



November 7, 2019

Submitted electronically via email to Calder.Lynch@cms.hhs.gov

Calder Lynch, MHSA
Acting Deputy Administrator and Acting Director Center for Medicaid & CHIP Services
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

**RE: CMCS Informational Bulletin: Medical Loss Ratio (MLR) Requirements
Related to Third-Party Vendors**

Dear Acting Director Lynch:

The Medicaid Health Plans of America (MHPA) is the national trade association representing 94 private sector health plans that contract with state Medicaid agencies in 37 states plus the District of Columbia to provide comprehensive, high quality health care to more than 23 million Medicaid enrollees in a coordinated and cost effective way. Our member plans offer comprehensive, coordinated care that supports the health care needs of Medicaid beneficiaries while also managing costs for our state and federal partners.

We request your assistance in addressing several issues that have emerged as a result of the above referenced May 15, 2019 Center for Medicaid and CHIP Services (“CMCS”) Medical Loss Ratio (MLR) Requirements Related to Third-Party (the Bulletin). The Bulletin created new policy requirements (examples provided below) for Medicaid managed care organizations (MCOs) that were not vetted nor previously communicated to the plans at the time Medicaid MCO rates and contracts (with states and providers) were finalized. These new requirements changed the MLR reporting formula in a way that could not be anticipated. Additionally, these requirements are set retroactively which is causing MCOs harm, especially in markets where states have a minimum MLR and follow the MLR reporting calculation.

Implementing the Bulletin’s guidance on states’ minimum MLR (or other risk mitigation programs) calculations would compromise the actuarial soundness of the rates since the financial recoupment paid by the Medicaid MCOs would likely be larger than anticipated.

Thus, MHPA respectfully requests that CMS withdraw the Bulletin. Alternatively, MHPA requests that CMS release additional clarifying guidance that incorporates stakeholder input and that the guidance is prospectively applied to ensure that it does not compromise the actuarial soundness of rates and any agreed upon minimum Medicaid MLR requirements.

MHPA requests clarifying guidance on the following items:

- I. We request CMCS clarify that the requirements in the final Medicaid managed care rule (the “MCO Rule”)¹ and the Bulletin apply only to the reporting MLR formula, not the rebate/remittance MLR.**

The Centers for Medicare and Medicaid Services (CMS) stated in the MCO Rule that it is up to each State to determine whether to require a minimum MLR in their Medicaid MCO contracts.² Notably, the Acting Deputy Administrator and Director Lynch at the AHIP National Conference on Medicaid commented that the Bulletin is limited to the *reporting* MLR.

- II. We request CMS clarify that states have discretion and the flexibility to choose whether to adopt a rebate/remittance MLR and, if they do, states determine the formula for the rebate/remittance MLR.**

If states impose a minimum MLR (or other risk mitigation program), CMS stated in the MCO Rule that it is up to each state to establish the remittance methodology.³ Therefore, there can be more than one methodology for calculating MLRs, such as:

- 1) A reporting MLR formula, which must follow the federal formula at 42 C.F.R. § 438.8; and
- 2) A rebate/remittance MLR formula for those states that decide to impose a minimum MLR.

However, many states have interpreted the Bulletin as mandating that states need to adopt the federal MLR formula for both reporting and rebate/remittance MLR calculations.

- III. We request CMS clarify the federal MLR reporting formula as established by the MCO Rule and redefined in the Bulletin, be implemented on a *prospective basis only*, and only after sufficient time is given for states: 1) To negotiate contracts with MCOs; 2) To allow time for MCOs to negotiate with provider/vendors; and 3) To align with other MLR calculations such as the formula used to establish with the minimum MLR and the state actuary’s projected MLR for rate development.**

The Bulletin’s new requirements were not previously communicated by CMS and were not known to the Medicaid MCOs at the time provider, vendor, and state contracts were negotiated; the Medicaid MCO rates were developed; and any state required minimum MLR levels were set. Medicaid MCOs may have negotiated provider and vendor contracts differently, in 2016-2019, had they known the new requirements for the MLR reporting formula. For example, plans could have included language in their PBM

¹ 81 Fed. Reg. 27498 (May 6, 2016).

² 81 Fed. Reg. 27532 (“Because remittances under this final rule will be imposed under state authority, we believe the state is best suited to determine the methodology for remittances.”)

³ 81 Fed. Reg. 27532 (“Because remittances under this final rule will be imposed under state authority, we believe the state is best suited to determine the methodology for remittances.”)

contracts to require the PBMs to pass through 100% of all of the rebates and “anything of value” that they received. Since this was not communicated, not all PBM contracts included this requirement, placing the impacted Medicaid MCOs at a financial disadvantage.

Medicaid MCOs may have also negotiated the state MLR rebate/remittance contract language (i.e., the calculation) differently, had they known CMCS’ new requirements for the MLR reporting formula. If the new requirements had been communicated in a clear and timely manner, plans would have realized that the MLR reporting calculations were not in alignment with their provider and vendor contracts, and potentially negotiated different contract language for the MLR rebate/remittance calculation.

Similarly, since the states and state actuaries did not have insight into this new MLR reporting calculation, they could not have taken it into account when any state-required minimum MLR levels⁴ (and rates) were calculated.⁵ Therefore, for Medicaid MCOs whose states use these MLR reporting requirements to calculate MLR rebates/remittances⁶, the resulting payables due to the state/federal governments are likely inaccurate and overstated, because the MLR formulas are not consistent. Misalignment of these formulas can have a significant impact on overall plan revenue. The resulting smaller revenue was likely not anticipated at the time by state actuaries when developing the rates, therefore jeopardizing the rates as not actuarially sound. This misalignment is causing Medicaid MCOs significant financial harm, which, in turn, destabilizes the financial soundness of the managed Medicaid programs.

States that adopt the federal MLR reporting formula as established by the MCO Rule and Bulletin for rebate/remittance purposes should do so only when in alignment with other MLR calculations. That is, the calculations must be aligned and used on a *prospective basis only*. This gives Medicaid MCOs time to align provider and state contracts with the calculation definitions.

IV. We request confirmation that CMCS will enforce actuarial soundness requirements.

As mentioned above, the Bulletin provided new information and changed the MLR reporting formula. Both state actuaries and health plan actuaries did not have advance notice of the new information and clarifications in the Bulletin. Additionally, there was no way to anticipate these changes. Given the changes set forth in the Bulletin,

⁴ Typically, states do not share the details about how their minimum MLR levels for rebate/remittance purposes were established. It is assumed that the minimum MLRs align with the MLRs developed by state actuaries during the rate setting process. Historically, the MLRs developed by state actuaries have not followed the MLR reporting formula.

⁵ CMS stated in the final Medicaid MCO rule that the rule requires MCOs to calculate and report their MLR experience and states take it into consideration while setting actuarially sound rates. 81 Fed. Reg. 27498 at 27525 (May 16, 2016).

⁶ While our comments focus on state imposed minimum MLRs, these concerns could also pertain to other risk mitigation programs (e.g., risk corridors).

the MCO contracts with states and vendors may have been changed. However, they cannot be changed retroactively, and yet the Bulletin is seeking retroactive enforcement.

CMS has an obligation to step in and ensure actuarially sound rates are paid by confirming these MLR calculations are in alignment and should communicate this requirement to the states.⁷

Below are several examples of new requirements and definitions in the Bulletin that support our request for withdrawal and/or clarifying guidance:

V. Expansion of Pharmacy Rebates “Received and Accrued”

The preamble to the MCO Rule discusses a comment that requested CMS to add “and accrued” to the incurred claims deduction at § 438.8(e)(2)(ii)(B) for “prescription drug rebates received.” The preamble discussion notes that, “[i]n addition to pharmaceutical rebates *receivable* and claim overpayment receivables, the [National Association of Insurance Commissioners (NAIC)] Annual Statement includes other categories of health care receivables such as “capitation arrangement receivables, risk sharing receivables.”⁸ CMS agreed with the commenter and changed the regulatory language to “rebates received and accrued.”

Receivables, for purposes of the NAIC Annual Statement, are amounts that are owed to the reporting entity, which in this case the health plan. The Bulletin, however, provides that “[t]he regulation does not require that the Medicaid managed care plan itself receive the prescription drug rebate directly.” This interpretation of “received and accrued” is inconsistent with the definition of “receivable” and the preamble’s use of “receivable” in the context of pharmacy rebates. That is, the rebate, as clarified in the MCO Rule, must be received by or owed to the Medicaid MCO.

The Bulletin further expands the meaning of pharmacy rebates received and accrued to include “*something of value*.” Specifically, the Bulletin provides that, “*CMS interprets* this regulation to require that *any time a managed care plan receives something of value* for the provision of a Medicaid covered outpatient drug (e.g., manufacturer rebates, incentive payments, direct or indirect remuneration, goods in kind, etc.), regardless from whom the item of value is received (e.g., pharmaceutical manufacturer, wholesaler, retail pharmacy, etc.), *the value of that rebate* must be deducted from the amount of incurred claims used for calculating and reporting the MLR.” We believe this expansion of the rebate definition to include the deduction is also inconsistent with the regulatory definition.

⁷ In the final Medicaid MCO rule, CMS states that, “[u]nder section 1903(m)(2) of the Act and regulations based on our authority under section 1902(a)(4) of the Act, actuarially sound capitation rates ***must be utilized for MCOs***”. 81 Fed. Reg. 27498 at 27521 (May 16, 2016) (emphasis added).

⁸ 81 Fed. Reg. 27528 (emphasis added). The NAIC Annual Statement is a required report that provides an overview of a health issuer’s financial information for the previous year.

In support of its interpretation of “received and accrued,” the Bulletin suggests that the interpretation is consistent with the general requirements in 42 C.F.R. § 438.230: “Where the managed care plan is required to treat these additional items of value as deductions or exclusions from incurred claims under § 438.8(e)(2), receipt by a subcontractor rather than the plan itself does not change that requirement.” Section 438.230 does not support the Bulletin’s interpretation that “received and accrued” includes rebates or something of value received and retained by a subcontractor. Rather, Section 438.230 reflects well known federal “flow down” requirements that apply to relationships between Medicaid MCOs and subcontractors including provisions addressing the Medicaid MCO’s ultimate accountability for contract compliance; including within the written subcontract the delegated functions and reporting requirements of the subcontractor; and requiring the subcontractor to retain records and allow for inspection and audit by the State, CMS, and the OIG.

Similar flow down requirements exist in the Medicare Advantage and Part D regulations.⁹ Yet, CMS does not rely upon or interpret the Part D flow down regulation, for example, to require that rebates on Part D covered drugs that are retained by a PBM be treated as “value” obtained by the Part D sponsor that must be reported to CMS. Rather, *based on requirements including explicit authority in the Part D statute*,¹⁰ CMS promulgated a Part D regulation and sub-regulatory guidance that expressly provide for such treatment of PBM-retained pharmacy rebates.¹¹ In sharp contrast, there is no federal statute or CMS regulation that provides for such treatment of PBM-retained pharmacy rebates in the Medicaid MCO context. Rather, in apparent reliance on the Part D requirements that are not applicable to Medicaid MCOs, the Bulletin expanded the meaning of “rebates received and accrued” to apply to PBM-retained rebates. No provision of the MCO Rule including, but not limited to Section 438.230, supports the Bulletin’s position on pharmacy rebates.

Similarly, the private market regulation does not support the Bulletin’s interpretation of rebates received and accrued to include PBM-retained rebates. Pursuant to 45 C.F.R. § 158.140(b)(i), prescription drug rebates “*received by the issuer*” must be deducted from incurred claims.

⁹ See 42 C.F.R. §§ 422.504(i) and 423.505(i), respectively.

¹⁰ See 42 U.S.C. § 1395w-115(f)(1)(A) (requiring Part D sponsors to provide the Secretary with such information as the Secretary determines is necessary to carry out payment provisions of Section 1395w-115, including the calculation of reinsurance and risk-sharing).

¹¹ See 42 C.F.R. § 423.308 (definition of “actually paid”) and CMS’ annual Medicare Part D Direct and Indirect Remuneration (DIR) Reporting Requirements. The DIR Reporting Requirements provide that: “Per the regulations at 42 CFR 423.308, DIR is any form of price concession, *received either by the Part D sponsor or by an intermediary contracting organization (a Pharmacy Benefits Manager, or PBM, for instance)* with which the sponsor has contracted, from any source (including manufacturers, pharmacies, enrollees, or any other person or entity) that serves to decrease the costs incurred under the Part D plan by the Part D sponsor, either directly or indirectly.” DIR expressly includes rebates.

VI. Applicability of Private Market and Related CCIIO Guidance

The Bulletin adopts private market regulations and MLR guidance issued by CMS' Center for Consumer Information & Insurance Oversight ("CCIIO") despite CMS' decision not to adopt them in the MCO Rule.¹² In the preamble to the MCO Rule, CMS acknowledged there are inherent differences between the programs (Private Market and Medicaid), and as such, CMS used the same general calculation as the private market MLR rule but with differences in the numerator and denominator "to account for differences in the Medicaid program and population."¹³ However, there was no discussion of the differences or similarities between private market and Medicaid and no guidance on whether and when CCIIO technical guidance would apply. The Bulletin exacerbates this confusion by advising stakeholders to follow some technical guidance documents leaving Medicaid MCOs in limbo as to the applicability (retroactive or prospective) of the other CCIIO technical guidance documents.

While the preamble to the MCO Rule indicated that its approach *would be consistent* with [not the same as] the private market rules' treatment of non-claims costs for third-party vendors, it did not cite to or incorporate the applicable CCIIO technical guidance. More telling is the fact that, while the MCO Rule adopted verbatim certain private market rules regarding deductions from incurred claims, the MCO Rule did not incorporate (or even reference) the examples in the private market rules of amounts paid to third party vendors (including payments to PBMs) that must be excluded from incurred claims for reporting purposes. Compare 45 C.F.R. § 158.140(b)(3)(ii) to 42 C.F.R. 438.8(e)(2)(v)(2) (see chart below). Nevertheless, the Bulletin summarily adopts the CCIIO technical guidance dated May 13, 2011 and July 18, 2011.

Private Market Rule	MCO Rule	Bulletin
Deductions from incurred claims, 45 C.F.R. § 158.140(b)(3)(ii): "Amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management. For example, if an issuer contracts with a behavioral health, chiropractic network, or high technology radiology vendor, or a pharmacy benefit manager, and the vendor reimburses the provider at one amount but bills the	Deductions from incurred claims, 42 C.F.R. 438.8(e)(2)(v)(2): "Amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management."	"Medicaid requirements for managed care plans to account for expenditures by third-party vendors under subcontract follow the approach used to account for third-party vendors' expenditures in the MLR calculations for health insurance issuers subject to the requirements in 45 CFR Part 158" [citing to CCIIO technical guidance dated May 13, 2011 and July 18, 2011].

¹² As discussed in Section C.1 of this letter, the Bulletin also adopts Part D requirements that were never contemplated to apply to MCOs.

¹³ 81 Fed. Reg. 27522.

Private Market Rule	MCO Rule	Bulletin
<p>issuer a higher amount to cover its network development, utilization management costs, and profits, then the amount that exceeds the reimbursement to the provider must not be included in incurred claims.”</p>		
<p>Deductions from incurred claims, 45 C.F.R. § 158.140(b)(i): “Prescription drug rebates received by the issuer.”</p>	<p>Deductions from incurred claims, 42 C.F.R. § 438.8(e)(2)(ii)(B): “Prescription drug rebates received and accrued.”</p>	<p>“[A]ny time a managed care plan receives something of value for the provision of a Medicaid covered outpatient drug (e.g., manufacturer rebates, incentive payments, direct or indirect remuneration, goods in kind, etc.), regardless from whom the item of value is received (e.g., pharmaceutical manufacturer, wholesaler, retail pharmacy, etc.), the value of that rebate must be deducted from the amount of incurred claims used for calculating and reporting the MLR. CMS also interprets this requirement to apply equally regardless of whether the prescription drug rebate is received by the managed care plan (i.e., directly) or by a subcontractor (i.e., indirectly) administering the covered outpatient drug benefit on behalf of the managed care plan.</p>

Thank you for your attention to this important matter. Our member plans are committed to serving Medicaid beneficiaries. We believe that withdrawal or further clarification of this guidance would be the most appropriate action in support of the financial sustainability of the Medicaid program. Should you need any additional information, please feel free to contact me at sattanasio@mhpa.org.

Sincerely,

Shannon Attanasio

Shannon Attanasio

Vice President, Government Relations and Advocacy