Proposed Rule Affecting Safe Harbors for Prescription Drug Rebates

Medicaid and CHIP Payment and Access Commission

Chris Park
Overview

• Background
  – Anti-kickback statute and discount safe harbor
  – 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

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

## Estimated Change in Medicaid Spending, CY 2020–2029

<table>
<thead>
<tr>
<th>Type of spending</th>
<th>CY 2020–2029 change in spending ($ billions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduced rebates</td>
<td>$18.5</td>
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<tr>
<td>MCO capitation payments</td>
<td>1.3</td>
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<tr>
<td>Price reductions</td>
<td>-18.0</td>
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<tr>
<td><strong>Net federal impact</strong></td>
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<tr>
<td><strong>State impact</strong></td>
<td><strong>0.2</strong></td>
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</table>

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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March 8, 2019