Combined PRA Comments and responses

Comment 1.1: How should PBMs report amounts for reductions to incurred claims related to rebates, incentive payments, and pharmacy rate guarantees?

CMS Response: Thank you for your question. Reporting reductions to incurred claims (rebates, incentive payments, pharmacy rate guarantees):

Under 42 C.F.R. § 438.8(e)(2), incurred claims must reflect the net cost of covered services provided to enrollees. PBMs, as subcontractors, are required to report to managed care plans the amounts necessary to ensure accurate MLR calculation pursuant to 42 C.F.R. § 438.3(s)(8).

CMS has further clarified through subregulatory guidance that any value received in connection with a Medicaid-covered outpatient drug must be treated as a reduction to incurred claims, regardless of the source or timing of the payment. Specifically, the CMCS Informational Bulletin, “Medical Loss Ratio (MLR) Requirements Related to Third-Party Vendors” (May 15, 2019) interprets 42 C.F.R. § 438.8(e)(2) to require that rebates, incentive payments, direct or indirect remuneration (DIR), goods in kind, and similar arrangements reduce incurred claims used in MLR reporting.

Accordingly:

PBMs should report all post-adjudication financial adjustments related to CODs—including manufacturer rebates, pharmacy performance payments, incentive payments, and pharmacy rate guarantees—as reductions to incurred claims, even if settled retrospectively.

Separate identification from pharmacy claim payments:

Point-of-sale payments to pharmacies, and post-adjudication amounts representing value received by the managed care plan or PBM.

This approach is consistent with CMS’s authority under Section 1903(m)(2)(A)(x) of the Social Security Act (SSA) to ensure actuarially sound capitation rates and accurate reporting of medical expenditures.

Reporting of pharmacy rate guarantees:

Pharmacy rate guarantees constitute “something of value” received in connection with CODs and therefore fall squarely within the scope of 42 C.F.R. § 438.8(e)(2) and CMS’s May 15, 2019, CIB interpretation. As such:

- Rate guarantee amounts should be reported as reductions to incurred claims for MLR purposes.
- Any portion retained by the PBM rather than passed through to the managed care plan must be disclosed to avoid understatement of net drug costs.

Action(s) Taken: CMS is taking no action at this time and will evaluate if additional guidance is needed. The Division of Pharmacy is available to provide additional technical assistance.

Comment 1.2: Payments for Other Patient Services: What examples would be reflected in the "payments for other patient services" reported value?

CMS Response: Thank you for your question. Some examples of services included:

"Payments for other patient services" should encompass pharmacy- or PBM-related services that are directly tied to patient care but are not drug ingredient costs, consistent with 42 C.F.R. § 438.8(e)(1), which defines allowable incurred claims as those for covered services provided to enrollees. Examples include:

- Medication therapy management (MTM) services authorized under SSA § 1927(c)(2)(A)
- Pharmacist-led adherence and care coordination services
- Disease management or clinical intervention programs
- Patient education services delivered by pharmacies or PBM vendors

Action(s) Taken: CMS is taking no action at this time and will monitor if additional guidance is needed. The Division of Pharmacy is available to provide additional technical assistance.

Comment 1.3: Dispensing or Administering Provider Fees: Dispensing fees are included as part of the drug expense within incurred claims for MLR reporting purposes, whereas "administering provider fees" should be a reduction to incurred claims (transmission/transaction fees applied at the claim level). Typically, these claim transmission fees have not been reflected or netted by managed care plans and PBMs from claims incurred reporting on the MLR. For greater transparency, it would be beneficial to have dispensing and administering provider fee amounts reported separately.

CMS Response: Dispensing fees are part of the reimbursement for Covered Outpatient Drugs and are appropriately included in incurred claims under 42

C.F.R. § 438.8(e)(2) and SSA § 1927(k)(1), which defines covered outpatient drugs and associated dispensing.

Administrative fees applied at the claim level—such as transaction, switch, or transmission fees—do not represent patient care and therefore should be treated as reductions to incurred claims, not medical expenses. Including such fees in incurred claims would be inconsistent with 42 C.F.R. § 438.8(e), which limits claims incurred to the cost of covered services.

Action(s) Taken: CMS is taking no action at this time. However, CMS will continue to evaluate our authority under 42 C.F.R. § 438.3(s) for additional flexibility. The Division of Pharmacy is available to provide additional technical assistance.

Comment 1.4: Subcontractor Administrative Fees Reporting to the Managed Care Plan, and if "subcontractor administrative fees" should reflect administrative services contracted and performed by the PBM for the managed care plan, or other administrative fees assessed to the pharmacies?

In addition, should other reimbursement/recoupment arrangements between the PBM and the pharmacy, that should be netted against the managed care plan's incurred claims (such as transmission fees, rebates retained by the PBM, and pharmacy rate guarantees), be reported as non-claims costs for MLR reporting purposes?

CMS Response: Thank you for your questions. Under 42 C.F.R. § 438.3(s)(1)–(3), managed care plans must oversee subcontractors and ensure compliance with contractual and reporting requirements. "Subcontractor administrative fees" should therefore reflect administrative services performed by the PBM for the managed care plan, such as:

- Claims adjudication
- Network and formulary management
- Utilization management
- Compliance, reporting, and analytics

These fees should be reported as non-claims costs in accordance with 42 C.F.R. § 438.8(f).

Treatment of PBM–pharmacy financial arrangements:

- Reimbursement or recoupment arrangements between PBMs and pharmacies that reduce the net cost of CODs, such as:
  - Transaction or transmission fees,
  - Rebates retained by the PBM, and
  - Pharmacy rate guarantees

must not be reported as administrative costs. Consistent with 42 C.F.R. § 438.8(e)(2) and the May 15, 2019, CMCS CIB, these amounts represent value received in connection with covered outpatient drugs and therefore must be netted against incurred claims for MLR reporting purposes.

Action(s) Taken: CMS will be taking no further action at this time. The Division of Pharmacy is available to provide additional technical assistance.

Comment 2: Clear, standardized reporting requirements are essential for states and Medicaid managed care organizations (MCOs) to monitor pharmacy benefit managers (PBMs) to ensure effective spread pricing. Without precise definitions, states risk inaccurate medical loss ratio (MLR) calculations, improperly set capitation rates, and weakened oversight of Medicaid spending. This concern is heightened by H.R. 1, which increases fiscal pressure on states already facing tighter financing rules, cost shifts, and new administrative burdens, such as work requirements and frequent eligibility redeterminations. CMS action is needed to define and enforce PBM reporting requirements so states can safeguard Medicaid funds and hold PBMs accountable.

CMS Response: Thank you for your questions and comments. CMS acknowledges stakeholder concerns regarding transparency and reporting related to pharmacy benefit manager (PBM) arrangements in Medicaid managed care. Under section 1903(m) of the Social Security Act and implementing regulations at 42 C.F.R. Part 438, states are responsible for ensuring actuarially sound capitation rates and compliance with medical loss ratio requirements (42 C.F.R. §§ 438.4, 438.5, and 438.8). Existing regulations require managed care organizations to report sufficient data to support these obligations, including costs associated with pharmacy benefits (42 C.F.R. § 438.8(d)). States also retain authority to require additional reporting from MCOs and their subcontractors, consistent with section 1902(a)(30)(A) of the Act.

Action(s) Taken: CMS will continue to review existing authorities and provide technical assistance, as appropriate, to support state oversight and program integrity.