

Industry Voices—5 things the government should do to clear the path for value-based rebate arrangements

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In January 2019, the U.S. Department of Health and Human Services (HHS) published a proposed rule that would make sweeping reforms to the safe harbor regulations under the Anti-Kickback Statute (AKS), the federal law that prohibits most payments for referrals of items or services reimbursed by Medicare, Medicaid and other federal healthcare programs.

HHS' proposed reforms are expressly targeting Medicare Part D "drug rebate arrangements" between pharmaceutical manufacturers and pharmacy benefit managers (PBMs), whereby pharmaceutical manufacturers provide utilization-based retrospective discounts to PBMs in exchange for formulary placement or position.

Regulators and members of Congress have repeatedly expressed concern regarding the potential role of drug rebates in the maintenance of prices for drugs that are perceived to be excessive. They have taken aim specifically at the role of PBMs in pocketing large portions of such discounts that are paid several months after the time of sale rather than sharing larger portions of savings with beneficiaries at the point-of-sale.

If finalized, this reform to the AKS safe harbors would transform manufacturer discounting arrangements in the Medicare Part D program.

Specifically, under the reform measures, Medicare Part D rebates will no longer receive safe harbor protection unless they are "completely applied" at the point-of-sale to reduce the price upon which the beneficiary's cost sharing is based. For specialty tier drugs (drugs that are \$670 per month or more in 2019) to which a co-insurance applies, the beneficiary's out-of-pocket obligation would be calculated as the percentage of the "net" price of the drug after the full value of the reduction in price is applied.

For lower-tier drugs to which a fixed co-payment level applies, a plan sponsor could choose to apply reductions in price on branded prescription drugs to reduce co-payment amounts for the tier on which that drug is placed on the plan sponsor's formulary or apply such reductions in price to reduce co-payments for drugs on other formulary tiers, so long as the average cost to beneficiaries across formulary tiers does not exceed certain Medicare Part D actuarial equivalence standards. In both cases, a key feature of the proposal is that the discounts be applied at the point-of-sale when the beneficiary obtains the medication.

Nowhere does the proposal provide specific guidance on what the future may hold for what are commonly referred to in the industry as "value-based arrangements."

There is no formal legal definition for this industry term of art; it is an umbrella term that has been used by stakeholders and regulators to describe drug rebating arrangements that condition drug price on clinical outcomes or activities that are intended more closely to calibrate the clinical value of the drug with the price charged for the drug. For example, a value-based arrangement could include decreasing drug rebates to a PBM if a Part D plan population achieves an overall positive clinical outcome one year after the manufacturer's drug receives favorable formulary placement or position. In this example, the discounts to the PBM and its plan go down because the plans have achieved overall cost savings and better population-based health results by driving utilization through preferred formulary status for what is ultimately the better drug for most patients.

In nearly all cases, value-based arrangements involve a look back at de-identified clinical results or other de-identified data to understand whether the identified endpoint has been achieved or not. Discounting is thus necessarily adjusted retrospectively through a rebate mechanism, long after the patient has obtained his or her product at the point-of-sale.

The question then becomes: How do value-based arrangements survive, much less proliferate, in Medicare Part D if rebates other than point-of-sale price reductions are no longer protected under the safe harbor regulations?

HHS understands this is a problem but punts on solving it in the proposed rule. HHS broadly states that it “does not intend” for the reforms to have any effect on existing value-based arrangements, and it solicits comments on how the reforms might affect value-based arrangements and whether the proposals for reforms could protect any arrangements that are so-called “value-based.” HHS also states that there are “existing protections for value-based arrangements” without specifying what those might be.

In the final rule, HHS should clearly acknowledge the white elephant in the room and help solve for it. HHS should also:

1. **Clarify that current arrangements need not be unwound if the reforms are finalized.** If the safe harbor reforms are finalized in their current state, the question will arise as to whether existing value-based arrangements based on Medicare Part D rebates are vulnerable to risk under the AKS. This question may lead some stakeholders, in an abundance of caution, to unwind or refrain from renewing such arrangements, even if they are improving outcomes and decreasing costs for Medicare. To avoid this result, the HHS Office of Inspector General (OIG) should, at the very least, issue guidance indicating that it will exercise its enforcement discretion and refrain from prosecuting any value-based arrangements in effect or under negotiation at the time of the final rule for a reasonable grace period (e.g., two years).
2. **Explain the other possible safe harbors that may apply.** OIG has recognized in specific Advisory Opinions that the warranty safe harbor may apply to value-based arrangements based on the facts and circumstances. Other potential safe harbors that might be available depending on the nature of the arrangement could include the personal services safe harbor. OIG should provide an illustrative list of safe harbors, and recognize that value-based arrangements that fall outside the four corners of such safe harbors but meet key identified elements of those safe harbors may pose a low risk of fraud and abuse. This last point is particularly important given that the safe harbors were drafted prior to the existence of value-based arrangements, and may stymie the implementation of such arrangements by their rigid nature absent OIG expressing the view that such arrangements that adhere to alternate safeguards could still pose a low risk of fraud and abuse.
3. **Recognize that more than one safe harbor could apply.** Value-based arrangements are often novel in their design and can involve multiple components, including rebating and data purchases. OIG should explicitly recognize the varied market approaches to value-based arrangements, and its guidance should expressly recognize that more than one safe harbor may apply to such arrangements.
4. **Protect value-based arrangements in Medicare Part D to avoid a chilling effect in the commercial insurance markets.** Senator Braun recently introduced a bill that would extend the proposed rule reforms to the commercial insurance market by amending the Public Health Service Act to prohibit PBMs from receiving rebates from drug manufacturers. Another similar bill may also be soon introduced by Congressman Meadows. It is critical for HHS to take the lead in protecting value-based arrangements outside of Part D in a clear and forward-thinking manner to avoid a chilling effect on value-based arrangements in the commercial insurance marketplace, where such arrangements are also common.
5. **Move swiftly.** Given the accelerated pace of the AKS rebate reforms proposed to take effect on January 1, 2020, it is also essential that HHS move swiftly to clarify the protections afforded to value-based arrangements currently in place and under negotiation, as well as the protections that will be afforded to value-based arrangements if and when the reforms take effect. In particular, absent clarification from HHS, stakeholders will likely move to quickly reconceptualize

value-based arrangements and may be left with a smaller universe of options to share savings and improve outcomes in the absence of a rebate mechanism that occurs after the point-of-sale.

If there is a lag between the final rule and any clarifications that would protect value-based arrangements, stakeholders may prophylactically adjust or simply terminate their value-based arrangements rather than take a wait-and-see approach. That would be detrimental to all stakeholders.

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