congress continues to engage on drug pricing issues in the form of legislative and oversight activities. As one example, in recent days, the House Energy and Commerce Subcommittee on Health approved by voice vote legislation to prohibit the use of quality-adjusted life years and similar measures in coverage and payment determinations under federal health care programs, demonstrating that the debate on drug pricing issues is far from over and may continue to play out on a number of policy fronts. While stakeholders

will continue to contend with uncertainty on these fronts, what is certain is that drug pricing will continue to be a key area of focus inside and outside the Beltway given the consequential stakes for patients, public health and the entire health care and life sciences ecosystem.