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What 2024 Election Means For Drugs, Medicare And Medicaid

By **Stephen Forster, Alexander Hastings and Howard Young** (December 9, 2024, 6:52 PM EST)


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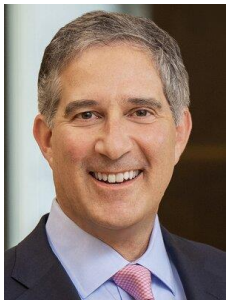
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Shortly after the new year, a Trump-Vance administration will control the White House, and the Republicans will hold a narrow majority in both the U.S. House of Representatives and U.S. Senate.

This control trifecta is likely to affect both legislative and regulatory processes and provide pathways for potential changes to the drug pricing and reimbursement landscapes.

While President-elect Donald Trump has yet to articulate priorities with respect to drug pricing and reimbursement, his reform efforts during his prior administration and the ongoing bipartisan focus on drug affordability suggest that drug pricing will continue to be under scrutiny.

We discuss herein key drug pricing programs and other areas to watch as the new Trump-Vance administration takes shape and members of the 119th U.S. Congress prepare to take the oath.

Inflation Reduction Act

The Inflation Reduction Act, signed into law by President Joe Biden in 2022, implemented sprawling reforms related to drug pricing, including formalizing the Medicare Drug Price Negotiation Program, establishing inflation rebates for certain drug price increases, and reforming drug costs under Medicare Parts B and D.

In the most recent State of the Union, the Biden administration signaled an intent to expand Medicare drug price negotiations under the IRA from the initial subset of 10 drugs to more than 500.

While the incoming Trump administration has not yet signaled whether it will be quite as aggressive on IRA implementation, the administration will face key program deadlines shortly after taking office, with a $2,000 out-of-pocket cap on Medicare drug spending set to roll out in January 2025 and the list of 15 additional high-cost drugs to be selected for negotiations due Feb. 1, 2025.

The IRA was controversial at the time it was signed into law and remains so today. And while wholesale

repeal of the act appears unlikely, the trifecta of control may provide the incoming administration with the ability to make significant modifications to its current form and scope. Alternatively, the administration could issue guidance over how drug price negotiations will proceed moving forward.

Section 340B Drug Pricing Program

The 340B program permits certain safety net healthcare providers, such as hospitals, to purchase outpatient drugs at a discount from pharmaceutical manufacturers.

Generally, lawmakers on both sides of the aisle have supported requirements for 340B covered entities, e.g., hospitals, to pass on any 340B drug cost savings directly to patients, with the prior Trump administration issuing an executive order requiring safety net hospitals to do so.

Most recently, California included Proposition 34 on its 2024 ballot, which — after passing with 51.5% voter support — will require certain healthcare providers to spend 98% of 340B revenue on direct patient care.

In the face of ongoing litigation related to the 340B program's requirements, Congress is likely best suited to address program reforms long-term, should bipartisan support hold into the next term.

Examples of current legislative efforts include the 340B Access Act and the 340B Patients Act. With what appears to be bipartisan support for program reform, all 340B program participants would be well advised to keep this on their radar as the Trump-Vance administration's healthcare priorities take shape.

Hospitals and health systems that have come to rely on the 340B cost savings and revenues, as well as pharmaceutical manufacturers, may see increased lobbying activity on these issues.

Pharmacy Benefit Manager Transparency

Pharmacy benefit managers remain under the microscope and subject to government scrutiny, and this trend is unlikely to change under the incoming administration.

The Federal Trade Commission issued its unfavorable report on PBM practices earlier this year, which was followed by a similar unfavorable report issued by the House Committee on Oversight and Accountability.

Reducing drug prices for patients has been and is likely to remain a bipartisan focus, and PBM price transparency has been a core part of that effort.

The first Trump administration attempted PBM reform through its regulatory authority and enactment of the Office of Inspector General's rebate rule. The proposed rebate rule would have amended the discount safe harbor regulation to eliminate protection for Medicare Part D price concessions, including rebates, that are offered by pharmaceutical manufacturers to plan sponsors, or PBMs under contract with them.

Although the rebate rule was withdrawn under the Biden administration, the incoming Trump administration may revisit these efforts and look for other ways to increase PBM price transparency and reduce patient out-of-pocket costs.

Drug Importation

The cost of prescription drugs in the U.S. remains a top healthcare priority with bipartisan support. The previous Trump administration finalized regulations, which the administration had initiated in 2019, toward the end of 2020 that created a pathway for states and Native American tribes to import certain prescription drugs from Canada in an effort to reduce the cost of drugs for U.S. consumers.

Under the final regulations, the U.S. Food and Drug Administration must approve a Section 804 importation program proposal before any drugs may be imported under the plan.

Despite efforts made by various states since the implementation of the final regulations, to date the FDA has only authorized the Florida importation program — Colorado has a plan pending with the agency — and there have also been operational challenges to state implementation of approved plans.

Despite these challenges, given that pharmaceutical drug pricing reform has bipartisan support and drug importation was a priority under the last Trump administration and an issue the president-elect discussed before the election, this may again become a renewed issue of focus for the incoming administration.

Bayh-Dole March-In Rights

The Bayh-Dole Act applies when businesses and other organizations conduct research and develop an invention that is either conceived of or first actually reduced to practice under a federally funded agreement.

One of the key policy objectives of the Bayh-Dole Act is to encourage researchers to use or commercialize such an invention so that the public can benefit from the U.S. government's financial support for the innovation.

To achieve this goal, the Bayh-Dole Act enables researchers to retain ownership of the patent rights, but the U.S. government simultaneously will hold a government purpose license and march-in rights to the patented invention that may be exercised if the titleholder does not achieve practical application or one of the three other statutorily defined criteria apply.

Drug pricing advocates have repeatedly argued that the U.S. government should use its Bayh-Dole Act rights in certain drug products to influence the price of those products. Some argue that the government should use its government purpose license to allow third parties to manufacture drug products covered by the Bayh-Dole Act and offer them at a lower price.

Others have argued that the government should march in on drug products covered by the Bayh-Dole Act by asserting that such products have not achieved practical application and are not available on reasonable terms due to their price.

To date, various U.S. government agencies, including the National Institutes of Health, have resisted this pressure and the federal government has never exercised its march-in authority.

That said, during both Trump's first presidency and Biden's presidency, use of march-in rights received attention within executive branch agencies and on Capitol Hill.

As a result, use of march-in rights or an expansion of the government purpose license to allow third-party manufacturing of drug products for the purpose of influencing price remains an area of bipartisan interest that could have immediate impacts on patent portfolios and longer-term impacts on the innovative ecosystem that the Bayh-Dole Act has created.

Most-Favored-Nations Drug Pricing Model

The previous Trump administration issued a most-favored-nation executive order in September 2020 that purposed to ensure that U.S. drug prices under Medicare would be at parity with drug prices in other countries. Specifically, the order called for models that would cap the price Medicare pays for certain Part B and Part D drugs.

In response to this order, the Centers for Medicare & Medicaid Services issued an interim final rule in November 2020 setting forth a most-favored-nation model that was designed to lower prescription drug costs for consumers by paying a cost equivalent to the lowest price that drug manufacturers receive in other similar countries for otherwise high-cost Medicare Part B drugs and biologicals.

Soon after CMS issued the rule, litigation was brought by pharmaceutical companies in several federal courts across the country challenging the proposal and seeking preliminary injunctions.

These challenges resulted in legal stays that prevented the rule from going into effect. The rule was ultimately rescinded by CMS in late 2021 under the Biden administration.

Given vigorous legal opposition to the proposed rule, it is unlikely this will surface as a priority for the incoming administration. However, trifecta control could change the analysis, and as such this should remain on the radar as the Trump administration continues to take shape.

Medicaid Reform

While the Medicaid program did not receive a lot of attention on the campaign trail, it appears program reform may surface as a priority for the incoming administration.

The Medicaid program is subsidized by the federal government and its expenditures have grown from $41 billion in 1985 to $805 billion in 2022, making it one of the fastest growing federal programs on the books.

And with ever-increasing expenses, and budget reconciliation a priority, it comes as no surprise that the Medicaid program may come under the microscope of the incoming administration when looking for cost savings.

While we cannot know for certain what Medicaid reforms, if any, the incoming administration may consider, certain reforms related to program enrollment, regular eligibility checks and work requirements have already been floated by members of the Republican Party as having the potential to yield savings of up to $260 billion.

While these cost-saving estimates could change, they are of a magnitude that is likely to garner serious consideration by the Trump-Vance administration and the new Congress. And if we look to the prior Trump administration for guidance on potential Medicaid reforms, there we find several previous Medicaid reform efforts that may resurface.

The first Trump administration, under its Section 1115 waiver policy, approved 13 waivers that allowed states to condition Medicaid eligibility on meeting work and reporting requirements and approved waivers that restricted eligibility, including by permitting states to charge premiums and lock out enrollees who are disenrolled for unpaid premiums.

These waivers were ultimately rescinded by the Biden administration in favor of several other reforms, including the Access Rule, Managed Care Rule, Long-Term Care Facility Staffing Rule, and streamlined Medicaid enrollment and renewal processes for the Medicare Savings Program as well as for Medicaid, Children's Health Insurance Program and the Basic Health Program.

The possibility exists that the incoming administration could delay implementation of certain provisions or issue new regulations that would undo the Biden administration's final regulations.

Alternatively, the incoming administration could issue subregulatory guidance to change eligibility or renewal policies on coverage and eligibility verification. With the trifecta, enacting new Medicaid reform legislation also remains on the table.

Medicare Advantage Expansion

Medicare Advantage, also known as Part C, is a Medicare-approved health plan operated by a private company that offers an alternative to Original Medicare for your health coverage.

These bundled plans include Part A, Part B and usually Part D, and may offer additional benefits that Original Medicare does not. More than half of Medicare beneficiaries — roughly 66 million people — are enrolled under Medicare Advantage plans.

However, despite growing popularity, Medicare Advantage plans have also garnered some critiques: Federal enforcers have taken aim at improper risk adjustments by MA plans, and MA beneficiaries have raised concerns regarding limited access to prescription medications based on formulary coverage and enrollee inability to switch from MA plans to traditional Medicare.

These issues, if validated, could present challenges to support for program expansion.

That said, Trump was an outspoken supporter of enhancements to MA plans during his first administration, e.g., telehealth, supplemental benefits for seniors with chronic disease, under which the Part C program grew.

And with the new Trump administration seeming to favor private sector program management over government agency program management, it would appear the incoming administration may support further expansion of Medicare Part C.

However, given that traditional Medicare fee-for-service also remains popular among beneficiaries, it remains to be seen whether the new administration will do more than allowing MA plans to vigorously compete for beneficiaries during open enrollment season.

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