



# Potential Recommendations on Medicaid Outpatient Drug Rebates

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Medicaid and CHIP Payment and Access Commission

Chris Park and Rick Van Buren

# Overview

- Background and rationale for potential recommendations on the Medicaid Drug Rebate Program
- Options include technical changes to how rebates are calculated and increased oversight
- Decide on whether to make a recommendation on any of these options
- Formal recommendations and vote in future meeting

# Medicaid Drug Rebate Program

- Optional benefit that is provided by all states
- Drug manufacturers must enter into a rebate agreement with Medicaid in order to have their products recognized for federal Medicaid match
- As part of rebate agreement, states generally must cover all of a drug manufacturer's drugs
- Statutorily defined rebates are paid by manufacturers to states and the federal government
- Rebates are separate from the payments Medicaid makes to pharmacies

# Brand Drug Rebates

- Basic – greater of 23.1 percent of AMP or AMP minus best price
- Additional – inflationary rebate equal to the amount that the drug's current quarter AMP exceeds its baseline AMP trended to the current period by the Consumer Price Index – All Urban Consumers (CPI-U)
- Over half of brand drug rebates are attributable to the inflationary rebate

# Correct Line Extension Formula

# Line Extension Drugs

- Line extension is a new version of the product that makes only minor changes to the originator product (e.g., an extended release formulation)
- Line extension is considered a new product and receives a new baseline AMP, essentially resetting the inflationary rebate to zero

# Line Extension Rebate

- The Affordable Care Act (ACA) authorized an alternative rebate for certain line extensions, which is essentially the inflationary rebate (expressed as a percentage) of the original drug
- Line extension drug rebate is the greater of standard rebate (basic + inflationary) or alternative rebate

# Line Extension Rebate Issues

- Drafting error in ACA reduces intended effect
  - Original intent was to calculate the additional inflationary rebate for the line extension drug on the original version's baseline AMP, rather than a new baseline
  - The ACA compares the alternative rebate to the entire rebate for the line extension instead of comparing it to just the inflationary rebate of the line extension
- Definition of line extension drug has not been finalized in regulations
  - But the Comprehensive Addiction and Recovery Act of 2016 specifically excluded abuse-deterrent formulations from the additional line extension rebate



# Potential Recommendations on Line Extension Drugs

- To align the statute with the original intent of the provision, Congress should make a technical correction to the alternative rebate calculation for line extension drugs in Section 1927(c)(2)(C). The correction would make the additional rebate the greater of the line extension's additional rebate or the highest additional rebate (calculated as a percentage of average manufacturer price) for any strength of the original single source drug or innovator multiple source drug.
- The Centers for Medicare & Medicaid Services (CMS) should finalize the definition of line extension drugs. A regulatory definition of a line extension drug will help ensure that drugs are categorized properly and the correct rebate amounts are collected.

# Considerations and Impact

- Federal savings – CBO estimates this would reduce Medicaid spending \$1 –5 billion over 5 years
- States
  - Line extension rebate accrues entirely to federal government
  - Could see reduction in supplemental rebates and potentially increase cost to state
- Drug manufacturers – pay higher rebates and could reduce development of line extensions
- Beneficiaries – may see reduction in medication options

# **Exclude Authorized Generics from the Brand Drug AMP**

# Authorized Generics

- An authorized generic is a generic version of a brand drug made by the brand drug manufacturer
- Are often introduced near the end of the brand drug's exclusivity period to compete with generic drugs
- Can make generic drugs much less profitable for generic manufacturers

# AMP Eligible Sales

- The statute generally directs manufacturers to calculate AMP based on sales from the manufacturer to wholesalers and retail community pharmacies
- The statute also directs manufacturers that produce an authorized generic version of a brand drug to blend the AMPs of the two drugs

# Medicaid Wholesalers

- Under the Medicaid statute, manufacturers can be considered wholesalers in certain circumstances
- Therefore, drugs sales from one manufacturer (primary manufacturer) to another (secondary manufacturer) may need to be included in calculating AMP
- Sometimes, the primary manufacturer and secondary manufacturer have a corporate relationship
- Sale not an arms-length transaction and could be designed to lower the brand drug's AMP

# Potential Recommendation on Blended AMP

- Congress should remove the requirement that manufacturers blend the AMP of a brand drug and its authorized generic. This would ensure that manufacturer rebates are based on the actual fair market value of the drug.

# Considerations and Impact

- Federal savings – CBO estimates this would reduce Medicaid spending (less than \$1 billion over 5 years)
- Drug manufacturers
  - pay higher rebates
  - will need to change which sales are included in AMP calculations
  - may urge Congress to exclude authorized generic sales from best price
- Providers – May increase federal upper limits (FULs), resulting in increased payments



# Strengthen Oversight of the Drug Rebate Program

# Manufacturer Reporting Requirements

- Manufacturers participating in the rebate program must submit certain data elements necessary for the proper functioning of the program, including
  - AMP
  - Best price for brand drugs
  - Whether the drug is a brand, generic, line extension, or authorized generic
  - Baseline AMP data

# Oversight and Enforcements

- The Medicaid statute splits enforcement between the Department of Health and Human Services Office of the Inspector General (OIG) and CMS
  - OIG is authorized to audit manufacturers and issue civil monetary penalties for noncompliance
  - CMS may terminate the participation of a manufacturer in the rebate program for noncompliance or other good cause
- Manufacturers can also be liable for violations of the False Claims Act or other government claims, prosecuted by the Department of Justice

# Informal Steps to Enforce Compliance

- CMS notifies manufacturers if it learns a drug is miscategorized in the rebate program
- Subregulatory guidance codified in the Covered Outpatient Drug final rule with comment
- Drug Data Reporting (DDR) system programmed to only allow manufacturers to classify drugs properly

# Enforcement Regime

## Shortcomings

- Relies on voluntary manufacturer compliance
- Limited tools to detect or enforce intentional noncompliance
  - CMS lacks explicit authority to reclassify drugs
  - drafting ambiguity leads to uncertainty on level of civil monetary penalties (CMPs)
  - termination from the rebate program terminates all of those manufacturer's drugs, which could harm beneficiaries
  - litigation can be prolonged, costly, and an administrative burden

# Possible Recommendations

- MACPAC could make one or more of the following recommendations:
  - OIG should conduct more regular audits of the rebate program
  - Congress should clarify the penalties, including the penalties for misclassifying drugs
  - Congress should give CMS clear authority to reclassify drugs
  - Congress should give CMS authority to terminate individual drugs from the rebate program for noncompliance or other good cause

# Considerations and Impact

- Federal government
  - CBO estimates no budgetary effect over current law baseline
  - administratively burdensome to determine if a drug is misclassified
  - terminating individual drugs from the rebate program would be a fundamental change to the rebate program
  - litigation costs may limit the government's willingness to use certain enforcement tools
- States – could result in higher rebates, but depends on the nature of a state's supplemental rebate arrangements
- Drug manufacturers
  - additional scrutiny of their drug classification decisions
  - subject to additional enforcement actions from CMS
- Beneficiaries – may see reduction in medication options

# Next Steps

- Decide on whether to make a recommendation on any of these options
  - Do Commissioners need additional information or analysis prior to making a recommendation?
- If Commissioners are interested in making a recommendation, staff can prepare a draft chapter
- Commissioners can vote on formal recommendations at a future meeting





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