



Certain Pharmaceutical Discounts No Longer Safe Under the "Safe Harbors"?

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On February 6, 2019, the Department of Health and Human Services ("HHS") published in the Federal Register a proposed rule to significantly curtail discount safe harbor protections afforded under the Anti-Kickback Statute ("AKS"), currently codified at 42 CFR §1001.952(h).

Specifically, the proposed rule would revise the regulatory definition of "discount" to remove from safe harbor protection under the AKS most prescription drug rebates paid to pharmacy benefit managers ("PBMs"), health care plan sponsors paid under Medicare Part D, and Medicaid managed care organizations ("MCOs"). By doing so, HHS aims to eliminate what the agency has publicly called a "[perverse incentive](#)" that rewards prescription drug list price increases and to incentivize manufacturers to lower list prices and to encourage PBMs to negotiate greater discounts. Given that the Center for Medicare & Medicaid Services is the single largest payor of prescription drugs in the nation, HHS aims to reduce government drug spending from federal health care programs and ultimately lower out-of-pocket costs for consumers.

To accomplish these twin goals, the proposed new rule also would establish new safe harbor protections for certain arrangements with pharmaceutical manufacturers. Specifically, the two delineated protections would apply directly to (i) certain point-of-sale price reductions offered by manufacturers on prescription pharmaceutical products payable by a plan sponsor under Medicare Part D or MCO, and (ii) specific fixed fee arrangements between manufacturers and PBMs for services provided by the PBMs. Importantly, HHS does not intend for the proposed rule to have any effect upon existing protections for value-based arrangements.

The proposed rule evidences the HHS' and the Administration's continued interest in reducing federal spending for pharmaceutical products. HHS proposes that the amendments, if finalized, would come into effect on January 1, 2020. The public can weigh in on the proposed rule, available in the Federal Register [here](#), during the open comment period through April 8, 2019. Interested parties have an opportunity to voice concerns and propose specific definitional language for the rule. Additionally, submissions can indicate whether the proposed effective date gives affected entities a sufficient transition period to fully restructure any arrangements that might fall outside the revised AKS discount safe harbor.



Laura F. Laemmler-Weidenfeld
Washington



Daniel A. Cody
San Francisco



Taylor A. Goodspeed
San Francisco

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