

## Summary of Trump Administration Drug Pricing and AKS Rulemakings and Implications for Life Sciences Companies and Health Care Providers

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November 25, 2020

On Friday, November 20, 2020, 60 calendar days prior to the inauguration of President-Elect Biden, the Trump administration released three rulemakings with significant implications for life sciences companies and healthcare providers. While aspect of these rulemakings may be challenged in federal court and/or reviewed by the incoming Biden administration, each raises novel policy and legal issues that are summarized below:

- The Department of Health and Human Services Office of Inspector General (OIG) issued a final rule entitled “Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection” that amends the longstanding “safe harbor” protection under Anti-Kickback Statute (AKS) for price concessions, including rebates, that are offered by pharmaceutical manufacturers to plan sponsors, or pharmacy benefit managers (PBMs) under contract with them, under the Medicare Part D program. Download our summary [here](#).
- The Centers for Medicare & Medicaid Services (CMS) issued an interim final rule implementing a “Most Favored Nation” Model scheduled to be phased in over seven years beginning on January 1, 2021 which links the Medicare Part B payment amount to providers for certain drugs and biologicals to international reference prices. Download our summary [here](#).
- Separately, OIG issued a final rule making modifications to other AKS safe harbors and the beneficiary inducement civil monetary penalties (CMP) law to address value-based contracting and other arrangements among health care providers. Download our summary [here](#).

CMS also issued a final rule entitled “Modernizing and Clarifying the Physician Self-Referral Regulations” amending its regulatory exceptions to the Stark Law, a summary of which will be issued in a separate alert.

If you have any questions about any of the topics discussed in these summaries, please contact your Foley Hoag attorney or any of the summary authors.

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