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Origins of the current rebate system & implications of changes to existing safe harbor regulations



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Overview

- History of the current rebate system: how did we get here?
- What is the “Anti-Kickback Statute”; What is a “Safe Harbor”; and who is the HHS Inspector General?
- What might be in the proposed rule?
- What are the key implications of a new safe harbor regulation?

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Current Rebate System

- Manufacturers and payers have been entering into agreements to discount drug prices in exchange for formulary placement, volume commitments, and administrative services for decades.
- In the mid-1990s, pharmacies sued manufacturers and health plans, arguing that the rebate system then in place violated the Robinson-Patman Act.
 - The Act is an oft-criticized Depression-era antitrust law that prohibits anticompetitive practices by producers, specifically price discrimination.
 - In particular, under the Robinson-Patman Act, it is a violation for a seller to offer a product for sale on different pricing terms to equally-situated distributors, if the effect of the different pricing terms is to reduce competition.
 - Pharmacies argued that up-front discounts (the rebating model then in effect) available to payers, but not to pharmacies, violated the Act.



Current Rebate System (cont.)

- The case (*In Re: Brand Name Prescription Drug Litigation*) was settled in 1996. Under the settlement agreement, manufacturers agreed to offer the same discounts to pharmacies and to payers, but only if the entity receiving the discount could demonstrate an ability to move market share.
 - But ascertaining movement of market share can only happen after the fact – up front discounts could no longer be used.
 - Thus, the current, retrospective rebate system took effect, under which purchasers receive rebates based on their proven ability to move market share.
- Now, in 2018, federal policy makers have suggested that this post-settlement rebate structure encourages manufacturers, plans and PBMs to raise drug prices.



The AKS and Related Safe Harbors

- The federal Anti-Kickback Statute (AKS) makes it a crime to pay or receive anything of value as an incentive or an inducement to use a health care service that is reimbursable by a federal health care program.
 - The AKS was enacted and signed into law by President Reagan in 1987.
- As such, a rebate paid to encourage a Medicare Advantage plan, a Part D plan or a Medicaid managed care plan to favor a particular drug would be, on its face, a violation of the AKS.
- However, the AKS contains a “statutory exceptions” which protect some arrangements from prosecution, including “a discount or other reduction in price obtained by a provider of services or other entity under [a federal health care program] if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity.”

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Discount Safe Harbor

- So let's break this down:
 - Let's say there are two equally effective products on the market treating a particular medical condition, and each product meets the definition of a covered Part D drug.
 - Manufacturer A provides a rebate to Part D plans that exceeds the rebate paid by Manufacturer B, so most Part D plans favor Manufacturer A's product in formulary design.
 - The AKS is implicated because Manufacturer A is paying something of value (the rebate) as an inducement to use its product, which is reimbursable by a federal health care program (Medicare Part D).
 - But the discount safe harbor protects Manufacturer A and the Part D plan from accusations of a violation because:
 - The rebate is a “reduction in price”;
 - It is obtained by an “other entity” (i.e., the Part D plan); and
 - The rebate will be disclosed to CMS (probably via DIR)

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The AKS and Safe Harbors (cont.)

- In addition to the statutory exception for discounts, Congress authorized HHS to create regulatory “safe harbors” from the AKS.
 - There are over 28 safe harbors which “protect” certain arrangements
 - At least four arguably protect the current rebate system:
 - Discount safe harbor (building off the statute)
 - Price reductions to eligible managed care organizations
 - GPO safe harbors
 - Shared risk safe harbor

- It is hard to see how HHS can achieve its policy goal of eliminating rebates under the current AKS safe harbor regime. The government cannot penalize conduct that is expressly permitted by statute and regulations.



The (impending) proposed rule

- In mid-July, it was announced that OMB was reviewing a proposed rule submitted by the HHS OIG entitled “removal of safe harbor protection for rebates to plans or PBMs involving prescription pharmaceuticals and creation of new safe harbor protection.”
 - The rule is listed as “economically significant”
 - As of today, the proposed rule has not yet been released.

- Another proposal – this time a Request for Information – was released on August 27th seeking comment and input on how existing regulations may act as barriers to coordinated or value based care.

- Finally, as of the writing of these slides, OMB was reviewing a rule from CMS entitled “Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Costs.”



The proposed rule (cont.)

- Until the proposed rule is published, we cannot know what the Inspector General is proposing. However, it is likely that one of four options may be under consideration:
 1. Complete elimination of some or all of the safe harbors that protect the current retrospective rebate system that ties rebates to list price.
 2. Modifications to the existing safe harbors – for example, protection only for rebate arrangements where 100% (or a high percentage) of rebates are passed through at point of sale.
 3. Safe harbor protection only for rebates on high-cost drugs – i.e., drugs above a certain cost threshold.
 4. Safe harbor protection – perhaps in the form of a new safe harbor – that protects value-based payment arrangements meeting certain parameters: for example, rebates permitted only in the case of the attainment of specified clinical parameters.



Key Questions

- How could OIG completely eliminate the discount safe harbor, since that safe harbor is statutory?
- How broadly will the proposed policy apply? Just to Medicare Part D? Or will it also include Medicaid managed care and Part B drugs? Will there be a spill-over effect into the commercial market?
- To the extent that the policy applies to rebates in the Medicare Part D program, how would the policy interact with Part D's non-interference clause?
- What will be the impact on Part D premiums? It is commonly understood – including in the recently-released Medicare Trustee's report – that rebates contribute to lower Part D premiums.
- Will the proposal cause a shift to up-front discounts? If so, how will that affect the prescription drug marketplace and the existing PBM industry? Will the injection of greater price transparency in the system ultimately lead to higher drug costs?
- How could an up-front, fixed price discount system work in the context of antitrust laws, in light of the 1996 settlement?
- What could be the intended and unintended impact on the structure of Part D (e.g., plan finder, preferred networks, prompt payment)?