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REBATE SAFE HARBOR  
Proposed Rule

PHARMACY FLASH



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*CMS released a proposed regulation entitled **Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees** on February 6, 2019.*

CMS developed these proposals, in part, with comments and input received from President Trump's Blueprint to Lower Drug Prices which was published in May 2018. The intent is to eliminate rebates so drug manufacturers will have an incentive to lower list prices, PBMs will have more incentive to negotiate greater discounts from manufacturers, and Medicare Part D enrollees will experience lower out-of-pocket expense at the pharmacy counter. It is unknown when or if a final rule will be published, and states and other stakeholders have until **April 8, 2019** to submit comments on the proposed rule.



## KEY PROPOSALS

- **Eliminates** safe harbor protection for drug manufacturer rebates paid to Medicaid MCOs, Medicare Part D plans, or their subcontracted PBMs.
- Creates a new safe harbor for **point-of-sale price reductions** offered by drug manufacturers.
- **Creates a new safe harbor** for fixed fees that manufacturers pay to PBMs for services rendered to the drug manufacturers. The PBM service fees covered in the new safe harbor must be a fixed payment, not based on a percentage of sales, must be consistent with fair market value for the service, and must not be based on volume.
- The safe harbor provisions are proposed to be implemented 60 days following the effective date of the rule, currently proposed to be January 1, 2020.



## MEDICAID IMPACTS

- No change to the federal Medicaid rebate format or calculation, although **Medicaid rebates could decline and net of rebate prices for drugs could increase** due to reduced impact of the Best Price and the CPI Penalty provisions.
- **Capitation rates would likely need to increase** in states without Uniform PDLs to make up for MCO/PBM lost rebates.
- Some states may consider **pharmacy carve out** of managed care or **uniform PDL** to reduce uncertainty around MCO rebates.
- The proposed implementation date of January 1, 2020 would not provide sufficient time for states and MCOs to plan and transition to the final rule.



## EXAMPLES OF UNCERTAINTIES

There are many uncertainties surrounding the implementation of elements proposed in the regulation, including but not limited to:

- Would there be an incentive for manufacturers to offer point-of-sale **price reductions** in Medicaid where there is minimal member cost sharing?
- **Will list prices materially change** if commercial plans still operate using a traditional rebate model?
- The changes proposed in the regulation would require significant change to IT systems and operations of PBMs, manufacturers, and health plans. **What is a realistic implementation date?**
- Does the regulation apply to all managed care programs including **PAHPs and PIHPs?** The proposed rule, in its reference to 1903(m) appears only to apply to Medicaid MCOs.



## NEXT STEPS

- States and other stakeholders have the opportunity to submit comments until **April 8, 2019**.
- Clients are encouraged to submit comments or requests for clarification on topics important to state Medicaid programs.

Links to the proposed rule and CMS summary are included for additional detail.

<https://www.federalregister.gov/d/2019-01026/p-5>

<https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf>



For more information, contact Sara Drake in the GHSC Pharmacy Practice