MACPAC

Review of Draft Chapter for June Report and Recommendations on Prescription Drug Policy: Grace Period and Cap on Rebates

Medicaid and CHIP Payment and Access Commission

Chris Park

Overview

- Review of draft chapter
  - Coverage of drugs
  - Cap on rebates
- Recap of March meeting
- Draft recommendations

Drug Coverage

- Medicaid must generally cover a drug as soon as it enters the market
- States do not have sufficient time to assess a new drug and develop coverage criteria
  - Pharmacy and therapeutics (P&T) committee process may take several months
- Some states' prior authorization policies prior to the P&T committee review may effectively be excluding coverage
- Other payers such as Medicare Part D and exchange plans have up to 180 days to make a coverage decision

Rebate Cap

- Medicaid drug rebates are capped at 100 percent of a drug's average manufacturer price (AMP)
- Rebate cap limits the inflationary penalty and restricts the amount of rebates that Medicaid can receive
- Once a drug hits the cap, manufacturers can raise prices without increasing net rebate obligations to Medicaid

March Recap

- Expressed support for grace period
  - Favored a 180-day grace period
- Dropped proposed recommendation that the grace period be paired with a coverage requirement at the end of the grace period
  - Include in discussion about the grace period
- Not a clear consensus as to whether the cap should be raised or removed completely
  - Drafted recommendation to reflect raising the cap to 125 percent of AMP

Grace Period

Draft Recommendation 1

- Congress should amend Section 1927(d)(1)(B) of the Social Security Act to allow states to exclude or otherwise restrict coverage of a covered outpatient drug for 180 days after a new drug or new formulation of a drug has been approved by the Food and Drug Administration and entered the market.

Recommendation 1: Rationale

- A grace period has the potential to improve beneficiary safety
- A 180-day period would allow most states to maintain their existing procedural timelines for the P&T committee to review drugs and develop coverage decisions
- A grace period would provide clear guidance to states on what is permissible
- It would be desirable for CMS to issue subregulatory guidance that provide expectations that states publish coverage criteria at the end of the grace period

Recommendation 1: Implications

- Federal spending
  - Congressional Budget Office (CBO) estimates federal savings of less than $25 million over 10 years
- States
  - Would help alleviate their administrative burden
- Beneficiaries
  - Could reduce potential harm
  - Could result in delayed access for some drugs
- Drug manufacturers
  - Could delay access to some of their products

Rebate Cap

Draft Recommendation 2

- Congress should amend Section 1927(c)(2)(D) of the Social Security Act to raise the cap on rebates to 125 percent of a drug's average manufacturer price.

Recommendation 2: Rationale

- Raising the cap would allow the inflationary penalty to achieve a greater effect
- Savings from higher rebates would allow states to provide the same level of drug coverage at lower cost
- The Medicaid inflationary rebate continues to exert downward pressure on price increases
  - Manufacturers have incentive to lower list prices on current drugs as well as curtail price increases on future drugs

Recommendation 2: Implications

- Federal spending
  - CBO estimates federal savings of $5–10 billion over 10 years
- States
  - Savings from higher rebates (approximately $2–5 billion)
- Beneficiaries
  - Unlikely to have a measurable effect
- Drug manufacturers
  - Would pay higher rebates
  - May lead to cost shifting and higher launch prices

Draft Recommendations

1. Congress should amend Section 1927(d)(1)(B) of the Social Security Act to allow states to exclude or otherwise restrict coverage of a covered outpatient drug for 180 days after a new drug or new formulation of a drug has been approved by the Food and Drug Administration and entered the market.
2. Congress should amend Section 1927(c)(2)(D) of the Social Security Act to raise the cap on rebates to 125 percent of a drug's average manufacturer price.

MACPAC

Review of Draft Chapter for June Report and Recommendations on Prescription Drug Policy: Grace Period and Cap on Rebates

Medicaid and CHIP Payment and Access Commission

Chris Park

April 11, 2019