Biden Takes Aim at Trump Administration Healthcare Policies

February 2, 2021

On January 28, 2021, marking a significant departure from the Trump Administration, President Biden issued an Executive Order with the stated purpose of strengthening the Affordable Care Act ("ACA") and Medicaid.

Biden's Executive Order: (i) directs the Department of Health and Human Services ("HHS") to consider establishing a Special Enrollment Period ("SEP"), providing qualifying individuals with a new opportunity to enroll in health insurance plans sold in ACA exchanges (sometimes referred to as "marketplaces") in certain states; and (ii) instructs the secretaries of HHS, Treasury and Labor to identify existing regulations and policies that conflict with the Biden Administration's health policy objectives and consider whether they can be suspended, revised or rescinded. Additionally, on January 29, 2021, HHS announced that it was postponing for two months implementation of certain parts of a final rule implemented by the Trump Administration last year that would effectively bar pharmaceutical benefit managers ("PBMs") from receiving rebates from prescription drug manufacturers. The following day, HHS and the plaintiff challenging the final rule stipulated that implementation of other terms of the final rule will be postponed for one year. We discuss these developments and what they mean for the healthcare industry below.

ACA Special Enrollment Period. Ordinarily, individuals are given a limited window (currently November through December in most states) to enroll in plans offered on ACA exchanges for the coming year. The Executive Order directs HHS to consider establishing an SEP—in light of the pandemic—to afford uninsured individuals an additional opportunity to enroll in ACA plans. Shortly thereafter, the Centers for Medicare and Medicaid Services ("CMS"), an entity within HHS, announced that it was creating an SEP from February 15, 2021 through May 15, 2021. During this time, individuals living in the 36 states served by the healthcare.gov platform can enroll in ACA plans. CMS also encouraged states that operate their own platforms to create their own SEPs. CMS plans to spend $50 million in outreach to encourage the uninsured to enroll in these plans.

Undoing Trump Administration Health Policies. The Executive Order directs the secretaries of HHS, Treasury and Labor and heads of other executive departments and agencies to review existing regulations, orders, guidance documents and policies to determine whether any provisions are inconsistent with the new Administration's policies, with focus on the following:

- Policies that may undermine the ACA's protections for people with pre-existing conditions, including COVID-related complications;
- Demonstration projects and waivers (or policies related to them) that may reduce or undermine coverage under Medicaid or the ACA;
- Policies that may undermine the ACA exchanges or individual, small group or large group insurance markets;
- Policies that may present barriers to enrollment in Medicaid or ACA plans; and
- Policies that may reduce the affordability of coverage or financial assistance for coverage.

To the extent agencies identify policies that are inconsistent with the Administration's objectives, they are instructed to consider whether such policies can be suspended, revised or rescinded, including through rulemaking where necessary. It is important to note that rulemaking is generally required to repeal existing rules, and any new rulemaking may be subject to legal challenge (*e.g.*, alleging failure to comply with requirements of the Administrative Procedure Act or that the new rule is allegedly "arbitrary and capricious").

Although it is not yet certain what actions will be taken as a result of this Executive Order, it is anticipated that HHS will either rescind or modify Trump-era regulations that were designed to facilitate the availability of low-cost, non-ACA plans, including regulations that allow for short-term limited duration health insurance ("SDLI") plans to be issued for terms in excess of three months (in states where such plans are lawful) and association health plans. These plans have been criticized by some because they lack certain of the ACA's consumer protection provisions and draw healthy people away from the "risk pool“ for ACA-qualified plans, thereby making ACA plans more expensive.

The Administration may also seek to rescind certain Medicaid waivers that were granted during the Trump Administration, including the waivers granted to 12 states that permitted the imposition of work requirements on certain beneficiaries. None of these waivers are currently in effect, although that could change after the Supreme Court hears a case next term addressing the validity of such waivers. Undoing Medicaid waivers may prove complicated because of letters sent by the former CMS administrator to states this past January asking them to agree, among other things, that a decision by CMS to withdraw a waiver would not go into effect for nine months (although it is not known what position HHS will now take with respect to the validity of these letters).

The policies outlined in the Executive Order are likely to result in more people being covered by ACA and Medicaid plans. That is likely to prove beneficial to insurers that offer plans on ACA exchanges or administer Medicaid plans and healthcare technology vendors that offer benefits administration and care management software solutions to such plans. An increase in plan enrollees is also likely to translate to increased demand for provider services, drugs and devices. Hospitals particularly benefit because they frequently provide care without regard for ability to pay—meaning that fewer self-pay/uninsured patients likely will translate into less bad debt or charity care writeoffs. However, if HHS decides to restore Obama-era regulations that limited SDLI plans to three months, that may prove harmful to insurers that sell such plans.

Delay in Implementation of PBM Rules. HHS announced that it is delaying for two months the implementation of certain provisions of a final rule issued in November 2020, discussed here, that would generally prohibit PBMs that administer Medicare Part D plans from receiving rebates from pharmaceutical manufacturers (with an exception if, among other things, the rebates were passed on to consumers at the point of sale). This rule has been challenged by the PBM industry in court. The parties to this proceeding stipulated on January 30, 2021 that implementation of other provisions of the final rule that were originally scheduled to go into effect in 2022 will be delayed until 2023. The PBM industry, health insurers and others have argued that the rule would result in higher drug costs and increased federal spending because PBMs would no longer be able to use the promise of favorable formulary placement as leverage to receive large rebates from the pharmaceutical industry; those rebates in turn reduced the overall cost of Part D plans.

HHS' announcement states that the purpose of the delay is "because of the pendency of litigation challenging the final rule, and the Department's interest in evaluating its position in that litigation." These comments suggest HHS may be considering repeal of the final rule.

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