



# Proposed Rule Affecting Safe Harbors for Prescription Drug Rebates



Medicaid and CHIP Payment and Access Commission

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# Overview

- Background
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  - Medicaid and Medicare drug rebates and coverage
- Summary of proposed rule
- Summary of actuarial analyses
- Potential areas for comment
  - Comments due April 8, 2019

# Anti-kickback Statute and Discount Safe Harbor

- Anti-kickback statute prohibits transactions designed to induce or reward referrals for items and services covered by federal health care programs
- Department of Health and Human Services (HHS) Office of Inspector General (OIG) created discount safe harbors for certain commercial transactions that offer discounts or reductions in price
- Prescription drug rebates qualify as discounts protected under the discount safe harbor

# Medicaid Drug Rebates

- Medicaid Drug Rebate Program statutory rebates
  - Basic rebate (e.g., 23.1 percent of average manufacturer price (AMP) for brand drugs)
  - Additional rebate if price increases faster than inflation
- State supplemental rebates
- Managed care organization (MCO) negotiated rebates
- States and MCOs may contract with pharmacy benefits manager (PBM) to negotiate rebates

# Medicare Drug Coverage

- Part D plans negotiate rebates (may use PBMs)
- Beneficiary cost sharing in deductible phase or under coinsurance is determined on list price and not net price (i.e., after rebate)
- HHS concern that current rebate structure creates incentives to raise list prices and shift a greater share of expenses to the beneficiary
- HHS wants to change the rebate structure so that a beneficiary's cost sharing is based on the discounted price

# Summary of Proposed Rule

# Eliminate Drug Rebate Safe Harbor

- Eliminate protection for manufacturer rebates on prescription drugs for Medicare Part D plans and Medicaid MCOs, including PBMs acting under contract with these plans
- Does not apply to rebates to other payers (e.g., commercial)
- Does not apply to rebates required under law (e.g., Medicaid Drug Rebate Program)
- HHS does not believe state supplemental rebates are affected
- Would go into effect January 1, 2020

# Create New Safe Harbor for Point-of-Sale Discounts

- Safe harbor protection for manufacturer discounts at the point of sale (POS) under certain conditions:
  - Have to be fixed and disclosed in writing in advance
  - Could not involve a rebate unless the full value of the reduction in price is provided to the dispensing pharmacy through what is known as a chargeback
  - Must be completely reflected in the price the pharmacy charges the beneficiary
- Would go into effect 60 days after publication of final rule



# Create New Safe Harbor for Flat-fee PBM Services

- Safe harbor protection for manufacturer payments to PBMs for services that a PBM provides to the manufacturer
- Requires a written agreement that covers all of the services the PBM provides to the manufacturer and the compensation for those services
- Payment must:
  - Be consistent with a fair-market value
  - Be a fixed payment not based on a percentage of sales
  - Not take into account the volume or value of any referrals between the manufacturer and the PBM's Medicare or Medicaid plans

# Summary of Actuarial Analyses

# Actuarial Analyses

- HHS commissioned actuarial analyses from three sources
  - CMS Office of the Actuary (OACT)
  - Milliman
  - Wakely Consulting Group
- Primarily focused on Medicare Part D
- Only OACT estimated the effect on Medicaid spending

# Manufacturer Response

- Manufacturers could convert some or all of their existing rebates to POS discounts or lower list prices
- Manufacturers may seek to recoup some of the price concessions they have previously given
  - POS discounts will not drive market share to the same degree
  - Lower list prices would be applicable to all payers
- Uncertainty in manufacturer response leads to wide range of effects, both in magnitude and direction

# Eliminating Medicaid MCO Rebates

- Shift from plan rebates to POS discounts is not particularly relevant to Medicaid as beneficiary cost sharing is nominal
- Capitation rates would increase as the MCO's net drug costs increase
- State could offset capitation rate increases by:
  - Including the managed care enrollees in their own supplemental rebate negotiations
  - Carving out the prescription drug benefit from managed care contracts

# Eliminating Medicare Part D Rebates

- Medicare POS discounts would not affect Medicaid best price
- Some uncertainty on how pharmacy chargebacks would be handled in calculation of AMP
- Lower list prices could:
  - Decrease Medicaid gross drug spending by decreasing payments to pharmacies
  - Decrease statutory rebates due to lower AMPs, particularly reductions in the inflationary component of rebates
- Decrease in statutory rebates may exceed the decrease in pharmacy payments, leading to increase in net Medicaid drug spending

# Illustrative Example of Effect on Medicaid Rebates

Category	Baseline	15 percent lower list price
Baseline AMP	1.00	1.00
Current AMP	1.47	1.25
Baseline CPI-U	151.60	151.60
Current CPI-U	175.00	175.00
Basic rebate	0.34	0.29
Inflationary rebate	0.31	0.09
Total rebate	0.65	0.38
<b>Net cost</b>	<b>0.81</b>	<b>0.87</b>

**Source:** Milliman. 2019. *Impact of potential changes to the treatment of manufacturer rebates*. Brookfield, WI: Milliman.

# Estimated Change in Medicaid Spending, CY 2020–2029

Type of spending	CY 2020–2029 change in spending (\$ billions)
Reduced rebates	\$18.5
MCO capitation payments	1.3
Price reductions	-18.0
<b>Net federal impact</b>	<b>1.7</b>
<b>State impact</b>	<b>0.2</b>

**Source:** CMS OACT. 2018. *Proposed safe harbor regulation*. Baltimore, MD: OACT.



# Potential Areas for Comment

- Actuarial analyses show great uncertainty on the effects of the proposed rule, and OACT estimated an increase in Medicaid spending
- HHS is soliciting comments on the extent, if any, to which supplemental rebates may be affected
- HHS has stated they may issue separate guidance to clarify the calculation of AMP and best price



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