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Every commercial health insurance issuer's guide for understanding pharmacy benefit managers and medical loss ratio reporting

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The medical loss ratio (MLR) provision of the Patient Protection and Affordable Care Act (ACA) has always required issuers to exclude pharmacy rebates received and administrative expenses paid from medical claims. Recent guidance from the Department of Health and Human Services (HHS) has provided additional clarity on how issuers should reflect costs for a variety of pharmacy benefit manager (PBM) services, which could have a significant impact on loss ratios for many issuers.

Loss ratios have been a key metric for almost as long as health insurance has existed. Prior to the passage of the ACA, this was generally evaluated in a simple fashion – medical costs divided by premiums – but as with many other elements of commercial health markets, the ACA added several wrinkles to this common measure. Since December 2010, issuers subject to the medical loss ratio (MLR) requirements of the ACA must include PBM fees in the administrative expense (i.e., "non-claims cost") component of the MLR. Many plan sponsors have a traditional ("spread") contracting model with their PBM (where no core administrative fees are paid by the plan sponsor to the PBM), and may not realize these "spread" amounts are still "fees" (or margin) the PBM is collecting that must be considered for MLR reporting requirements. In addition, the recent HHS Final 2021 Notice of Benefit and Payment Parameters[1] (Payment Notice), (i.e., the main rule-making document for commercial health markets), stated the treatment of rebates and price concessions retained by a PBM must also be reported in the expense component of MLR effective for calendar year 2022.

These changes are displayed in Figure 1 below.

FIGURE 1: FEES AND OTHER AMOUNTS RETAINED BY PBMS THAT MUST BE REPORTED IN THE ADMINISTRATIVE EXPENSE COMPONENT OF THE MLR

	2011 TO 2021	2022 AND BEYOND
Administrative fees paid to the PBM	Yes	Yes
Retail spread retained by the PBM	Yes	Yes
Prescription drug rebates retained by the PBM	Unclear	Yes
Other price concessions retained by the PBM*	Unclear	Yes

* There is still some uncertainty about amounts retained by a non-PBM third party

For many issuers, this concept seems overwhelming and confusing. The pharmacy supply chain is extremely complicated, and this article will provide further background and a guide for issuers to better understand the MLR requirements and how to work with their PBMs on meeting the reporting requirements.

Background

One of the core consumer protections of the ACA is the requirement that "consumers receive value for their premium payments."[2] This requirement was formalized in the Interim Final MLR Rule[3] published on December 1, 2010. In order to meet this legislative goal, the regulation outlined in significant detail which expenses were effectively claims cost and contributed value to an

[1] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice of Requirement for Non-Federal Government Plans. A Rule by the Health and Human Services Department on 5/14/2020. Retrieved on September 8, 2020, from https://www.federalregister.gov/documents/2020/05/14/2020-10045/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2021

[2] The Public Health Service Act, 2718(b), as established by the ACA. Retrieved on September 8, 2010, from https://www.govinfo.gov/content/pkg/COMPS-8798/pdf/COMPS-8798.pdf

[3] Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements under the Patient Protection and Affordable Care Act. A Rule by the Health and Human Services Department on 12/01/2010. Retrieved on September 8, 2020, from https://www.federalregister.gov/documents/2010/12/01/2010-29596/health-insurance-issuers-implementing-medical-loss-ratio-mlr-requirements-under-the-patient

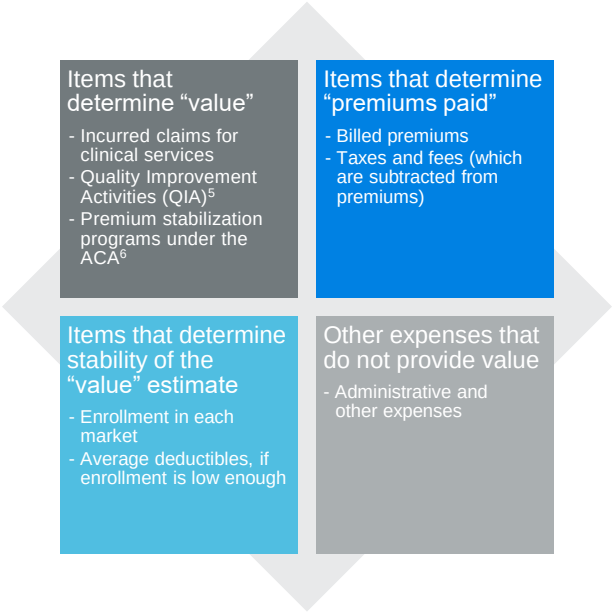
insurance product and which expenses were considered non-claims costs and those that did not. Issuers that participated in these reformed markets were left scrambling to implement these new regulations, and in this rush, some issuers may have overlooked requirements surrounding third party vendors such as PBMs.

Under 45 CFR §158.140(b)(1) and 45 CFR §158.140(b)(3), issuers are required to:

- Reduce incurred claims by the amount of prescription drug rebates they receive (45 CFR §158.140(b)(1)).
- Exclude from incurred claims the amount by which the cost billed by a third party vendor, such as a PBM, to the issuer "exceeds the reimbursement to the provider" (45 CFR §158.140(b)(3)). This is commonly referred to as PBM "spread" in which the PBM retains a portion of the drug cost and described in more detail later in this article.
- Exclude any "administrative services that do not represent compensation or reimbursement for covered services" from incurred claims (45 CFR §158.140(b)(3)).

The MLR calculation was revised in the 2014 Payment Notice published on March 11, 2013[4], and has remained essentially unchanged since. In essence, plans are required to report items in four broad categories, outlined in Figure 2.

FIGURE 2: KEY COMPONENTS OF MEDICAL LOSS RATIO REPORTING



The MLR is then calculated by determining what percentage "value" is of "premiums paid," adjusting for cost stability.[7]

Under these original rules, as established by the Interim Final MLR Rule and revised in the 2014 Payment Notice, it is clear issuers must exclude any rebates they receive and any administrative fees they pay to PBMs. It has been somewhat less clear whether rebates received and retained by the PBM were required to be included in the calculation of the MLR. However, the 2021 Payment Notice clarified this potential ambiguity[8] and added language in 45 CFR §158.140(b)(1)(B) so all rebates and price concessions "received and retained by the issuer … or a [PBM]" (to the extent associated with paying for administrative expenses) must be removed from incurred claims starting with calendar year 2022 experience.

Note that issuers are allowed to count an administrative expense as a QIA if the activity falls into one of the categories set forth in federal regulation. **This concept is important because it allows issuers to adjust, or move, fees considered QIA from the administrative expense component to the claims component for purposes of calculating the issuer's MLR.[9]**

In this article, we provide concrete examples of how PBM fees/margin, rebates, and QIA should be considered for calculating the MLR under different PBM arrangements. With the added language in the 2021 Payment Notice, the 2022 MLR calculation will become more complex as rebates and other price concessions retained by the PBM will have to be reflected in the 2022 MLR calculation.

Pass-through contract example

The most straightforward PBM arrangement for issuers is a pass-through contract, where the amount the issuer pays its PBM for retail pharmacy claims is the exact amount the PBM reimburses the retail pharmacy, i.e., the PBM does not retain a portion of the drug cost that it does not pass on to the retail pharmacy. PBMs obtain margin on retail pharmacy claims through the core and other add-on administrative fees, which is reported as an administrative expense in calculating the MLR.

[4] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014. A Rule by the Health and Human Services Department on 3/11/2013. Retrieved on September 8, 2020, from https://www.federalregister.gov/d/2013-04902/p-1279

[5] Quality improvement activities include certain specified types of expenses that are designed to improve healthcare quality, and are outlined in 45 CFR §158. 150-151.

[6] Risk adjustment, reinsurance, and risk corridors

[7] The full calculation is symbolically complex and can be found at https://www.federalregister.gov/d/2013-04902/p-1279.

[8] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans. A Rule by the Health and Human Services Department on 5/14/2020. Retrieved on September 8, 2020, from https://www.federalregister.gov/d/2020-10045/p-953

[9] In lieu of classifying separate expenses as quality improvement activities, issuers can estimate the amount of quality improvement activities using a flat 0.8% of premium pursuant to 45 CFR §158.221(b)(8).

Figure 3 below is a simplified example demonstrating the concept of a pass-through arrangement, assuming no member liability:

FIGURE 3: PHARMACY BENEFIT MANAGER PASS-THROUGH CONTRACT EXAMPLE

	PHARMACY REIMBURSEMENT FROM PBM	CLIENT REIMBURSEMENT TO PBM	PBM MARGIN	ANNOTATION
Average wholesale price	$200.00	$200.00	N/A	A
Discount off AWP	17.00%	17.00%	0.00%	B
Ingredient cost	$166.00	$166.00	$0.00	C = A * (1 – B)
Dispensing fee	$1.50	$1.50	$0.00	D
Administrative fee per claim	$0.00	$0.75	$0.75	E
Total cost	**$167.50**	**$168.25**	**$0.75**	**F = C + D + E**

In this arrangement, the PBM does not retain a portion of the ingredient cost or dispensing fee, but there is a $0.75 per claim administrative fee paid by the issuer to the PBM. This arrangement is more straightforward than the traditional arrangement, described further below, in that PBM margin from retail pharmacy claims is transparent, i.e., the fees are typically based on the number of eligible members, e.g., per member per month, or a per claim amount. However, the issuer needs to collect detailed information from the PBM as to which activities the PBM performs, and what portion of the fees (if any), meet the definition of QIA so the issuer can properly allocate the PBM fees to calculate the MLR.

Traditional/Spread contract example

Pass-through arrangements have become more popular in the last decade due to plan sponsors' desire for more transparency in the drug costs paid to the pharmacy. However, the traditional "spread pricing" arrangement between issuers and the PBM was the more common type of arrangement for many years. This means the amount the issuer pays its PBM for retail pharmacy claims may be *more than* the amount the PBM reimburses the retail pharmacy, i.e., the PBM will reimburse the retail pharmacy one amount but explicitly charge the issuer a higher amount and retain the difference. This spread amount is retained by the PBM in lieu of collecting a core administrative fee. PBMs obtain margin on retail pharmacy claims through retaining a portion of the drug cost, which should also be reported as an administrative expense in calculating the MLR under the guidelines established by the Interim Final MLR Rule. Figure 4 below is a simplified example of how the PBM may retain a portion of the drug cost (again assuming no member liability in this example). In this example, 0.25% spread on ingredient cost and $0.25 spread on dispensing fees results in a total margin of $0.75 for the PBM.

FIGURE 4: PHARMACY BENEFIT MANAGER TRADITIONAL / SPREAD CONTRACT EXAMPLE

	PHARMACY REIMBURSEMENT FROM PBM	CLIENT REIMBURSEMENT TO PBM	PBM MARGIN	ANNOTATION
Average wholesale price	$200.00	$200.00	N/A	A
Discount off AWP	17.00%	16.75%	0.25%	B
Ingredient cost	$166.00	$166.50	$0.50	C = A * (1 – B)
Dispensing fee	$1.50	$1.75	$0.25	D
Administrative fee per claim	$0.00	$0.00	$0.00	E
Total cost	**$167.50**	**$168.25**	**$0.75**	**F = C + D + E**

This arrangement adds a layer of complexity. The issuer not only needs to collect information from the PBM as to which PBM activities are considered QIA (similar to the pass-through arrangement), but also needs to obtain the total amount the PBM received from the issuer that it did not pass on to retail pharmacies, i.e., the spread. Prior to the publishing of the Interim Final MLR Rule in December 2010 and the advent of the MLR requirement, this spread amount was a black box for many issuers. An issuer in a spread pricing arrangement should be working with its PBM to obtain this information so it can accurately report and calculate its MLR. Some of the spread amount may be allocated to claims cost if it is considered a QIA as defined under the federal regulation.

Note that if the PBM owns its own mail and specialty pharmacy, the PBM is considered the provider of services and may retain a portion of the drug cost related to the PBM's direct provision of such pharmacy services. Because the PBM's wholly owned pharmacies are considered the provider of services and not a third-party in this situation, the drug cost portion of the margin from mail and specialty pharmacy claims can be considered a claims payment for purposes of the MLR.

PBM retained rebates – The newest commercial market MLR change

The reporting of PBM retained rebates and price concessions is not new to the Medicare market, and similar rules are now coming to the commercial market. For several years in the Medicare market, items referred to as direct and indirect remuneration (DIR) are part of reporting requirements. The Center for Medicare and Medicaid Services (CMS) defines DIR as follows:

> *Direct and Indirect Remuneration (DIR) are fees, payments, or payment adjustments made after the point-of-sale that change the cost of Part D covered drugs for Part D sponsors and must be reported to CMS as DIR. DIR results from payment arrangements negotiated independent of CMS, between Part D sponsors, PBMs, network pharmacies, drug manufacturers, and other parties involved in the administration of the Part D benefit.*[10]

The definition of rebates can vary by PBM and are defined in each client's PBM contract. The PBM may be collecting monies from manufacturers or pharmacies that it does not pass on to the client – this is known as "PBM retained rebates." Retained rebates will be considered administrative expenses for the commercial issuer starting with the 2022 calendar year MLR calculation. Some issuers may be allowing the PBM to retain a portion of rebates in lieu of an administrative fee in their pass-through contract arrangement; any retained rebate will need to be reported as an administrative expense in 2022 and beyond.

Based on conversations with many of our clients, many issuers believe they are receiving 100% of rebates and price concessions because their PBM contract specifies the issuer shall receive 100% of rebates. However, there may be manufacturer or pharmacy remunerations not included in the definition of a rebate in the client's contract, and therefore the PBM may be retaining these amounts. For example, if the client contract does not include price protection in the definition of a rebate, the PBM may be retaining these amounts while still passing through 100% of the base rebates. Other price concessions retained by PBMs may include market share rebates, incentives related to therapeutic drug switching, and/or manufacturer administrative fees, but HHS is still evaluating which items should be considered a price concession as noted in the release of the 2021 Payment Notice.

As mentioned, in the 2021 Payment Notice, HHS is revising the treatment of rebates in the commercial market effective for calendar year 2022. The new provision seeks to clarify the treatment of retained rebates and price concessions, requiring issuers to reduce incurred claims by the amount of rebates and price concessions ***retained by a PBM*** and include these amounts in the administrative expense component of the MLR filing. HHS had originally proposed this change take effect for 2021, but recognized that issuers may need time to re-evaluate PBM contracts in light of this new rule and appropriately account for the change when setting premium rates.[11] HHS also postponed defining price concessions in the final rule. As such, the current state of potential ambiguity surrounding retained rebates remains through 2021 MLR reporting in 2022. Regardless of the current treatment of retained rebates and other price concessions, issuers are strongly urged to begin these conversations with their PBM as soon as possible to prepare since pricing for the 2022 calendar year will be conducted in the spring and summer of 2021. For MLR purposes, the definition ultimately adopted by HHS will determine what new amounts must be reported rather than definitions used in a specific PBM contract.

[10] Medicare Part D – Direct and Indirect Remuneration (DIR). (January 19, 2017). Retrieved on September 8, 2020, from https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir

[11] Responses to comments on MLR provisions in Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans. A Rule by the Health and Human Services Department on 5/14/2020. Retrieved on September 8, 2020, from https://www.federalregister.gov/d/2020-10045/p-963

PBM cost adjustments in the MLR calculation

Figure 5 provides a simplified example of how PBM costs and margin should be considered in MLR calculations:

FIGURE 5: PHARMACY BENEFIT MANAGER COSTS - MEDICAL LOSS RATIO ADJUSTMENTS

	PRIOR TO CALENDAR YEAR 2022		STARTING IN CALENDAR YEAR 2022	
COMPONENT	**PASS-THROUGH CONTRACT**	**TRADITIONAL (SPREAD) CONTRACT**	**TRADITIONAL (SPREAD) CONTRACT**	**ANNOTATION**
Annual issuer claims cost before prescription drug rebates	$100,000	$100,000	$100,000	A
Issuer received pharmacy rebates	$15,000	$15,000	$15,000	B
Core administrative fee, e.g., per retail claim	$3,000	$0	$0	C
Total retail pharmacy spread retained by the PBM	$0	$3,000	$3,000	D
Prescription drug rebates and price concessions retained by the PBM*	$0	$0	$5,000	E
Total administrative fees, retail pharmacy spread, and rebates retained by the PBM	**$3,000**	**$3,000**	**$8,000**	F = C + D + E
QIA portion of margin, i.e., portion of fees, spread, and retained rebates allocated to QIA	$90	$90	$240	G = Portion of C specifically related to QIA
Non-QIA portion of margin	$2,910	$2,910	$7,760	H = F – G
Net claims cost to issuer, prior to adjustments	$85,000	$85,000	$85,000	I = A – B
Adjusted claims cost for MLR	**$85,090**	**$82,090**	**$77,240**	J = A – B – D – E + G
Other administrative expenses and margin**	$12,000	$12,000	$12,000	K
Adjusted administrative expense for MLR	**$14,910**	**$14,910**	**$19,760**	L = F – G + K
Medical loss ratio	**85.1%**	**84.6%**	**79.6%**	M = J / [J + L]

*Potentially not reported prior to calendar year 2022, so represented as $0 in the MLR calculation for illustrative purposes

**Allocated portion of overall health plan expenses and margin, net of federal and state taxes and regulatory fee

Assuming PBMs have the same margin and issuers have the same level of expenses under each arrangement, Figure 5 demonstrates the importance of understanding how different PBM arrangements and the changes in the 2021 Payment Notice affect the MLR. A PBM spread contract effectively lowers the MLR compared with the pass-through arrangement when drug costs are projected to be the same under both arrangements and the core administrative fee equates to the same amount of retail spread retained by the PBM; starting in calendar year 2022, any PBM retained rebates and price concessions will also lower the MLR.

Conclusion

While it originated in the simple idea of providing value for premiums paid, the MLR requirement is a complicated formula. The inclusion of PBM spread and retained rebates adds a tremendous amount of complexity in the already complicated pharmacy supply chain. Issuers should work collaboratively with their PBMs to obtain and document this information so they can accurately report and calculate their MLR. If issuers have not already considered these components, Milliman can assist in understanding the complexities and initiating these conversations as soon as possible with the PBM, especially due to the changes made to commercial market MLR reporting in the 2021 Payment Notice. Drug costs at retail pharmacies retained by the PBM have been in the MLR calculation since the first federal reporting in 2011, and with the announcement in the 2021 Payment Notice, additional PBM margin components will need to be considered, making the calculation of the MLR more complex to issuers.

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