



FEBRUARY 3, 2021

FDA and Life Sciences

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Implementation of Final Rule Excluding PBM Rebates from Discount Safe Harbor Delayed Until 2023

Pharmaceutical Care Management Association (“PCMA”) lawsuit results in delayed implementation of Final Rule while Biden Administration review is ongoing

Pursuant to a [Court Order](#), implementation of the U.S. Dept. Health and Human Services (“HHS”) Office of Inspector General (“OIG”) November 2020 [Final Rule](#) modifying the Anti-Kickback Statute (“AKS”) discount safe harbor will be delayed until at least January 1, 2023. If implemented, the Final Rule would “remove” certain safe harbor protections for manufacturer rebates to pharmacy benefit managers (PBMs) and health plans and add two new safe harbors in an effort to alter drug pricing in the Medicare Prescription Drug Benefit (“Part D”) and Medicaid Managed Care. King & Spalding published a client alert discussing the Final Rule, which is available [here](#).

IMPLEMENTATION OF FINAL RULE CHANGES TO THE DISCOUNT SAFE HARBOR DELAYED UNTIL 2023

Soon after the Final Rule was published, the Pharmaceutical Care Management Association (PCMA), a trade association representing the PBM industry, filed suit against HHS, challenging the Rule. While that suit is still ongoing, on January 31, 2021, PCMA and HHS reached a judicially approved agreement to delay implementation of the revisions to the discount safe harbor until January 1, 2023.

Specifically, among other aspects, the Final Rule provided that changes to the discount safe harbor – including loss of discount safe harbor protection for manufacturer rebates to Part D plan sponsors – would go

into effect on January 1, 2022. Those changes would have meant that the discount safe harbor would explicitly exclude from its purview manufacturer rebates to Part D plan sponsors. Accordingly, these very near-term effective dates required PBMs, plans, and manufacturers to quickly consider the impact of the Final Rule on their arrangements, including whether revisions and renegotiations of existing rebate and service arrangements would be needed. At a minimum, the court-approved delay affords the industry more time to address and advance Medicare Part D contracting issues.

NEW ADMINISTRATION TO REVIEW STATUS HEARING DURING THE DELAY AND EVALUATE IMPLEMENTATION OF THE NEW SAFE HARBORS

Although the provisions of the Final Rule that created the new safe harbors were slated to go into effect on January 29, 2021, on that same day that the new safe harbors were to take effect, the Biden Administration placed a 60-day freeze on finalization of the Rule to afford an opportunity for further review and to consider the revisions to the AKS safe harbor regulations. The 60-day freeze extends the effective date of the new safe harbors to March 22, 2021. If the Biden Administration more permanently reverses implementation of the Final Rule, or at least the changes to the discount safe harbor, the PCMA litigation may become moot.

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King & Spalding continues to closely monitor this situation and is pleased to assist clients with analysis of the potential implications.



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