Health Industry Alert

Akin Gump
STRAUSS HAUER & FELD LLP

President Biden's 'Promoting Competition' Executive Order: Key Health Care Actions to Follow

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Background

As has been widely reported, earlier this summer, President Biden issued Executive Order (EO) 14036, "Promoting Competition in the American Economy." The EO provides insight into how the Biden-Harris administration plans to increase economic growth and innovation across industries by promoting efforts to enhance competition. This Alert focuses on what may be particularly significant efforts by the administration to impact the health care and life sciences sector, including insurers, hospitals and hospital systems, and prescription drug manufacturers. The EO tasks the U.S. Department of Health and Human Services (HHS) with several follow-on actions in the coming months, setting the stage for forthcoming developments. We describe below these four key efforts to consider, and why they matter, as the Biden-Harris Competition EO is implemented this fall and beyond.

1. Paving the way for biosimilars and interchangeable biological products

The EO directs the Secretary of HHS, through the Administrator of the Centers for Medicare & Medicaid Services (CMS), to prepare for Medicare and Medicaid coverage of interchangeable biological products and for payment models to support increased utilization of generic drugs and biosimilars.

Why this matters? This charge to CMS is very broad and could take many forms. The absence of a specific timeline for carrying out this directive suggests that the administration may take an iterative approach and look to use any number of tools in CMS's toolkit, such as changes to reimbursement codes and/or establishing new codes for interchangeable biological products. How CMS seeks to increase utilization of generic drugs and biosimilars by Medicare and Medicaid raises many questions. Would the payment models be mandatory, voluntary or some combination of the two? Would the payment models be limited to stand-alone Part D plans and/or also include Medicare Advantage prescription drug plans? Would there be changes intended to incentivize greater prescribing of generic and biosimilar products? As of 2019, 34 percent of Americans were covered by either the Medicare or Medicaid programs, and this percentage is only growing, so any changes CMS implements on this front could

Contact Information

If you have any questions concerning this alert, please contact:

John R. Jacob
Partner
jjacob@akingump.com
Washington D.C.
+1 202.887.4582

Haidee L. Schwartz
Partner
hschwartz@akingump.com
Washington D.C.
+1 202.887.4080

M. Todd Tuten
Senior Advisor
ttuten@akingump.com
Washington D.C.
+1 202.887.4203

Matthew Hittle
Senior Policy Advisor
mhittle@akingump.com
Washington D.C.
+1 202.416.4687

Louis T. Agnello
Counsel
lagnello@akingump.com
Washington D.C.
+1 202.887.4212

be precedent setting and far-reaching, potentially affecting a significant number of Medicare and Medicaid beneficiaries.[1]

2. A new era for FTC in health care?

Yes, it appears so. The EO lays out a whole-of-government approach by the Biden-Harris administration to competition policy, with an emphasis on the Federal Trade Commission (FTC), and on actions intended to promote competition for consumers through generic drugs and biosimilars. The EO encourages the Chair of the FTC, in the Chair's discretion, to consider working with the rest of the Commission to exercise the FTC's statutory rulemaking authority, including in the areas such as unfair anticompetitive conduct, or agreements in the prescription drug industries such as agreements to delay the market entry of generic drugs or biosimilars. The EO also charges the Secretary of HHS, with the Chair of the FTC, with "identifying and addressing any efforts to impede generic drug and biosimilar competition, including but not limited to false, misleading or otherwise deceptive statements about generic drug and biosimilar products and their safety or effectiveness".

Why this matters? The EO signals support for an even greater focus on health care by the FTC, particularly on prescription drug markets and actions that are seen as anticompetitive to the market entry of generic drug and biosimilar products. While this approach is not unprecedented, the EO clearly reflects an intent to leverage the broader authority of the FTC going forward in the near term. Some members of Congress have echoed similar calls for increased oversight and enforcement. Notably, how the FTC approaches this charge could be precedent-setting for the pharmaceutical industry, both from the innovator and competitor perspectives, as well as American consumers' access to these products and any savings associated with them.

3. Are hospitals in the hot seat?

Yes, potentially. The EO raises concerns about health care consolidation, including consolidation between hospitals. It calls on the Department of Justice and FTC to make changes to its merger guidelines for hospitals in addition to emphasizing vigorous enforcement of antitrust laws generally. The EO also charges the Secretary of HHS to support hospital price transparency initiatives. Recent actions by the Biden-Harris administration demonstrate its commitment to more aggressively leveraging these authorities to respond to perceived anticompetitive behavior in the marketplace.

Why this matters? Even with increased federal funding for provider relief, many hospitals and other providers have struggled during the COVID-19 pandemic due to their specific market pressures and patient demographics. These pressures have increased with the surge in the Delta variant, at the same time as many payers are considering cut-backs in coverage and payment policies adopted in the earlier stages of the pandemic. Providers' efforts to achieve greater efficiencies and leverage expanded market strength are driving a new wave of consolidation, which is prompting increased oversight and enforcement activity—driven in part by a desire to ensure hospital systems comply with mandated pricing transparency rules. These pressures may manifest themselves in legislative activity by Congress to tie coverage expansions to enhanced compliance requirements, as well as increased enforcement by the FTC, with it potentially exploring different, novel theories of anticompetitive harm in health system mergers.

4. More to come on drug pricing

Drug pricing continues to be at the forefront of health policy considerations, and the EO continues this trend. It expresses concern that Americans are paying too much for prescription drugs and affirms that drug pricing is going to continue to be an area of focus for the Biden-Harris administration, including support for aggressive legislative reforms in this area. However, the full extent of the administration's work in this area remains to be seen. The EO charges HHS, not later than August 23, 2021, to submit a report to the White House with a "plan to continue the effort to combat excessive pricing of prescription drugs and enhance domestic pharmaceutical supply chains," among other provisions. On September 9, 2021, HHS made available this report, which outlines potential legislative policies and administrative actions "already underway or under consideration" by the Department.

Why this matters? Numerous drug pricing action items are laid out in the EO and the HHS report; however, what the Biden-Harris administration will do on this front has not yet been fully revealed. HHS' drug pricing considerations overlap with an evolving legislative landscape for related issues on Capitol Hill. Which of the action items currently under consideration by the Biden-Harris administration will be pursued and in what form? The Biden-Harris administration has repeatedly called on Congress to allow Medicare to negotiate drug prices. Regardless of how the legislative landscape on drug pricing evolves, the administration may choose to pursue reforms through existing statutory authorities, such as demonstrations initiated by the Center for Medicare and Medicaid Innovation (CMMI), thus fueling further speculation in this policy area for the time being.

We will be closely tracking these efforts. If you have any questions about any of these four efforts, or the EO in general, please let us know.

[1] https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

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