Health Care Policy Proposals and the 2024 Election

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As the general election quickly approaches, many Americans are wondering what the next four years will look like. While not a central issue in this election, health care policy impacts the delivery, affordability and sustainability of employer-sponsored health plans. Those in the employee benefits industry should understand the proposed health care policies of both candidates, pending health care legislation in Congress and any forthcoming guidance and rulemaking from the outgoing Biden administration. A closer look into each of these topics offers a glimpse of what the next presidential administration may bring.

Presidential candidates' stances on health care and prescription drug policy

Former President Donald Trump's approach is marked by a focus on reducing government intervention, emphasizing deregulation and market-driven solutions. Vice President Kamala Harris advocates for a more expansive role of government in health care, aiming to expand and enhance the Affordable Care Act (ACA) and Inflation Reduction Act prescription drug pricing programs.

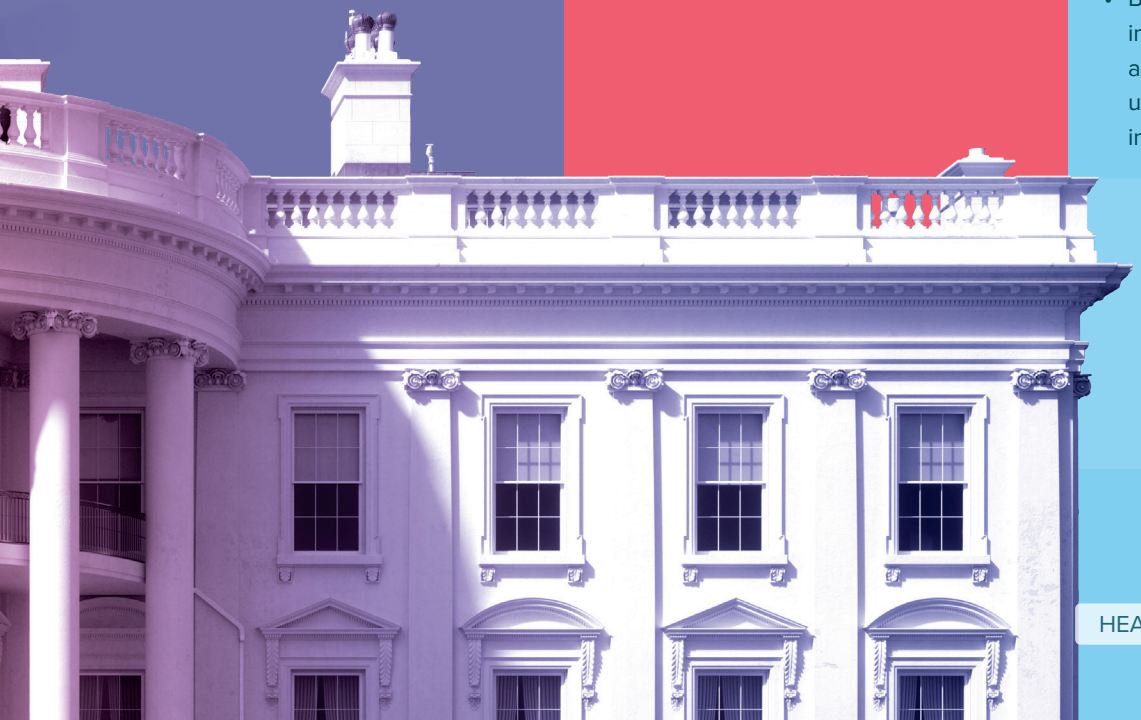
THE CANDIDATES' STANCES ON HEALTH CARE AND PRESCRIPTION DRUG POLICY ARE AS FOLLOWS:

Donald Trump

- Likely to reinstate and expand upon previous Executive Order 13948, aimed at lowering prescription drug prices
- Previously proposed a "most favored nation" system, which established an international reference price for certain Medicare Part B drugs that was later invalidated in court
- Removed the safe harbor for Medicare drug rebates, later delayed to 2032 by the Biden administration
- Issued a final rule establishing the FDA's Section 804 drug importation pathway that allows importation of certain drugs from Canada
- Removed tax penalties under the individual mandate and proposes changes that would cap total federal spending on Medicaid programs
- Supports protection of Medicare
- Vows to continue previous Trump administration efforts regarding surprise medical bills and transparency

Kamala Harris

- Supports march-in rights for drug patents, where the federal government can "march-in" and seize a patent for a drug developed with government funding and license it to a lower-cost competitor
- Is likely to continue the path of the Biden administration with further expansion of the Inflation Reduction Act's Medicare Drug Price Negotiation Program
- Supports the Food and Drug Administration's (FDA) Section 804 drug importation pathway, previously finalized by the Trump administration, and the continued implementation of this initiative
- Proposes to protect and expand Medicare by raising taxes on high earners and closing tax loopholes
- Proposes to permanently extend the enhanced ACA subsidies, which were temporarily established under the American Rescue Plan Act and later renewed by the Inflation Reduction Act
- Biden-Harris administration delayed implementation of the Trump administration's drug rebate rule until 2032, which delays projected increases in Medicare spending
- Has previously called for the Department of Health and Human Services to set fair prices for drugs that are sold for a cheaper price in an economically comparable country or when a drug's price increases faster than inflation



Health care legislation in Congress

After the election, Congress will reconvene for a “lame duck” session, which is a lawmaking session that occurs after an election and before the successor’s term begins. In recent years, post-election congressional meetings have largely focused on negotiating appropriations packages and continued funding for the federal government. Legislators also use these end-of-year sessions to consider any major remaining issues or policies that may be set to expire.

Drug pricing legislation

Pharmacy benefit manager (PBM) reform has remained a top priority for congressional committees over the past two years and will continue to be considered as a potential policy rider to be included as part of a broader spending package. This is especially probable given the strong bipartisan support for many of these measures and the increased state and federal scrutiny facing the PBM industry.

Late this summer, the House Committee on Oversight and Accountability held a prominent hearing considering consolidation in the PBM industry and reported favorably on the Delinking Revenue from Unfair Gouging (DRUG) Act, a proposal that delinks a PBM’s compensation from the list price of a drug.

This proposal would shift PBM compensation to a flat fee-for-service payment model. Critics of this approach argue that delinking a PBM’s compensation would remove the incentive for a PBM to negotiate steeper discounts off the price of drugs and would eliminate popular value-based care arrangements. Other noteworthy proposals incorporate provisions from the House-passed Lower Costs, More Transparency Act, which includes the codification of the Trump administration’s transparency rules (think machine-readable files and member cost comparison tool) and requirements for site neutral payments in Medicare. Some of these provisions already exist as administrative rules but codifying them into federal statute provides a higher level of permanence compared to administrative rules which can be more easily amended or repealed. Pundits also agree that, at a minimum, Congress will likely pass a spread pricing ban for Medicaid. There are also calls to extend this provision to the commercial market.

Telehealth flexibility

A popular measure that has received continued support since the end of the COVID-19 emergency is the extension of telehealth flexibilities. These flexibilities have enabled high-deductible health plans with health savings accounts to offer pre-deductible telehealth services to participants. Without an additional temporary or permanent extension, relief will expire on December 31, 2024, for calendar year plans. Passage of the Telehealth Benefit Expansion for Workers Act would also allow employers to offer telehealth as a standalone benefit.

During the COVID-19 emergency, the U.S. Department of Labor temporarily allowed employers to expand telehealth offerings to individuals ineligible for full medical benefits. This flexibility ended at the end of the 2023 calendar year.

Recent and anticipated rulemaking from the Biden administration

The Biden administration has remaining policy goals and agenda items to wrap up before the end of the term. Given President Biden's decision not to seek reelection, the coming months will be the administration's final opportunity to tie up any loose ends and solidify its impact. The following is a look at some outstanding health care-related regulations that are anticipated by the year's end.

Copay accumulator rule

After the Washington D.C. district court invalidated the Department of Health and Human Services' (HHS) rule allowing plans to decide whether to count manufacturer copay assistance toward a participant's deductible and maximum out-of-pocket, the Court directed HHS to engage in further rulemaking on the topic. The Court held the 2021 rule was "arbitrary" because it allowed a plan to choose its own definition of cost-sharing in a way that was inconsistent with the ACA's existing definition. The Biden administration announced a non-enforcement policy of the ruling and will likely address the issue in the Notice of Benefit and Payment Parameters Final Rule for 2026. These annual rules are typically released in November and finalized in April of the year prior to the rule going into effect. Most stakeholders suspect the administration will rewrite the rule in favor of payors. Either position will likely be met with legal challenges.

Essential Health Benefits (EHB) designations

In the final Notice of Benefit and Payment Parameters for 2025, the Departments of HHS, Labor and the Treasury (the tri-agencies) indicated that if a health plan covers prescription drugs in excess of the plan's current definition of EHB, the additional drugs would also be considered EHBs. This means all covered drugs would be deemed EHBs and, therefore, subject to the ACA's maximum out-of-pocket limit and annual and lifetime dollar limit prohibitions. In a subsequent FAQ guidance document (FAQ 66), the tri-agencies clarified this requirement only applies to individual and small group market plans and not large group market or self-funded group health plans. However, the tri-agencies have indicated that they do intend to align these requirements for the large and self-insured market in future rulemaking. Application of this policy to the self-insured market would inhibit plan sponsors' ability to use innovative plan designs intended to reduce drug costs, such as copay maximizer programs.

Mental health parity final rule

In mid-September, the tri-agencies released the long-awaited mental health parity final rule, which detailed a new comparative test for employers to ensure that mental health benefits are on par with medical and surgical coverage. The initial draft of this rule was proposed in 2023 and criticized by stakeholders as vague and burdensome for employers. Employers are still unclear on the exact requirements and benchmarks needed for a complete non-quantitative treatment analysis, an area where parity violations continue to persist. This rule is also likely to be met with legal challenges as several employer interest groups have argued the rule exceeds the Departments' authority established in the underlying mental health parity law.

Closing thoughts

Employers should remain aware that these proposals could impact their delivery and management of prescription drug benefits. As these dynamics unfold, employers must work with their vendors to determine how these new policies, as well as any subsequent litigation, may impact their plans to ensure any necessary changes are implemented. Employers Health will continue to monitor these developments and release timely updates for its employer clients.

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