Insight

Zombie Rebate Rule Could Create Troubling Precedent

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EXECUTIVE SUMMARY

- One recent executive order on health care directs the Secretary of Health and Human Services (HHS) to complete a rulemaking that the agency previously announced as withdrawn, though it never published a formal notice of withdrawal in the Federal Register.
- Despite stakeholders and the public considering the rule dead, HHS is likely to rely on a previously published proposed rule and completed public comment period to quickly move toward finalizing the rule.
- Such a move would appear be a precedent-setting action that would negatively impact regulatory certainty and undermine confidence in the regulatory process.

INTRODUCTION

A recent executive order (EO) directs the Secretary of Health and Human Services (HHS) to complete a rulemaking seeking to ensure that rebates offered by drug manufacturers to health plan sponsors and pharmacy benefit managers get passed along to Medicare patients. The rulemaking in question refers to a rule proposed in early 2019 but announced as withdrawn a few months later. Since a withdrawal notice was never published in the Federal Register, however, it is an open question whether HHS will proceed to a final rule or re-propose the rule for additional public comment. Both the timing and public comments by a former administration official indicate that the former is most likely.

Regardless of the merits of the rule, reviving a rulemaking declared withdrawn would damage regulatory certainty. Just as troubling is that such a move appears to be without precedent – meaning that this case could open the door to future administrations reviving "dead" rules in similar fashion. This analysis explores the potential issues and their implications for the future.

BACKGROUND

Last month, President Trump issued a series of EOs focused on health care. One of those EOs, "Lowering Prices for Patients by Eliminating Kickbacks to Middlemen," directs the Secretary of HHS to "complete the rulemaking process he commenced." This phrase refers to a proposed rule, commonly called the rebate rule, proposed in February 2019. In July 2019, after the 60-day public comment period concluded, the Trump Administration announced in a statement to media that "the President has decided to withdraw the rebate rule." Typically, when a rule is withdrawn, the agency that proposed it will publish a notice in the Federal Register. This constitutes a final agency action, which means if the agency intends to move forward with a similar rule in the future it needs to re-start the rulemaking process.

HHS never published a withdrawal notice in the Federal Register. Surely, however, the announcement signaled to all potentially affected stakeholders that the rule was "dead." That belief was likely reinforced when the rule

was listed under Completed Actions as withdrawn in the Fall 2019 Unified Agenda of Regulatory and Deregulatory Actions.

In light of last month's EO, and in particular the phrasing "complete the rulemaking process," HHS appears to have two options for how to proceed. The first option would be simply to proceed as though its proposed rule and the subsequent public comment period satisfies the notice and comment requirement of the Administrative Procedure Act (APA). This option would allow HHS to issue a final rule without any further comment opportunity. In order to ensure this move would satisfy APA requirements, HHS would just have to demonstrate in the final rule that it considered the comments stemming from the February 2019 proposed rule. Indeed, a former Trump Administration HHS official recently wrote that this option is likely. The second option is to issue a new proposed rule (or a supplemental proposed rule) and open a new comment period. Once that comment period is over, HHS could then issue a final rule.

CONCERNS WITH PROCEEDING TO FINAL RULE

There is a clear advantage of expediency with the first option, which makes it HHS's most likely choice. It would also raise a couple of problems from a good governance and administrative-policy perspective.

The first problem is regulatory uncertainty. An important element of administrative policy is that the process by which rules are made is predictable. When an agency announces that a rule is withdrawn, there is often a lag before the announcement is published in the Federal Register, but it is usually a formality. Accordingly, the regulated community assumes the announcement itself means that the rulemaking is withdrawn. Stakeholders begin to make decisions, both financial and otherwise, under the belief that the possible regulatory change will not occur. If withdrawal announcements are essentially meaningless, stakeholders may have to continue to plan for possible regulatory changes. This situation would likely affect investment decisions and limit growth opportunities. It is economically important that withdrawal announcements are dependable.

The second problem is that the underlying assumptions and conditions the agency believed justified the proposed rule may have changed, and the public would not have an opportunity to raise those changes to ensure they are addressed. In the example of the rebate rule, the EO adds a layer of conditions that the proposed rule did not meet. Section 4 of the EO calls on the HHS secretary to confirm that the rule "is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs." The Centers for Medicare and Medicaid Services' Office of the Actuary, which in part analyzes agency actions for their impact on federal spending, concluded in its analysis of the proposed rule that beneficiary premiums would increase by about 19 percent and federal spending would increase by $13.5 billion in 2020. It would appear based on this analysis that finalizing the previously proposed rule unchanged would run counter to the goals of the EO, and some commenters may want the opportunity to highlight that fact.

A PRECEDENT-SETTING ACTION

Just as troubling is that if HHS finalizes the previously proposed rule, the action would appear to be the first time in recent history, if not longer, that a rule would be announced as withdrawn then come back without being re-proposed. While this is difficult to verify given the informal nature of withdrawal announcements, the American Action Forum (AAF) was unable to find any instances going back to 2000.

It would, however, be the first time that a previously proposed economically significant rule has been withdrawn from the Unified Agenda only to be finalized in the same form. AAF analyzed the 181 economically

significant actions that were withdrawn from Unified Agenda, according to Office of Information and Regulatory Affairs' (OIRA) data. None was eventually finalized without a new proposed rule and opportunity for public comment. Those that were eventually finalized, such as rules dealing with greenhouse gas emissions from motor vehicles or flight crewmember rest requirements, were re-proposed and had entirely new Regulation Identifier Numbers from OIRA.

If HHS proceeds to a final rule in this case, it would set a troubling precedent that could destabilize the regulatory process. Future administrations may use this rule to justify similar maneuvers for political benefit. Imagine a future administration proposing a controversial rule and accepting public comment, announcing it as withdrawn before an election to avoid negative political consequences, then quickly finalizing it soon after. The public and affected stakeholders would feel rightly deceived, and political accountability would have been subverted.

CONCLUSION

As HHS revives the rebate rule at the direction of the president, it faces two options. It can rely on a proposed rule and comment period prior to the rule's announced withdrawal to expediently issue a final rule, or it can re-propose the rule for public comment. Out of convenience, it is likely HHS will choose the first option.

If HHS does so, it will have negative consequences on regulatory certainty. It will also set a dangerous precedent that undermines the purpose of the regulatory process—to ensure transparency, predictability, and accountability as the government creates regulations.