MACPAC

Draft Chapter: Improving Operations of the Medicaid Drug Rebate Program

Medicaid and CHIP Payment and Access Commission

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Session Overview

- Review draft chapter
  - Medicaid Drug Rebate Program
  - Authorized generics
  - Oversight and enforcement mechanisms
  - Next steps
- Review and discuss draft recommendations

Medicaid Drug Rebate Program

- 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

Rebate Calculations

Rebate component	Brand	Generic
Basic	Greater of: 1) 23.1 percent of AMP 2) AMP minus best price	13.1 percent of AMP
Additional (inflationary)	amount that the drug's AMP exceeds inflation over time	amount that the drug's AMP exceeds inflation over time
Line extension[1]	Basic rebate amount plus greater of: 1) inflationary rebate on line extension 2) Inflationary rebate (expressed as percentage) of original drug	NA
Federal offset	• 0 to 8 percent of AMP • Difference between line extension rebate under current formula and formula prior to Affordable Care Act	2 percent of AMP

AMP is average manufacturer price.

[1] Reflects the revised formula as passed in the Bipartisan Budget Act of 2018. This formula will apply to rebate periods beginning October 1, 2018.

Authorized Generics

- Authorized generic is a generic version of a brand drug made by the brand drug manufacturer
- The statute directs manufacturers that produce an authorized generic version of a brand drug to blend the average manufacturer prices (AMP) of the two drugs
  - blending the AMP of a brand drug and authorized generic can significantly reduce a brand drug's AMP
- If the primary and secondary manufacturer have a corporate relationship, the transfer price may be used to lower the brand drug's AMP

Oversight and Enforcement

- Manufacturers classify their drugs as brand or generic
- CMS has limited authority to address misclassifications
  - may terminate a manufacturer's rebate agreement, which would exclude all of a manufacturer's drugs from the program
  - no intermediate sanctions
- Office of Inspector General (OIG) found approximately 3 percent of drugs were potentially misclassified
- OIG recommends that CMS pursue:
  - legislative authority to compel manufacturers to submit accurate data or enhance its enforcement authority
  - authority to suspend potentially misclassified drugs from participation in the Medicaid rebate program

Line Extension Rebate

- Bipartisan Budget Act of 2018 corrects the drafting error on the alternative line extension rebate
  - Congressional Budget Office estimates federal savings of $5.7 billion over 10 years
- Federal offset on the line extension rebate remains in place
  - could potentially reduce state supplemental rebates up to 10 percent
- In December, Commissioners expressed interest in allowing states to share in the line extension rebates

Next Steps

- Continue work on future policy options
- Requirement to cover new drugs immediately
  - potential grace period to allow states to develop coverage criteria
- Medicaid's ability to manage drug utilization and the need for any additional tools that may be available to other payers
- Additional utilization management tools or value-based contracts for high cost specialty drugs

Draft Recommendations

Draft Recommendation 1

To ensure that manufacturer rebates are based on the price of the drug available to wholesalers and pharmacies, Congress should remove the statutory requirement in section 1927(k)(1)(C) that manufacturers blend the average manufacturer price of a brand drug and its authorized generic.

Draft Recommendation 2

Congress should give CMS authority to reclassify drugs that it has determined that a manufacturer has classified inappropriately for the Medicaid Drug Rebate Program, or give CMS authority to suspend individual drugs from participating in the rebate program until the manufacturer has corrected the drug's classification.

Draft Recommendation 3

Congress should amend Section 1927(b)(1)(C) to allow states to share in the rebates for line extension drugs under the alternative rebate formula.

Draft Recommendations

1. To ensure that manufacturer rebates are based on the price of the drug available to wholesalers and pharmacies, Congress should remove the statutory requirement in section 1927(k)(1)(C) that manufacturers blend the average manufacturer price of a brand drug and its authorized generic.
2. Congress should give CMS authority to reclassify drugs that it has determined that a manufacturer has classified inappropriately for the Medicaid Drug Rebate Program, or give CMS authority to suspend individual drugs from participating in the rebate program until the manufacturer has corrected the drug's classification.
3. Congress should amend Section 1927(b)(1)(C) to allow states to share in the rebates for line extension drugs under the alternative rebate formula.

Final Recommendations for Vote

Recommendation 1

To ensure that manufacturer rebates are based on the price of the drug available to wholesalers and pharmacies, Congress should remove the statutory requirement in section 1927(k)(1)(C) that manufacturers blend the average manufacturer price of a brand drug and its authorized generic.

Recommendation 2

Congress should give the Secretary of Health and Human Services the authority to level intermediate financial sanctions to compel drug manufacturers to submit accurate drug classification data and strengthen enforcement actions. These authorities could include clear authority to reclassify an inappropriately classified drug and to level civil monetary penalties for the submission of inaccurate drug classification data.

Recommendations

1. To ensure that manufacturer rebates are based on the price of the drug available to wholesalers and pharmacies, Congress should remove the statutory requirement in section 1927(k)(1)(C) that manufacturers blend the average manufacturer price of a brand drug and its authorized generic.
2. Congress should give the Secretary of Health and Human Services the authority to level intermediate financial sanctions to compel drug manufacturers to submit accurate drug classification data and strengthen enforcement actions. These authorities could include clear authority to reclassify an inappropriately classified drug and to level civil monetary penalties for the submission of inaccurate drug classification data.

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