

RESULTS-BASED CONTRACTING: THE NEED TO RECONSIDER THE ANTI-KICKBACK STATUTE

Despite the promising benefits of results-based contracts (RBCs) (also called value-based contracts), uptake has been hindered by a range of barriers, including a lack of clarity in the Anti-Kickback Statute (AKS). The AKS is a federal law that prohibits the offering of anything of value with the intent to induce the purchase of items or services paid for by federal health care programs. The terms of the statute are broad, which can cause hesitation for biopharmaceutical companies and plans interested in pursuing these results-based contracts.



LACK OF CLARITY LIMITS UPTAKE OF RBCs

For prescription medicines, the AKS draws into question the ability of innovator companies to work with a health plan on RBCs, including partnering on things like company-sponsored patient education, medication adherence assistance or data analysis. And violation of the AKS could result in steep fines, prison and exclusion from federal health care programs, including Medicare and Medicaid, for both parties involved. As a result, interested innovator companies and plans exercise extreme caution when considering RBCs.

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SAFE HARBORS AND EXCEPTIONS HELP PROTECT BENEFICIAL ARRANGEMENTS

Given potential ambiguity in the statute's broad language, Congress created exceptions to the AKS and directed the Secretary of Health and Human Services (HHS) to create safe harbors for the AKS. To date, Congress has created ten exceptions and HHS has created 28 safe harbors to protect certain warranties, discounts, equipment rental, electronic health records and payments made to bona fide employees. HHS has not yet provided clarity about the inclusion of RBCs within existing safe harbors and exceptions, nor has the agency created a RBC-specific safe harbor.

The AKS has had a dampening effect on the uptake of RBCs; current contracts must be written with an eye toward ensuring every variable strictly avoids even the possibility of violating the AKS. Therefore, it is fair to say that current RBCs don't offer the same benefit for plans or patients that could be had if the threat of federal investigation or prosecution was not overhanging.



WHAT THE FEDERAL GOVERNMENT CAN DO: CREATE A CLEARER PATH WITH A NEW SAFE HARBOR

Congress and/or HHS could accelerate the proliferation of RBCs by creating a new exception or safe harbor that protects biopharmaceutical companies and plans that enter into RBCs.

Currently there is an exception and a safe harbor for discounts and rebates, where protection is provided if certain disclosure requirements are met. Without this safe harbor, innovators would not be able to provide discounts and rebates. A safe harbor for results-based contracts could allow for price adjustments based on meeting an outcome or permit the bundling of services and pharmaceuticals.

Providing safe harbor protection to RBCs could enable entities to more fully participate in the burgeoning value-driven health care system.

