MHDO Maine Health Data Organization

Information | Insight | Improvement

90-590 Maine Health Data Organization

Chapter 247: Uniform Reporting System for Non-Claims Based Payments and Other Supplemental Health Care Data Sets

(Routine Technical)

Section I. Basis Statement

The Maine Health Data Organization is authorized by statute to collect health care data. This Chapter contains the provisions for filing non-claims-based payment information and other supplemental health care data sets.

This proposed rule adds new data fields and updates others to ensure collection of complete and accurate aggregated, claims-based substance use disorder (SUD) payment data and non-claims-based prescription drug rebate data.

The MHDO Board met on February 2, 2023, and authorized the MHDO to initiate rulemaking to Chapter 247, as required under 22 MRSA §8705-A. A public hearing was held on August 3, 2023, with a comment deadline of August 14, 2023. The MHDO board met on December 7, 2023, and unanimously voted to adopt the changes as proposed and amended, as outlined in the Basis Statement (dated December 7, 2023).

The following represent the proposed changes to the rule and the rationale for these changes:

1. Update Chapter Summary. (page 1)

   Justification: The proposed changes to the summary provide a more specific overview of the chapter's contents.

2. Introduce definitions for Pharmacy Benefits Manager, Pharmacy Benefits Manager Compensation, and Rebate. (section 1, pages 2-3)

   Justification: These definitions specify data element requirements in the new data file type DR – Prescription Drug Rebates and are consistent with definitions in related data collection rules 90-590 C.M.R. Chapters 243 and 570.

Original version distributed to the Board of Directors on 9/7/23; revised version for distribution on 12/7/23. Unanimously adopted by board at 12/7/23 board meeting.

3. Reorganize and clarify the General Requirements. (section 2(A), pages 5-6)

   Justification: The proposed revisions in this section are based on the first years' experience of data submission and the use of the data. The revisions provide the clarity requested from both payors as well as the end user of the data specific to the general requirement of submitting non-claims-based payments and other supplemental data. In addition, there is a new requirement for the submission of prescription drug rebate data.

4. Delete data element Insurance Type/Product Code (NC003, page 9).

   Justification: The amount fields in file type NC – Non-Claims-Based Payments are aggregated by population (NC011~~2~~), not by product code (NC003); therefore, the field is not used (left blank).

5. Modify or clarify the descriptions of data elements Total Plan-Paid Dollars SUD Claims-Based Payments Not Reported to MHDO (AC008) and Total Plan-Paid Dollars on Claims/Claim Lines Sent to MHDO where SUD Codes Were Removed (AC009); add data element Total Plan-Paid Dollars SUD Claims-Based Payments Related to Primary Care (AC010). (pages 11, 12)

   Justification: These changes better articulate the differences between data elements AC008 and AC009. The new data element AC010 is required because not all SUD-related payments are for behavioral health.

6. Add new value of DR – Prescription Drug Rebates to header and trailer record elements HD004 and TR004 – Type of File (pages 7, 8); add new file type DR – Prescription Drug Rebates for non-claims-based prescription drug rebate data with relevant data elements including Drug Code (DR005), Drug Name (DR006), Generic Drug Indicator (DR007), Specialty Drug Indicator (DR008), Total Count of Prescriptions Filled (DR009), Total Quantity Dispensed (DR010), Total Pharmacy Expenditure Amount (DR011), Total Manufacturer Prescription Drug Rebates (DR012), Total Pharmacy Prescription Drug Rebates (DR013), Percent Rebate Retained by PBM (DR014) and Total PBM Compensation Amount (DR015). (pages 12-15)

   Justification: The collection of pharmacy rebate data improves the transparency and accuracy of prescription drug reporting in the State under 22 MRSA §8736, and validating compliance with 24-A MRSA §§4350-A and 4350-D.

7. Delete definition for Redacted Payments. (page 4)

   Justification: The term "Redacted Payments" is not used in the language of Rule Chapter 247 and therefore has been removed.

8. Modifies the descriptions/definitions of currency fields in Non-Claims-Based Payments (NC), Aggregated SUD Claims-Based Payments (AC), and Prescription Drug Rebate (DR) file types to not imply a decimal and round to nearest integer. (pages 9-12, 14-15)

   Justification: There is no value in retaining the decimal for large, aggregate dollar amounts.

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Section II. Names of Individuals that Submitted Comments

The following is a list of individuals and affiliations that made oral comments at the public hearing and/or submitted written comments to the Maine Health Data Organization (MHDO) regarding the proposed rule:

1. Kristine M. Ossenfort, Elevance Health, Senior Government Relations Director
2. Dan Demeritt, Maine Association of Health Plans, Executive Director
3. Sam Hallemeier, Pharmaceutical Care Management Association, Director, State Affairs
4. Dan Green, Community Health Options, Director of Informatics

Section III. Summary of Comments Received by Submitter with Proposed Agency Response & Action

1. Elevance Health submitted the following comment(s):

Comment(s):

1. First, we believe it is essential to protect the confidentiality of the Pharmacy Rebate data being reported. Any submission reporting structure established must fully ensure the safeguards against the release and public disclosure of negotiated prescription drug rebates:

MHDO Staff Response: Pharmacy Rebate data reported under both 90-590, Chapter 243, Uniform Reporting System for Health Care Claims Data Sets, and Chapter 247, Uniform Reporting System for Non-Claims Based Payments, and Other Supplemental Health Care Data Sets, is not a releasable field per the requirements of 90-590, Chapter 120, Release of Data to the Public. MHDO however has the authority to use all the pharmacy data it collects to meet its annual reporting requirements as defined in Title 22, Chapter 1683, §8712 and §8736. MHDO is prohibited from reporting data that would allow for the determination of individual prescription drug pricing contract terms covering a manufacturer, wholesale drug distributor or pharmacy benefits manager.

Recommended Board Action: None

2. As we read the proposed rules (Chapter 243 and Chapter 247), data submitters are being requested to include SUD data via monthly submission and also as a part of an annual

aggregated SUD submissions. This seems duplicative and the need for it in both forms is unclear.

MHDO Staff Response: Staff agrees there is no value in collecting both aggregated and detailed claim data for the same time periods. However, given the annual reporting mandates, there can be no data gaps. Since Chapter 243 is prospective and Chapter 247 is retrospective (one calendar year), collection of the aggregated data must continue until we have a full year of detailed claims data that we can access for the mandated reporting. In other words, collection of aggregated claims data must continue for two additional reporting cycles--until August 2025, which includes 2024 data. In the first quarter of 2026, there will be a complete year (2025) of detailed claims data, making the further collection of aggregated data unnecessary.

Under this scenario, staff recommends that the board suspend the enforcement of the collection of aggregated SUD data under Chapter 247 beginning with the data submissions due in August 2026, until the rule can be updated through a rule-making process.

Recommended Board Action: Suspend the enforcement of the collection of aggregated SUD data under Chapter 247 beginning with the data submissions due in August 2026, until the rule can be updated through a rule-making process.

3. Finally, we would note that these changes will take time to implement. As a result, we would suggest that if the rules are adopted, that they have an effective date of no earlier than January 1, 2025

MHDO Staff Response: The need for the proposed changes, continues to be a significant priority for those using the MHDO data for analyses specific to the opioid epidemic and other behavioral health matters. MHDO also recognizes that the payors need time to implement these changes. Therefore, we propose extending the effective date to January 1, 2025, to give the payors the extra time requested to implement the proposed changes.

Recommended Board Action: Agree to the implementation date of January 1, 2025.

2. Maine Association of Health Plans submitted the following comment(s):

Comment(s):

Pharmacy Benefit Managers (PBMs) are sophisticated businesses charged with driving bargains and delivering good patient outcomes amidst the many complications created by pharmaceutical manufacturers to protect market share, pricing power, and profits. PBMs negotiate in confidence

across the supply chain to advantage consumers and advance the business interests of carriers operating in a competitive marketplace.

1. MeAHP suggests striking the PBM reporting requirement from the proposed rules.

MHDO Staff Response: Over the last ten years, MHDO's governing statute has been amended to include greater transparency requirements, specifically in the costs of prescription drugs. The Pharmacy Benefits Manager (PBM) is a key entity in the pharmaceutical supply chain and as stated negotiate payment rates with pharmacies for the drugs the pharmacies dispense. So, although rebates play a role in amounts ultimately paid by payors, amounts paid by payors and consumers to pharmacies are determined by contract pricing established and managed by PBMs. The proposed change to collect PBM compensation will provide greater transparency into prescription drug pricing along the highly complex pharmaceutical supply chain.

Recommended Board Action: None

2. Additional topics for consideration include:

PBM Compensation Definition: PBM compensation is not fully and accurately defined in the proposed changes to Rule Chapters 243 and 247. The proposed definition does not capture the compensated value PBMs produce across the pharmaceutical supply chain.

MHDO Staff Response: MHDO's definition of PBM Compensation is derived from the definitions specified in Maine Insurance Code, 24-A MRSA §4350-D, Treatment of pharmacy benefits manager compensation.

Recommended Board Action: None

3. The rule does not reflect how rebate activity is calculated nor does it specify if compensation includes payments for claims costs and administrative costs.

MHDO Staff Response: Payors should report rebate amounts as calculated for accrual by the payor or its designee. Rebate values proposed under Rule Chapter 247 should reflect amounts accrued relative to claims incurred during the prior calendar year with no limitation on paid date or rebate received date. As defined, PBM compensation is the total value of payments made by the payor to its pharmacy benefits manager that is not paid to the pharmacy (e.g. administrative fees). There is no limitation on the type or value of payments made to the pharmacy benefits manager except that the total amount of payment must be reduced by any amounts paid by the pharmacy benefits manager to the pharmacy. To clarify, MHDO Staff recommends adding the language below to DR015, section 2(B).

Recommended Board Action: Accept the clarification in the description of data element DR015, section 2(B). "PBM compensation does not include any compensation paid by a manufacturer, developer, or labeler for the performance of services."

4. Operationalizing PBM Reporting: Many of MeAHP's members operate in multiple states and are concerned that Maine-specific definitions and data reporting may deviate from other state and federal reporting requirements. Further, we are concerned that data requirements created as part of this rulemaking run counter to established business practices of PBMs and carriers.

MHDO Staff Response: To streamline and reduce administrative burden for our data submitters, when considering the addition of new data elements, MHDO's first choice is to adopt a standard definition that currently exists in state law or regulation. If that does not exist, we then look to other states that have developed similar definitions if appropriate for our purpose. In fact, most of the new data elements and definitions added to Chapter 243 over the last several years align with the All-Payer Claims Database Common Data Layout (APCD-CDL™). However, even with the wholesale adoption of the APCD-CDL, it is likely that there will still be state specific and possibly federal mandates that are not aligned. MHDO's goal is to minimize administrative burden and, to the extent possible, leverage reporting standards and definitions when they exist. It is our experience that there are times when transparency mandates run counter to established business practices of those entities that we are required to report on. MHDO is required to strike a balance between transparency and confidentiality. To date, there is no evidence that the release of MHDO claims data, including pharmacy data, has resulted in an anticompetitive market. In fact, as stated by several payors, *transparency fosters a competitive market*.

Recommended Board Action: None

Rebates:

5. The definition of rebates is overly broad, particularly the reference to "reconciliations that also reflect other contractual agreements," and likely extends beyond formulary rebates. Narrowing the definition can improve the information collected for Maine's consideration and help with the operational concerns of carriers.

MHDO Staff Response: The proposed definition of Rebate in Chapter 247 is consistent with the definition of the same term in MHDO's Rule Chapter 570*, Uniform Reporting System for Prescription Drug Price Data Sets (a major-substantive rule).*

Recommended Board Action: None

6. We also understand that rebates may be not received until 150-180 days after a PBM submits requests to the manufacturer.

MHDO Staff Response: Rebate values reported under Chapter 247 should reflect amounts accrued whether payment for the rebate was paid or received in the reported time-period.

Recommended Board Action: None

7. Chapter 247 Reporting Timelines: The timing and frequency of drug rebate file submissions is not clear. Monthly or quarterly filing will not align with length of the rebate cycle. An annual reporting should occur several months after the end of the calendar year (June or July) to ensure claims have cleared the rebate cycle.

MHDO Staff Response: There is no proposed change to the annual filing period for each submission under Chapter 247, which will include rebate data if the proposed changes were adopted. The submission period covers the previous completed calendar year and is due to MHDO by August 31.

Recommended Board Action: None

3. Pharmaceutical Care Management Association submitted the following comment(s):

Comment(s):

Pharmacy Benefit Manager Compensation

1. The Proposed Rules for Chapters 243 and 247 include a new definition for "Pharmacy Benefits Manager Compensation," stating:
   'Pharmacy benefits manager compensation' means the difference between:
   i. the value of payments made by a carrier to its pharmacy benefits manager, and
   ii. the value of payments made by the pharmacy benefits manager to dispensing pharmacies for the provision of prescription drugs or pharmacy services with regard to pharmacy benefits covered by the carrier.

   PCMA respectfully requests that this definition change. Currently, the language in the Proposed Rules does not accurately capture the process for any "compensation" with respect to PBMs and the greater pharmaceutical supply chain. Thus, we request that the definition of "Pharmacy Benefit Manager Compensation" in the Proposed Rules be changed to:
   '*Pharmacy benefits manager compensation' means any direct or indirect financial benefit, but shall not include any compensation paid by a manufacturer, developer, or labeler for the performance of services.*

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MHDO Staff Response: MHDO's definition of PBM Compensation is derived from the definitions specified in Maine Insurance Code, 24-A MRSA §4350-D, Treatment of pharmacy benefits manager compensation. The definition the commenter has asked us to consider does not align with the definition in the Maine Insurance Code. However, staff supports including language in the description of data element DR015, PBM Compensation Amount, that states, *PBM compensation does not include any compensation paid by a manufacturer, developer, or labeler for the performance of services.*

Recommended Board Action: Accept the clarification in the description of data element DR015, section 2(B). "PBM compensation does not include any compensation paid by a manufacturer, developer, or labeler for the performance of services."

2. Next, we question whether the MHDO is going beyond its authority in seeking claim-level rebates and spread pricing information. A PBM client may choose between a spread pricing model that can protect them from future prescription drug price increases or a pass-through model which would pass-through the variability of pharmacy reimbursement amounts.

MHDO Staff Response: MHDO Data are obtained to fulfill MHDO's legislative mandate to create and maintain a useful, objective, reliable and comprehensive health information database that is used to improve the health of Maine citizens and to issue reports promoting public transparency of health care quality, outcomes and costs, 22 MRS §§ 8712 and 8736. The MHDO is required by its governing statute to make the data it collects publicly available and accessible to the broadest extent consistent with the laws protecting individual privacy, and confidential information. MHDO has broad authority to define and collect health care data prescribed in its data collection rules. As policy makers and stakeholders continue to debate the issue of prescription drug costs and look to the MHDO for information on the components of prescription drug pricing, it is important to access all aspects of prescription drug pricing, including rebates and PBM compensation.

Recommended Board Action: None

3. PCMA also respectfully requests that any data reporting for this language be reported in the aggregate, so it does not expose confidential, proprietary information. If drug manufacturers access this data, it may lead to anti-competitive issues such as price collusion.

MHDO Staff Response: Pharmacy Rebate data and PBM compensation data reported under both 90-590, Chapter 243, Uniform Reporting System for Health Care Claims Data Sets, and Chapter 247, Uniform Reporting System for Non-Claims Based Payments and Other Supplemental Health Care Data Sets, is not a releasable field per the requirements of 90-590, Chapter 120, Release of

Data to the Public. MHDO however has the authority to use all the pharmacy data it collects to meet its annual reporting requirements as defined in Title 22, Chapter 1683, §8712 and §8736. Consistent with the payment data on CompareMaine, MHDO will not report data that would allow for the determination of individual prescription drug pricing contract terms covering a manufacturer, wholesale drug distributor or pharmacy benefits manager, 22 MRS §8733(2). Pharmacy rebate and PBM compensation impact the costs of prescription drugs. These data elements are currently missing from MHDO's reporting. Collecting this data will allow MHDO to provide a more comprehensive report on the pricing of prescription drugs, and potentially answer questions that MHDO receives from the Legislature, the Maine Prescription Drug Affordability Board and other stakeholders regarding the amount and impact of rebates and PBM compensation.

Recommended Board Action: None

Rebate

4. The Proposed Rules for Chapters 243 and 247 include a new definition for "Rebate," stating:

'*Rebate' means a discount, chargeback, or other price concession that affects the price of a prescription drug product, regardless of whether conferred through regular aggregate payments, on a claim-by-claim basis at the point-of-sale, as part of retrospective financial reconciliations (including reconciliations that also reflect other contractual arrangements), or by any other method. 'Rebate' does not mean a 'bona fide service fee', as such term is defined in Section 447.502 of Title 42 of the Code of Federal Regulations, published October 1, 2019.*

This definition is overbroad with its reference to "reconciliations that also reflect contractual arrangements." It appears to not consider how rebates are reconciled and likely goes beyond formulary rebates.

PBMs do not calculate rebates on a claim-by-claim basis. Therefore, PCMA respectfully requests that the MHDO strike the language in both Proposed Rules for the definition of "rebate" that states, "on a claim-by-claim basis at the point-of-sale," because this is an inaccurate understanding of the process for the calculation of rebates related to prescription drugs. Narrowing this definition will provide the MHDO with data that is more precise and of actual value.

MHDO Staff Response: The proposed definition of Rebate in Chapter 247 (and Chapter 243) is consistent with the definition of the same term in MHDO's Rule Chapter 570*, Uniform Reporting System for Prescription Drug Price Data Sets, (a major-substantive rule).*

Recommended Board Action: None

5. Redacted Payments
   The Proposed Rule for Chapter 247 strikes the existing definition for "Redacted Payments," which states,
   '*Redacted payments' means payments in which an entire claim or some portion of a claim that would normally be part of the payor's medical or pharmacy claims submission to the MHDO was removed or altered prior to submission to conform to the requirements of 42 CFR Part 2.*

PCMA respectfully requests that the MHDO understand that data reporting occurs in the aggregate.

MHDO Staff Response: The term "Redacted Payments" is not used in the language of Rule Chapter 247 and therefore has been removed.

Recommended Board Action: None

6. Drug rebate reporting elements
   Existing statute via 22 Maine Revised Statutes Annotated ("MRSA") §8736 states:
   Beginning November 1, 2020 and annually thereafter, the organization shall produce and post on its publicly accessible website an annual report, including information developed from the disclosures received pursuant to this subchapter on trends in the cost of prescription drugs, analysis of manufacturer prices and price increases, the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and cost sharing and any other information the organization determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the State. The report may not make public any information that is confidential pursuant to section 8733. The organization shall submit the report required by this section to the joint standing committee of the Legislature having jurisdiction over health data reporting and prescription drug matters and the committee may report out legislation to the first regular or second regular session of the Legislature, depending on the year in which the report is submitted.

Based on existing statutory language, PCMA respectfully requests that any reporting entity, including PBMs, be notified in advance if the data at issue is to be shared with other state government entities, including agencies. The MHDO is seeking information that is confidential and proprietary related to drug rebates and reimbursements. We previously expressed this concern in a September 2020 letter to the MHDO.

MHDO Staff Response: Pharmacy Rebate data and PBM compensation data reported under both 90-590, Chapter 243, Uniform Reporting System for Health Care Claims Data Sets, and Chapter 247, Uniform Reporting System for Non-Claims Based Payments and Other Supplemental Health

Care Data Sets, is not a releasable field per the requirements of 90-590, Chapter 120, Release of Data to the Public. MHDO however has the authority to use all the pharmacy data it collects to meet its annual reporting requirements as defined in Title 22, Chapter 1683, §8712 and §8736. MHDO is prohibited from reporting data that would allow for the determination of individual prescription drug pricing contract terms covering a manufacturer, wholesale drug distributor or pharmacy benefits manager, 22 MRS §8733(2).

Recommended Board Action: None

7. PCMA respectfully requests that language be included in the Proposed Rule to state that data elements such as rebate, expenditure, or other data relevant to the purposes of MHDO's activities should be limited to activities in the State of Maine. The reporting of any data beyond that is outside the purview of the MHDO's regulatory authority.

MHDO Staff Response: For over 20 years, the MHDO has exercised its authority to collect health care, including medical and pharmacy data for Maine residents, wherever they may obtain services, as required in 22 M.R.S.A. Chapter 1683 and 90-590 Chapter 243 Sec 2. For clarification, staff recommends adding pharmacy to section 2(A)(1).

Recommended Board Action: Accept the clarifying language in 2(A)(1). "Payors that: i) provide medical and pharmacy benefits to Maine residents; and ii) are not excluded from submitting health care claims data sets under 90-590 Chapter 243 Sec 2(A)(9)(a-b); and iii) reimburse providers by means other than a Fee-for-Service model shall submit to the MHDO or its designee the following complete data sets, if applicable."

8. It would also be prudent for the MHDO to recognize the reality that PBMs cannot determine the timing and frequency of drug rebate file submissions. Monthly or quarterly reporting could result in inaccurate information for the MHDO as there can be a lag in reporting reconciliation between PBMs and manufacturers. PCMA requests that if a PBM report annually, the submission date should be in July to ensure most claims have cleared the rebate cycle.

MHDO Staff Response: There is no proposed change to the annual filing period for each submission under Chapter 247, which will include rebate data if the proposed changes were adopted. The submission period covers the previous completed calendar year and is due to MHDO by August 31.

Recommended Board Action: None

9. Finally, PCMA again respectfully requests that any data reporting for this language be reported in the aggregate. To do otherwise could expose confidential proprietary

information. If external parties access such data, it may lead to anti-competitive issues, as well as price collusion.

MHDO Staff Response: Pharmacy Rebate data and PBM compensation data reported under both 90-590, Chapter 243, Uniform Reporting System for Health Care Claims Data Sets, and Chapter 247, Uniform Reporting System for Non-Claims Based Payments and Other Supplemental Health Care Data Sets, is not a releasable field per the requirements of 90-590, Chapter 120, Release of Data to the Public. MHDO however has the authority to use all the pharmacy data it collects to meet its annual reporting requirements as defined in Title 22, Chapter 1683, §8712 and §8736. Consistent with the payment data on CompareMaine, MHDO will not report data that would allow for the determination of individual prescription drug pricing contract terms covering a manufacturer, wholesale drug distributor or pharmacy benefits manager, 22 MRS §8733(2). Lastly, the MHDO has been releasing health care data to authorized users for over ten years, and specifically pharmacy data for the last five years. To date, there is no evidence that the release of MHDO data has resulted in an anticompetitive market. In fact, as stated by several payors, *transparency fosters a competitive market.*

Recommended Board Action: None

4. Community Health Options submitted the following comment(s):

Comment(s):

1. DR012 – Total Manufacturer Prescription Drug Rebates
   Should the rebates be reported based upon what was actually received during the calendar year or based on the date of service of the prescription claim that was the basis for the PBM to invoice the manufacturer? Note: rebate payments and claw backs can occur for a period up to 2 years after being invoiced to the manufacturer.

MHDO Staff Response: Rebate values reported under Chapter 247 should reflect amounts accrued for claims incurred during the prior calendar year with no limitation on paid date or rebate received date whether payment was paid or received. The annual filing under Chapter 247 covers the previous completed calendar year and is due by August 31 of the following year (allowing 8 months of reconciliation).

Recommended Board Action: None

2. DR013 – Total Pharmacy Prescription Drug Rebates. If a Payer does not receive any direct or indirect remuneration from pharmacies, would field be left blank or fill with "0"?

MHDO Staff Response: If a payor, and any pharmacy benefits manager under contract with the payor, does not receive any direct or indirect compensation from pharmacies, please populate DR013 with '0'. This field is formatted as a number (not text) with no decimal places and rounded to nearest integer.

Recommended Board Action: None

3. DR014 – Percent Rebate Retained by PBM. If a Payer receives 100% of Rebate and Manufacturer Administrative Fees from the PBM, would field be left blank or fill with "000"?

MHDO Staff Response: In the scenario described in the comment above DR014 would be populated with '0'. This field is formatted as a number (not text) with two decimal places implied.

Recommended Board Action: None

Statutory Authority: 22 MRSA §§8703(1); 8704(1) & (4); and 24-A MRSA §6951

Effective Date: TBD