Trump Administration Withdraws Proposed Rebate Rule

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In an unexpected turn of events, the Trump administration has apparently reversed course and has withdrawn the proposed rule that would have amended the discount safe harbor under the Anti-Kickback Statute to eliminate protections for certain drug rebates paid by pharmaceutical manufacturers. "Based on careful analysis and thorough consideration, the president has decided to withdraw the rebate rule. The Trump administration is encouraged by continuing bipartisan conversations about legislation to reduce outrageous drug costs imposed on the American people, and President Trump will consider using any and all tools to ensure that prescription drug costs will continue to decline," White House Deputy Press Secretary Judd Deere said in a statement.

As we <u>reported</u> back in February, in addition to the removal of the safe harbor protections, the proposed rule would have created two new safe harbors to protect: (i) certain point-of-sale discounts on prescription pharmaceutical products; and (ii) certain fixed fee service arrangements between manufacturers and PBMs.

This latest move comes on the heels of the Congressional Budget Office's <u>estimate</u> that implementing the proposed rule would have increased federal spending by about \$177 billion over the next decade, where spending for Medicare would have increased by about \$170 billion and spending for Medicaid by about \$7 billion.

In June, the White House issued an <u>executive order</u> aimed at improving price and quality transparency in healthcare. Moreover, last week the president announced his intentions to deliver an executive order that would create a "favored nations" clause, where U.S. spending for drugs would be tied to prices paid by other countries.

In a statement, HHS spokesperson Caitlin Oakley said that "Secretary Azar is fighting alongside President Trump to lower prescription drug costs and protect America's seniors." Needless to say, this has been a very busy week for the White House, and we anticipate continued movement in this space. We will continue to monitor closely and will track any further developments.

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