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Trends in Medicaid Drug Policy

Association for Community Affiliated Plans

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Key Questions

State Medicaid programs, the Trump administration, Medicaid MCOs, manufacturers, and Congress are all considering reforms to the drug coverage and reimbursement system under Medicaid and other payers.

Will these efforts actually reduce costs?

What will happen to beneficiary access to drugs?

Do states and Medicaid managed care organizations (MCO) have sufficient legal flexibility to enact change?

What States Are Doing: Alternative Drug Reimbursement Arrangements

- Four states have received CMS approval to enact value-based purchasing arrangements through supplemental rebate agreements: Colorado, Michigan, Oklahoma, and Washington.
  - E.g., Melinta Therapeutics pays higher rebates to Oklahoma if its bacterial skin infection drug fails to keep patients out of the hospital.
- Louisiana and Washington have selected manufacturers (Gilead and Abbvie) to participate in their capped financing models for Hepatitis C drugs.
- Legal barriers.
  - Best price.
    - Avoided through supplemental rebate agreements.
    - But such exception does not apply to Medicaid MCO rebates.
  - Anti-kickback statute.
  - 1927 rebate reporting and timing requirements.
  - State laws on budgetary appropriations.

What States Are Doing: Drug Price "Caps"

- New York:
  - If cap exceeded, DURB recommends target supplemental rebate.
  - If manufacturer does not pay at least 75% of target, faces penalties (e.g., transparency requirements, PA, non-coverage under managed care, end of prescriber prevails).
- Maryland:
  - Drug Affordability Review Board to set ceiling prices for government programs.
  - Likely will result in seeking increased supplemental rebates under Medicaid.
- Massachusetts (*proposed*):
  - State can set a target value for high-cost drugs.
  - If manufacturer supplemental rebates are insufficient, manufacturer can be referred to Health Policy Commission for disclosures/testimony or AG re consumer protection laws.
- States relying more on information from effectiveness research organizations such as the Institute for Clinical and Economic Research (ICER).
- Caps are more effective for drugs that have competitors.
- States cannot legally deny coverage, but reputational impact.

What the Administration is Doing: Proposed Rebate Rule

- Proposal: Rebates not passed through at a point-of-sale would no longer have protection under the discount safe harbor (applies rebates paid to MCOs only).
- Goals
  - Lower *list* prices.
  - Lower cost sharing.
  - Lower profits of "middlemen."
- No direct benefit to Medicaid beneficiaries because cost sharing is very low.
- OACT estimate: Proposed rule would increase Medicaid costs by $2 billion over 10 years (compared to nearly $200 billion for Medicare Part D).
- Carve out incentive: MCOs can't demand rebates for preferred placement, but states can.
- Legislation to extend to commercial market: higher likelihood of lower list prices.
- Potential impact on Medicaid even if exclude Medicaid MCOs (lower list prices, rebates).
- If adopted as proposed, primary effect will be lower Part D cost sharing in exchange for higher Part D premiums and higher government spending.

What's Next: Gene Therapies

- Gene therapies have potentially tremendous clinical benefits, but very high costs.
- List prices of approved CAR Ts:
  - Kymriah: $475,000.
  - Yescarta: $373,000.
- List prices of approved gene therapies:
  - Luxturna for a form of blindness: $850,000 (both eyes).
  - Zolgensma for spinal muscular atrophy (SMA): $2.1 million.
- Populations for approved therapies are quite small, but will increase with new approvals.
- Proposals to address cost:
  - VBP (potentially over many years).
  - Risk sharing.
  - Reinsurance.
  - DRG reforms.

What's Next: New Policies

- MACPAC: Proposes 180-day coverage grace period for new therapies.
- Possible Section 1927 waiver?
  - CMS denied Massachusetts waiver seeking a closed formulary.
  - CMS has proposed demonstration but states would lose guaranteed rebates.
  - Reemergence under a block grant demonstration?
- End of rebates outside of Medicaid and a drop in list prices?
- Less Medicaid MCO control of drug management.
  - Growing use of unified formularies by states.
  - Return of drug carve outs?
    - Impact of OIG safe harbor rule.
    - Wider use of value-based purchasing.
- Further efforts to target PBM spread pricing following Ohio model (e.g., NY).
- Legislation intended to give states and MCOs more flexibility on VBP and other models.

Thank You!