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Drug Rebate Proposal Fundamentally Changes Current System, Raises Critical Questions


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Summary

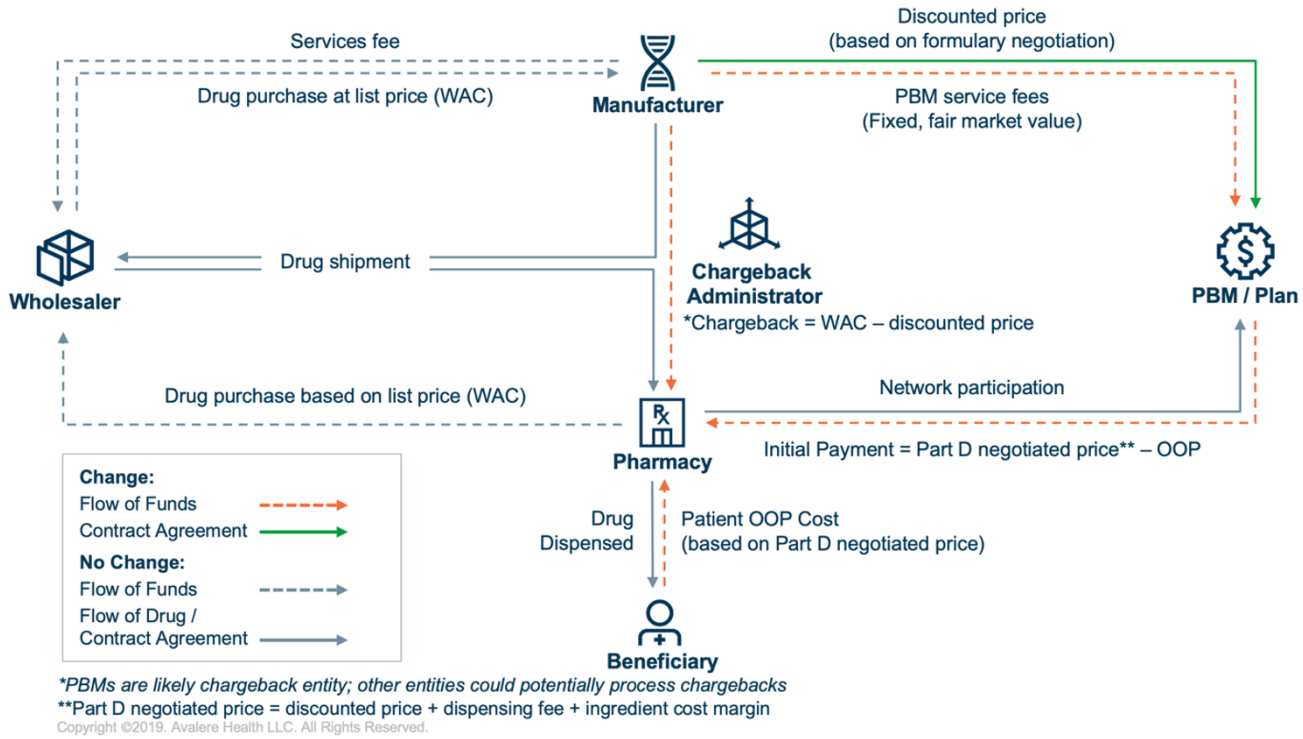
The swift proposed implementation timeline will require stakeholders to evaluate quickly operational requirements, behavioral responses, cross-program implications, and impact on contractual arrangements.

The Anti-Kickback Statute (AKS) safe-harbor rule released on January 31 proposes the elimination of the current safe-harbor protections for prescription drug rebates and a move toward a system of point-of-sale price reductions. In addition, the rule proposes the creation of a new safe harbor for certain fixed, fair-market-value service fees paid to PBMs by manufacturers. While the proposed changes are consistent with the administration's focus on reducing patient out-of-pocket costs and addressing incentives within the current rebating system, they also pose challenges and raise significant issues for stakeholders to consider.

The proposed changes would introduce new incentives into the market that could fundamentally reshape how payers and manufacturers negotiate, and also require a series of significant operational changes. Given drugs' complex flows of information and funds, replacing the rebate structure may alter business practices and arrangements across the supply chain for drug

manufacturers, wholesalers, health plans, pharmacy benefit managers (PBMs), pharmacies, and patients (Figure 1).

Figure 1: Model of supply chain using point-of-sale price reductions in place of rebates



While the proposed rule outlines the broad parameters of a new system, it does not address key questions that will be critical to stakeholders. They include:

What resources are necessary to implement a new chargeback system? To reconcile the difference between a pharmacy's acquisition cost and the point-of-sale discounted price negotiated between a manufacturer and payer, the rule proposes to implement a system of chargebacks. The rule does not dictate a specific chargeback administrator but seeks feedback on possible chargeback flows via a wholesaler or PBM. While feasible, operationalizing a chargeback system will require investment in personnel, data, and technology by pharmacies, payers and PBMs, manufacturers, and potentially others. Moreover, additional clarity may be necessary as part of the rule-making process to ensure that pharmacies are reimbursed at levels that exceed their acquisition costs, rather than based on the discounted price of medications.

Can key players be ready for 2020? With the 2020 contracting processes between manufacturers, PBMs, and payers well underway, stakeholders will need to move quickly to

adjust their agreements in time for mid-2019 bids in Part D for the 2020 plan year. In addition, operational changes will need to begin in earnest to ensure new chargebacks and financial flows are feasible and tested before January. The looming 2020 election and the administration's desire to show progress on drug prices make it likely the proposed timeline will hold.

Are innovative contracting arrangements protected? While the rule acknowledges it "does not intend for this proposal to have any effect on existing value-based arrangements," the administration declines to provide an explicit safe harbor. As a result, some current contracts that rely on performance to determine drug prices, among other agreements, may not be feasible under the rule as written. In response, stakeholders may seek to shape the final regulations to protect innovative contracting arrangements, while preserving the spirit of the proposed policy.

How will PBM service fees shape the relationship between PBM and manufacturer? The proposed rule creates a new safe harbor for manufacturer–PBM service fees that are calculated as fixed amounts, based on "fair market value," and do not account for the volume or value of drugs. With limited additional clarity on what types of arrangements may qualify under this new safe harbor, stakeholders will need to assess what current arrangements would be permitted and how these changes may affect contracting. Absent the current rebate system, fee-based arrangements are likely to evolve and play a role in negotiations between manufacturers and PBMs moving forward.

How will states react? The rule proposes to repeal the safe harbor for rebates negotiated by Medicaid managed care organizations, while preserving protection for mandatory rebates under the Medicaid Drug Rebate Program along with those achieved through state-controlled supplemental rebate agreements. As a result of these changes, the CMS Office of the Actuary indicates that the rule would result in $200 million in additional state Medicaid spending. Given these dynamics, states may be incentivized to re-evaluate their approach to drug benefit management in managed care, potentially in favor of state-controlled options.

How will proposed changes interact with other policies? In parallel with the proposed AKS changes, other policy reforms are taking shape. Notably, pending rules on Part D protected classes and the Part B International Pricing Index could have complex interactions with changes to rebate system, as would already announced policies like indication-based formularies in Part D and cross-benefit management of drugs in Medicare Advantage. Strategies for 2020 and beyond will need to account for the interaction of these potential changes, rather than any one reform in isolation.

Will the commercial market be affected? The administration is limited in its ability to apply

the AKS to the commercial insurance, leading Secretary Azar to call on Congress to take legislative steps to apply the proposed changes more broadly. While action by Congress on this topic is unlikely in the near term, the commercial market may still see an impact from the regulatory changes. New incentives in government programs often “spillover” to non-government insurance, either due to voluntary adoption or behavioral responses that extend across markets and programs. Reforms to the regulations governing the federal AKS may also have an impact on rules governing commercial markets in states, potentially leading to broader implications that could vary based on geography.

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