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HHS Issues Controversial Drug Rebate Reform Final Rule

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Before the COVID-19 pandemic derailed even the best-laid plans, the Trump Administration and Congress were focused on a different public health issue: drug pricing. For years, President Trump has targeted "Big Pharma" as unreasonably driving up drug costs, while both the House and Senate have taken aim at pharmacy benefit managers (PBMs), as well as drug manufacturers, for their respective impacts on drug pricing. On Friday, November 20, the Administration took bold action by releasing a contentious rule designed to disrupt the drug supply chain status quo. The Pharmaceutical Rebates final rule will alter how drug discounts offered by pharmaceutical manufacturers to plan sponsors or their PBMs, and service fees paid by such manufacturers to PBMs, are treated for purposes of the federal Anti-Kickback Statute (AKS).

As we discuss below, the policies set out in this final rule are not surprising, in light of other actions taken by the Trump Administration to date. However, the transformational effects the rule will have on the drug supply chain, coupled with a lack of consensus among lawmakers and industry stakeholders about the best approach to drug pricing reform, ensures that litigation of this new rule will inevitably ensue.

How did we get here?

Proposed Rule

As our readers will recall, the Department of Health & Human Services (HHS) first issued a proposed rule to eliminate safe harbor protection under the AKS for rebates paid by drug manufacturers to plan sponsors or their PBMs back in February 2019. The proposed rule sought to:

- Amend the discount safe harbor to the AKS to remove protection for drug price reductions paid by manufacturers to plan sponsors under Medicare Part D or Medicaid MCOs (directly or through PBMs) unless the price reduction was required by law; and
- Create two new safe harbors to protect certain point-of-sale (POS) discounts on prescription drugs and certain fixed fee service arrangements between manufacturers and PBMs.

The goal of the proposed rule was to eliminate discount safe harbor protection for formulary rebates paid by pharmaceutical manufacturers to plans and PBMs and force plans and PBMs to pass along to patients at the POS the rebates in order to lower patients' drug costs at the pharmacy counter. Plans and PBMs currently use those rebates to lower premiums or to provide other plan benefits.

The Administration abruptly withdrew the proposed rule in July 2019 after the Congressional Budget Office estimated that it would have significantly increased federal spending - to the tune of $177 billion over a decade. But, as it has done before, the Administration again changed course and apparently reconciled any fiscal concerns it had about the proposed rule, resulting in an Executive Order (discussed below) and the release of the final rule last week.

Executive Order

The President took executive action on pharmaceutical rebates earlier this year, issuing an Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen in July (Rebate EO). (This order was accompanied by several other orders addressing drug pricing and supply chain issues; read more about those here.) These executive orders came on the heels of Trump's June 2019 Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First, which sought to broadly improve price and quality transparency in health care. The Rebate EO revived the proposed rule, directing the HHS Secretary to complete the rulemaking process.

Final Rule

The rule as finalized does not include many material changes from the rule as proposed – which is somewhat surprising, considering that HHS received comments on the proposed rule from 26,000 commenters. HHS's response to many of the comments it received was that the comments were outside the scope of the rule (e.g., many comments were about the rule's impact on and administration of the Medicare Part D program).

For those comments that were within the scope of the rule, many addressed the impact of the final rule on the pharmaceutical supply chain or asked HHS for clarity on contracting for and administration of the POS discounts safe harbor. According to HHS, the pharmaceutical supply chain is sophisticated, and HHS is confident that supply chain stakeholders will sort these concerns out without HHS dictating any specific form, which could stifle innovation.

HHS did incorporate a few substantive changes into the final rule that are worth noting. HHS removed Medicaid MCOs from the scope of the changes to the discount safe harbor. (Medicaid beneficiaries already have low cost-sharing so the same benefits as in Part D do not apply, and many commenters were concerned that the rule would raise costs for Medicaid programs.) Also of note, the rule is now scheduled to go into effect January 1, 2022.

What about the costs?

The Rebate EO that revived the rule included as a condition that HHS Secretary Alex Azar confirm that the rule would not increase federal spending, premiums, or patient out-of-pocket costs. Understandably, many people thought this condition was a loophole that would ultimately prevent a final rule and that the Rebate EO itself was purely theatrics.

But on November 20, 2020, Secretary Azar did, rather surprisingly, publicly confirm that, in his view, "the Final Rule implementing the Executive Order is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs." In explaining his view, Secretary Azar does not explicitly state why the rule won't increase costs, but rather relies on his long experience in the industry and the government in support of his conclusion. Secretary Azar has previously made clear his belief that pharmaceutical manufacturers will lower list prices due to

increased transparency in the system and the elimination of rebate payments – which is a key underpinning of the final rule. Manufacturers' lowering of drug prices, however, is far from guaranteed.

What happens now?

Although this final rule has been issued, it remains an open question as to whether HHS formally withdrew the proposed rule last year. The proposed rule was listed on the Office of Management and Budget's website as withdrawn, however no formal Federal Register publication of withdrawal ever occurred. If the proposed rule was indeed withdrawn, HHS would have to start over with a new notice of proposed rulemaking (NPRM).

These uncertainties set the stage for Administrative Procedure Act challenges and potential lawsuits. Some industry stakeholders are already preparing for litigation. PCMA, the industry group that represents PBMs, has already stated that it "will explore all possible litigation options to stop the rule from taking effect and destabilizing the Medicare Part D program that millions of beneficiaries rely on."

There is undoubtedly much more to come with respect to this final rule. Stay tuned - we'll continue to update you as things develop.

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