

# COVINGTON

## The November Election and Health Care/Pharmaceutical Policy: Three Federal Issue Areas to Watch

Health Care and Rx Policy Implications

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The outcome of the national elections next month will have consequential public policy implications across industry sectors in 2021 and beyond—none more so than in the health care/pharmaceutical space. Three key issue areas for stakeholders to watch that have been highlighted by the pandemic are health care insurance coverage, prescription drug pricing, and issues/initiatives around pharmaceutical supply chain security and “Buy American” policies. The difference between success now and in the future in a Biden Administration in each of these key issue areas could rest to some degree on whether the Senate pursues repeal of the filibuster rules or employs budget reconciliation mechanisms given that many proposals have typically garnered majority, but not supermajority, support.

### Health Insurance Coverage

The Affordable Care Act (ACA) has been front and center in presidential politics, with each side vowing to ensure protections for pre-existing conditions but otherwise diverging in approach to health insurance coverage. The pandemic has only increased the attention on coverage, including the disparate impacts of COVID-19 given underlying health disparities in the U.S.

- If Trump Wins. The Administration is currently looking to the Supreme Court to invalidate the remaining pieces of the ACA (“Obamacare”), including the pre-existing condition protection. If the ACA is thrown out, there will be immediate pressure on the Administration and the GOP in Congress to fulfill the President’s commitment on pre-existing conditions.
  - Even if the ACA is upheld, Trump and the GOP ran on and will be expected to fulfill their pledge to “repeal and replace” the law with something they promise will provide better care.
- If Biden Wins. Whether or not the ACA remains intact, a Biden Administration will be pressed by progressives to expand the law – from their perspective with a “Medicare for All” model. For his part, look for a President Biden to take more of an incremental approach – likely ACA + a so-called “public option” on the exchanges to provide for competition with private plans, which he self-describes as “Bidencare.”
  - The Democratic platform also calls for rolling back the authority to sell short-term insurance plans and for greater coverage via lowering of the Medicare eligibility age, expanding subsidies for plans sold on the individual market, and providing coverage in states that did not expand Medicaid.

## Drug Pricing

The cost of pharmaceuticals remains a populist issue – one that historically was more associated with Democrats but that has now crossed over the aisle, in large part because of President Trump’s continued focus. Look for this issue to garner continued attention regardless of the election results.

- If Trump Wins. Candidate Trump in 2016 and during the early part of his first term had some modest success in using the bully pulpit to “name and shame” manufacturers to press for commitments to lower prescription drug prices, but did not in his first term come together with House Democrats to enact systemic reform.
  - In the waning days of the 2020 campaign, President Trump issued a series of Executive Orders (EOs) and other drug pricing-related announcements – to allow wholesalers and pharmacists to import certain Rx drugs from Canada (via FDA authorization of state or tribal plans), to eliminate Medicare Part D rebates to certain “middlemen,” to provide Medicare recipients \$200-\$300 in Part D co-pay assistance (via “Trump Cards”), to pass through to patients 340B program discounts on insulin and Epipens, and to link certain payments for Medicare Part B drugs (with exploration for expansion into Part D) to lower prices paid in identified foreign countries (“Most Favored Nation”). All of these initiatives face administrative and/or legal hurdles to implementation – but look for a second term Trump Administration to proceed with some or all of them. It remains to be seen whether there will be a real effort to work with congressional Democrats on legislative reform.
- If Biden Wins. Repeal of the “non-interference” clause so as to authorize direct drug price negotiations between the Medicare Program and manufacturers is a centerpiece of the Democratic platform; look for progressives to push a Biden Administration to make this issue an early legislative priority – especially if Democrats control both chambers of Congress as well as the White House. Similarly, Democrats will likely consider their own version of “Most Favored Nation” by pegging drug price limits to median prices in OECD countries, as well as some form of importation – perhaps by expanding the scope of drugs that individuals may bring in from specified countries.
  - A Biden Administration might pursue other long talked about reforms – including a limit on drug price increases (no higher than the inflation rate), a cap on out-of-pocket costs for seniors, elimination of tax breaks for Rx advertisements, an end to “pay-for-delay” deals, resuscitation in some form of the ACA’s IPAB (independent public review board ala the private sector ICER to evaluate Rx value and recommend price parameters), and, if they are really ambitious, “march-in rights” related to drugs developed in whole or part from taxpayer money. Success with most of these proposals likely would be as challenging in a Biden Administration as it has been in the current Administration.

## Pharmaceutical Supply Chain/“Buy American”

The pandemic and related geopolitical tensions with China have resulted in increased attention on issues around overreliance on foreign supplied active pharmaceutical ingredients (API) and finished drug products (as well as other medical supplies/countermeasures) and resultant interest in advancing “Buy American” and related “re-shoring” policies. While there are some differences in approach, i.e. carrot vs. stick, both presidential candidates are using similar

rhetoric in describing their respective plans in this area and there is bipartisan support on the Hill to engage on this issue.

- If Trump Wins. In response to the pandemic, the Administration entered in to limited contracts with the private sector to “re-shore” production of certain generic drugs to the U.S. And, in August 2020, President Trump issued what is referred to as the “Buy American” Executive Order, which calls on federal agencies to purchase “essential medicines” and other medical products made in the US. This EO is not self-executing, but rather directs FDA to make the essentiality determination by the end of this month; the EO also provides for a number of exemptions based on cost, availability and the “public interest” and does not apply to the Medicare program. The implementation and effect of the EO remains to be determined, but look for a second Trump Administration to continue letting “re-shoring” contracts and to otherwise pursue “Buy American” policies to strengthen the domestic supply chain.
- If Biden Wins. Similarly, Vice President Biden has campaigned on a platform of improving self-sufficiency of the pharmaceutical and medical product supply chain – and has pledged to increase domestic manufacturing capacity to avoid future shortages of critical goods. While release of a comprehensive strategy is pending, Biden has vowed to employ greater use of authorities under the Defense Production Act (DPA) and Procurement Act of 1949, using BARDA to make science-based purchasing decisions (including the possible use of compulsory licensing), some form of “Buy American” requirement for federal purchase of drugs, tax and other incentives to encourage on-shoring of pharmaceutical manufacturing, requirements for companies to develop plans to address shortages/disruptions, and increased federal stockpiles as well as promotion of surge manufacturing capacity.

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