Insight

Competition EO Opens Door to Antitrust Enforcement and the Public Option

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Executive Summary

- The Biden Administration's latest executive order (EO), "Promoting Competition in the American Economy," contains several health care provisions, from drug pricing reforms to over-the-counter hearing aids to proposals to fight hospital consolidation and improve price transparency.
- Most of the health-related directives either emphasize that the administration will continue to implement the laws passed by Congress or encourage independent agencies to follow particular policies.
- The EO includes a directive for the Department of Health and Human Services to implement standardized options in the national health insurance exchanges; this directive appears to be a step toward a public option and may be the most consequential health directive of the EO.

Introduction

President Biden's most recent executive order (EO), "Promoting Competition in the American Economy," attempts to counter a rising tide of what the administration sees as anti-competitive behavior in large sectors of the American economy. The EO directs numerous regulatory agencies to propose new rules and recommendations to prevent anti-competitive behavior.

The health care sector is among those targeted by the EO. The Biden Administration calls out hospital consolidation and price transparency, drug price increases, the insurance marketplace, and hearing aid access in this order, and proposes several actions in all of these areas. The president also re-emphasized his support for a public option and having Medicare negotiate drug prices, although there are no specific orders toward these objectives. Some of these actions are more binding than others; given the independence of the Federal Trade Commission (FTC) and the Department of Justice (DOJ), several of the proposals surrounding antitrust enforcement are "encouraged" rather than required and lack the strength of enforcement. Additionally, a few of the proposals are merely directing the continued implementation of existing federal law. One directive to standardize options on the national exchanges, however, may prove to be the most impactful of the EO's health care initiatives.

Overview of the EO's Health Care Sections

Drug Pricing

The majority of the EO's health care sections are focused on policies intended to lower drug prices through a variety of means, particularly generic drugs and biosimilars. The EO encourages the FTC to create regulations banning "pay-for-delay" agreements, in which brand-name drug manufacturers pay a generic producer to delay the entrance of a generic version of a drug into the market. The Department of Health and Human Services (HHS) is required to perform a number of items, including submitting a plan that would combat the "excessive

pricing" of prescription drugs and reduce the amount the federal government pays for drugs.

The EO also directs HHS to promote biosimilars and generic drugs by continuing to improve the approval framework and by educating providers and patients on generics and biosimilars, as authorized by the Advancing Education on Biosimilars Act of 2021. HHS is further instructed to clarify biologics regulations by finalizing the Biologics Regulation Modernization rule and to work with the FTC to identify and address efforts to impede generic and biosimilar competition. HHS must continue to implement the CREATES Act of 2019 to help generic companies more quickly obtain brand-drug samples, as well as prepare for Medicare and Medicaid coverage of biosimilars and for payment models that promote the use of generics and biosimilars. Additionally, the Food and Drug Administration (FDA) is instructed to send a letter on its concerns about how current patent law may delay generic and biosimilar competition to the United States Patent and Trademark Office as well as the Department of Commerce.

The EO also directs the FDA to work with states and Indian Tribes who seek to implement drug importation programs under Section 804 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the implementing rule for which was finalized by the Trump Administration in 2020.

Hearing Aids

The FDA Reauthorization Act of 2017 legalized the sale of over-the-counter hearing aids without a prescription or screening prior to purchase. The EO requires the FDA to publish a proposed rule on over-the-counter hearing aids and implement the legislation, which the FDA had not done up to this point.

Hospitals

The EO calls on HHS to support existing price transparency initiatives for hospitals and insurers as well as any changes required by the No Surprises Act passed at the end of last year. As noted in a recent Weekly Checkup , hospital compliance with the new price transparency rule that went into effect at the beginning of this year has been less than stellar, and the Biden Administration is likely sending a signal to hospitals that they will crack down on non-compliance.

Hospital consolidation also finds itself a target of Biden's EO, with explicit mention multiple times. The EO affirms the administration's aim to enforce antitrust laws against hospitals, although it only specifically encouraged the DOJ and the FTC to take steps. Much of the trustbusting aspects of the EO come in the form of encouragements to the FTC and DOJ to use the full power of various antitrust laws and court rulings, as well as some general provisions for interagency cooperation on antitrust actions.

Health Insurance

The EO directs HHS to implement standardized options on the national Health Insurance Marketplace. The Biden Administration claims that the variety of health insurance options with different levels of coverage and different premiums and deductibles makes comparison shopping difficult.

Implications

The EO contains a lot of "encouragement" for independent agencies to achieve specific policy outcomes, which makes one question just how independent the White House wants these agencies to be. That said, there are other barriers to antitrust enforcement against hospitals (namely funding and manpower), so much of the antitrust actions in health care for this EO can be seen more as statements of policy rather than directives for immediate

actions.

The action on drug pricing is different, however, as the Biden Administration seeks to use all available levers to take action on drug prices. In requiring a plan from HHS to combat excessive drug prices and "price gouging," the administration is laying the groundwork for further actions on drug pricing. Another government report isn't news, but this action indicates a nod to the progressives that the White House is willing to ruffle feathers on drug pricing. Using the government to reduce drug prices, a notably liberal cause, is countered with some nods to bipartisanship: Biden seems to be taking the potential of biosimilars and generics seriously and clearly views them as a market-friendly way to decrease drug prices. Much of the EO is just emphasizing to the agencies the need for speed in getting biosimilars and generics approved and on shelves. The development of payment models to encourage the use of generics and biosimilars in Medicare and Medicaid are likely to have the largest impact on the drug market, given the power of the health safety-net programs. How quickly these efforts can be implemented and when consumers will see their purported benefits remain to be seen.

Repeatedly, this EO contains directives, such as hospital price transparency or importation of prescription drugs, that are just the administration saying "we will continue to implement current law." The standardization of insurance options on the exchanges is not one of those directives. Of all the health directives in the EO, the health insurance standardization might prove the most impactful. It's unclear what exactly the administration means by "standardized options," but it looks an awful lot like a move that inches toward a public option. The exchanges already have a base set of essential health benefits (EHB) that require coverage of 10 different categories, and limits on cost sharing and lifetime spending caps for services within these categories. So why the need for standardization on the national exchange? Currently, plans are allowed some variation as to what services within the 10 EHB categories they cover, and in the state exchanges this flexibility has led to variation in services covered between states. "Standardization" might mean even more federal government input into what services must be explicitly covered, further decreasing the variation in plans in favor of a government-specified coverage option. Combine this standardization with a potential push by many Democrats to offer free care through the exchanges, and you have what is essentially the public option. The standardization directive is too vague to know for certain, but it is also vague enough to be a stepping stone toward a public option.

Conclusion

The Biden Administration's EO provides a good indication of which health policies the administration is likely to pursue going forward. There are nods to the Democratic base with plans to reduce drug prices through government action, but also an acceptance of market power through the push to promote generics and biosimilars. The suggested antitrust actions by the FTC and DOJ are just that: suggestions. The independence of these agencies does not allow for President Biden himself to bring the hammer down on hospitals or drug companies, and so the policy proposals lack teeth. Hospital consolidation is a growing problem, but that reality will require more money and broader authorities that only Congress can provide. The hearing aids provision was an easy win that the Trump Administration curiously never picked up despite the relevant law's passage in 2017. Tucked in one of the shortest health passages of the EO was a surprising step in the direction of a public option for health insurance: standardizing options on the national exchanges. That provision may prove to be one of the most consequential health directives in this EO.