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HHS Abandons Proposal to Reform Drug Manufacturer Rebate System

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On Thursday, July 11, 2019, the White House administration reversed course on the Department of Health and Human Services' (HHS) recent proposal to reform drug manufacturer rebate system. As we previously <u>reported</u>, HHS's February 6, 2019 proposed rule sought to modify the Anti-Kickback Statute safe harbor protection with the aim of lowering prescription pharmaceutical product prices and out-of-pocket costs for consumers (primarily Medicare Part D and Medicaid Managed Care Plan members). With the proposed rule, HHS hoped to encourage medication manufacturers to pass discounts directly to consumers and develop a transparent framework for the prescription drug product market.

The public comment period for the proposed rule closed at midnight on April 8, 2019, with over 25,000 comments received. The pharmaceutical industry welcomed the proposed rule. Pharmaceutical Research and Manufacturers of America (PhRMA) informed HHS in April that it considers the proposed reform of the rebate system to be urgent. On the other hand, payers, pharmacy benefit manager and providers have opposed the proposal, collectively warning that the elimination of the safe harbors could lead to higher costs for patients.

According to several reports, the administration's decision to back away from the proposed rule is based on the prospects of bipartisan legislation aimed at reducing drug costs, as well a concern that the proposed rule would have imposed increased drug costs on seniors. In a <u>May 2019 report</u>, the Congressional Budget Office estimated that the proposed rule would increase federal spending by about \$177 billion from 2020 to 2029, with increases in Medicare Part D plan premiums. HHS officially withdrew notice of its pending final rule on <u>July 10, 2019</u>.

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