

# 90-590 Maine Health Data Organization

Chapter 243: Uniform Reporting System for Health Care Claims Data Sets (Routine Technical Rule)

#### Section I. Basis Statement

The Maine Health Data Organization is authorized by statute to collect health care data. This chapter governs the provisions for filing health care claims data sets from all third-party payors, third-party administrators, Medicare health plan sponsors and pharmacy benefits managers. The provisions include identification of the organizations required to report; establishment of requirements for the content, format, method, and time frame for filing health care claims data; establishment of standards for the data reported; and compliance provisions.

This proposed rule adds new fields to collect de-identified substance use disorder (SUD) data, prescription drug rebate data, and additional dental claims information. It modifies fields in the medical claims file to better account for the payment arrangement type at the claim level. It also removes obsolete requirements, definitions, and sources.

The MHDO Board met on February 2, 2023, and authorized the MHDO to initiate rulemaking to Chapter 243. This is a routine technical rule. The MHDO held a public hearing on August 3, 2023, with an August 14, 2023, deadline for written comments. 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 summary and justifications are updated as of September 5, 2023, to reflect changes in response to public comments.

Below is a summary of these rule changes.

1. Add definitions for Pharmacy Benefits Manager Compensation (1(U)), POS (1(X)), Rebate (1(Z)), Substance Use Disorder (1(CC)), and SUD Claims File (1(DD)). [page 3]

**Justification:** Additional definitions clarify the new reporting requirements.

 Add data elements to eligibility (ME) consistent with the APCD Common Data Layout (APCD-CDL™): Grandfathered Plan Indicator (ME116), Metal Tier (ME117), Enrolled Through a Public Health Insurance Exchange (ME118), and Cost-Sharing Reduction Indicator (ME119). [pages 28-29, 32]

**Justification:** The new fields in the eligibility file (ME116-ME119) provide researchers with the information needed to understand and report on plan enrollment, cost, and member benefits for those enrolled in a public health insurance exchange.

3. Add Service Line Date – From (MC3343), and Service Line Date – Thru (MC3354) to the medical claims file. [pages 62-6359, 74-750]

**Justification:** New date fields MC3343 and MC3354 can be used for reporting claimline service dates, when available, thereby improving the completeness and accuracy of reported data.

4. Add new data elements Total POS Rebate Amount (<u>PC1143</u>), Member POS Rebate Amount (<u>PC1154</u>), and PBM Compensation Amount (<u>PC1165</u>) to the pharmacy claims file. [pages <u>82-8376</u>, <u>8679</u>]

**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.

Add new data elements consistent with the APCD Common Data Layout (APCD-CDL™) for Oral Cavity (DC112-DC116), Tooth Number(s) or Letter(s) (DC117, DC123, DC129, DC135), and Tooth Surface (DC118-DC122, DC124-DC128, DC130-DC134, DC136-DC140) to the dental claims file. (pages <u>93-9786-90</u>; <u>100-10193-94</u>)

**Justification:** The Dental Quality Alliance (DQA) has developed several quality indicators that rely on dental data from claims. While the Children's Oral Health Network has only used a measure that requires medical emergency department claims from the DQA measure, CMS is requiring MaineCare to use measures that use these items from the dental claim for reporting on the Children's Health Improvement Program (CHIP).

 Delete Add new Substance Abuse Disorder Medical Claims File (SM) and Substance Abuse Disorder Pharmacy Claims File (SP) specifications and mappings to national standard formats. [pages <u>87</u>, 12-18, <u>20-21</u>, 10295-14033] **Justification:** MHDO concurs with payor comments that collection of 42 CFR Part 2 SUD-related data with other medical and pharmacy claims data in existing file types is the more efficient approach.

7. Add data elements to medical claims (MC) and pharmacy claims (PC) files: Member Age (MC332, PC112), Substance Use Disorder (SUD) Indicator (MC333, PC113). [pages 62, 74, 82, 86]

Justification: The Substance Use Disorder Indicator (MC333, PC113) and Member Age fields (MC332, PC112), used in conjunction with modified date fields (MC017, MC018, MC059, MC060, MC069, MC334, MC335, PC017, PC032) permit a uniform, complete collection of de-identified SUD data, which is necessary for accurate reporting of behavioral health care expenditures in Maine, as mandated in PL 2021 c. 603.

8. Modify data element descriptions for Date Service Approved (MC017, PC017), Admission Date (MC018), Claim Date – From (MC059), Claim Date – Thru (MC060), Discharge Date (MC069), Service Line Date – From (MC334), Service Line Date – Thru (MC335), Date Prescription Filled (PC032). [pages 35, 40-42, 62-63, 78, 79]

<u>Justification:</u> To provide guidance on how to populate date fields when a record is flagged as containing SUD data.

9. Modify data element descriptions for personal identifiers/demographic information, including MC004-MC016, MC101-MC106, MC206 – MC253, MC327-MC329, PC004-PC016, and PC101-PC109. [pages 33-35, 45-46, 48-55, 61, 76-78, 81]

Justification: Clarifies that personal identifiers and demographic information are to be left blank only when a record is indicated as containing 42 CFR Part 2 SUD-related data when the value of MC333 or PC113 is 'Y'.

7-10. Modify or clarify general requirement for Capitated Claims, and data element descriptions, uses, code set values or mappings for Procedure Code (MC055), Claim Date – From (MC059), Claim Date – Thru (MC060), Quantity (MC061), Paidrepaid Amount (MC0634), Payment Arrangement Indicator Type (MC331), Service Line Date – From (MC334), Service Line Date – Thru (MC335), Paid Amount (PC036), Co-pay Amount (PC040), Coinsurance Amount (PC041), and Deductible Amount (PC042). [pages 4-5, 39-41, 62-6358-59, 66, 74-75, 79-804]

Justification: Clarifies the requirements for the submission of capitated claims data (including capitation payments, services provided, and service dates). Changes to Payment Arrangement Indicator Type (MC331) and the amount fields provide the

clarification necessary for the payors to provide uniform reporting of APC and capitation payment data.

8.11. Retire data elements for ICD-9 coding, including Admitting Diagnosis (MC039), E-Code (MC040), Principal Diagnosis (MC041), Other Diagnosis – 1 – 12 (MC042-MC053), and ICD-9-CM Procedure Code (MC058) [pages 37-40, 662]; Prepaid Amount (MC064; pages 41, 67), DRG and DRG Version (MC071, MC072; pages 420, 673), APC and APC Version (MC073, MC074; page 430, 41, 673); Payment Arrangement Type Indicator in the pharmacy and dental claims files (PC111; pages 8275, 76, 8679; DC111; pages 9386, 10093).

**Justification:** Obsolete and unused fields are retired.

9.12. Delete external sources (Appendix A; pages 14, 15 and 18), the definition of Prepaid Amount (1( $\frac{VW}{I}$ ); page 3), and the general requirement for Prepaid Amount (2(A)( $\frac{13}{I}$ ); page 6).

**Justification:** Obsolete or unused external sources, definitions and requirements are deleted.

13. Changed the spelling of 'Payer' to 'Payor'.

<u>Justification:</u> The spelling of this term is now consistent with 22 M.R.S. Chapter 1683 §8702 (8).

# **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. Bernie Inskeep, UnitedHealthcare, Regulatory Financial Operations, APCD Program Director
- 2. Kristine M. Ossenfort, Elevance Health, Senior Government Relations Director
- 3. Dan Demeritt, Maine Association of Health Plans, Executive Director
- 4. Dan Green, Community Health Options, Director of Informatics
- 5. Sam Hallemeier, PCMA, Director, State Affairs
- 6. Karynlee Harrington, MHDO, Executive Director

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

# 1. UnitedHealthcare submitted the following comment(s):

The proposed rule adds two additional Type of File codes for substance use disorder (SUD) claims—SM Substance Use Disorder Medical Claims and SP Substance Use Disorder Pharmacy Claims. We respectfully suggest that for both reporting payors and the Maine Health Data Organization, this proposed rule change will cause an unnecessary increase in technical and administrative burdens, where a less complex and potentially problematic method is available to identify the SUD data sought.

In addition to the additional resources needed for the addition of additional types of files submitted, implementation of this rule change and the submission of separate medical and pharmacy files for SUD claims would increase the likelihood that files will not be passed per the APCD specification due to the high variation that will likely be demonstrated in the separated and reduced number of SUD medical and pharmacy files submitted. By separating out SUD medical and SUD pharmacy files, these smaller files will naturally exhibit greater than acceptable variation. Requisite variance requests and monthly reviews caused by the higher percentage of variation will also likely increase administrative burden on the Maine Health Data Organization.

SUD claims data could utilize the current layout with a deidentification process defined for all health plans to implement uniformly. Rather than creating two new Types of Files for submission, we comment that SUD data should be defined by the organization using the diagnoses and procedure codes and submitters can deidentify those rows of data in the existing layouts for payors to flag SUD claims. This would result in the same data without the risk of the production and administrative burdens associated with submitting significantly smaller separate SUD Medical and SUD Pharmacy claims.

**MHDO Staff Response:** The MHDO agrees with commentor and therefore proposes to eliminate the new files and collect de-identified SUD data within the existing medical and pharmacy claim files.

**Recommended Board Action:** Adopt the revisions detailed above in the summary of proposed changes items 6-9. In the revised draft of the proposed rule, these changes are reflected in the elimination of proposed subsections 2(B)(4)(e,f) (page 7), portions Appendix A (pages 12-18), and Appendices G-1, G-2, H-1, and H-2 (pages 101-139), as well as the addition of data elements and the modification of data element descriptions in the medical claims (Appendices D-1 and D-2) (pages 33-35, 40-42, 45-46, 48-55, 61-63, 66, 74-75) and pharmacy claims (Appendices E-1 and E-2) files (pages 76-78, 79, 81-82, 85).

# 2. Elevance Health submitted the following 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 90-590, Chapter 243, Uniform Reporting System for Health Care Claims 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. The public disclosure of negotiated rebate amounts, on a drug-by-drug basis (both at the NDC-level and DIR reporting), could enable violations of anti-trust rules and negatively impact competition. Any disclosure of claims information must be in the aggregate and must be properly protected to ensure the data could not be reverse engineered to determine confidential drug rebate information.

**MHDO Staff Response:** Pharmacy Rebate data reported under 90-590, Chapter 243, Uniform Reporting System for Health Care Claims 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

3. We also believe it is important to ensure that the confidentiality of this data is protected – under both state Freedom of Access and federal Freedom of Information laws – from independent queries and to ensure any information released for public reports meets our proprietary standards.

MHDO Staff Response: Pharmacy Rebate data reported under 90-590, Chapter 243, Uniform Reporting System for Health Care Claims 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

4. We also welcome opportunities to review the data used for reporting public reporting purposes to avoid improper comingling of data and ensure appropriate data safeguards and aggregation criteria to prevent against data re-identification.

MHDO Staff Response: Thank you.

# Recommended Board Action: None

5. From a technical perspective, we cannot accurately provide some of the requested rebate data, as part of the monthly mandated APCD files. The only data element available at the claim level is the Member POS Rebate Amount (PC114). Based upon how our Pharmacy rebate programs are administered, the total POS rebate amount (PC113) is equal to the Net POS rebate on a claim, which is \$0 as a result of an increase in plan paid. We are unclear on the definition of the PBM Compensation amount (PC115) at the claim level – we need additional detail to be provided before we can confirm our ability to support the population of this newly proposed claim level data element.

MHDO Staff Response: If the total POS rebate amount totals \$0 then populate the total POS rebate amount field (PC1143) with \$0. As defined, PBM compensation amount (PC1165) 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 for the claim except that the total amount of payment must be reduced by any amounts paid by the pharmacy benefits manager to the pharmacy. For example: If a payor pays a PBM \$25.50 for a pharmacy claim of which \$25.00 is for the payor contracted amount for the drug and \$0.50 is an administrative fee and the PBM then pays the dispensing pharmacy \$24.00 for the pharmacy contracted amount, the PBM compensation amount for the claim would be \$1.50 (\$25.50 - \$24.00). In this example, the PBM compensation amount is comprised of an administrative fee and spread pricing revenue.

Recommended Board Action: None

6. Monthly or quarterly reporting of rebate information will not provide meaningful data, given the length of a rebate cycle. If a PBM is required to report this information on an annual basis, the submission date to report data for the previous calendar year should be as late as possible, in order to allow for claims to clear the rebate cycle. Otherwise, the reported data will be incomplete and inaccurate.

MHDO Staff Response: The rebate values reported under Rule Chapter 243 should reflect rebate amounts accrued at the point of sale. MHDO has an interest in ascertaining the frequency with which POS rebates are provided and the impact of such rebates on claim costs. Given the lag in the rebate cycle the 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 31of the following year (allowing 8 months of reconciliation).

# Recommended Board Action: None

7. The definition of prepaid amount has been deleted from the text of the proposed rule, but it was retained as a data element (MC064), with a new and different requirement to populate the total per-member, per-month (PMPM) capitated amount within the claim file. We question the need for the State to require a total per-member, per-month (PMPM) capitated amount at a claim level for every claim for a single member.

MHDO Staff Response: In order to retain the credibility of the claims payment data in the all-payors claims data, as fee-for service payment models transition to other payment models, it is essential that the all-payors-claims data (APCD) is structured in a way to capture both the payment and utilization data for these types of arrangements. To date, there is no national standard for how best to capture non-fee for service payment data in the APCD. However, there are several states, including Massachusetts and Colorado that have been collecting capitation data at both an aggregate and granular level. Based on the comment provided, MHDO staff is proposing a few revisions to better define the proposed changes in Chapter 243 specific to the reporting of capitation. We are proposing that per member per month (PMPM) amounts paid to providers be reported as separate claim lines at the member month level with the PMPM amount reported in the MC063 field (paid amount) and that a new code '09' be created for the MC331 field to identify the payment as PMPM payments. The MC064 field will no longer be required on any claim. The proposed changes require that claim lines for capitated services be submitted with a zero '0' in MC063 and the code '09' in MC331.

Original version distributed to the Board of Directors on 9/7/23; revised version for distribution on 12/7/23, and board unanimously voted to adopt the changes as proposed and amended.

<sup>8 |</sup> Page

**Recommended Board Action:** Adopt the following new language.

1) Subsection 2(A)(2), page 4

Capitated Service Claims. Claims for capitated services shall be reported with all medical, pharmacy, and dental claims file submissions. In addition, claim records shall be included for payments made to providers for capitated service contracts. Specifically, a claim line for each member for each month shall be included, with the monthly member amount in the paid amount field (MC063), and the code value '09' in the Payment Arrangement Type Indicator field (MC331). On these records, the Procedure Code field (MC055) shall be left blank. The service date fields (MC059 and MC060) shall be populated with the first and last days of the month covered by the payment. The Quantity field (MC061) shall be set to 1.

2) Changes to Appendix D-1 data elements MC063 and MC331, pages 41 and 61

MC063 Paid Amount 1/1/2003 Number 10 Includes any withhold amounts. For services delivered

under a capitation agreement, set to 0, and set MC331 =

'091' to indicate capitation. For the claim lines

documenting the capitation contract, this field will be the per member per month (PMPM) amount, and MC331 =

<u>'09'.capitated claims, set to 0.</u>

Do not code decimal point. Two decimal places implied.

MC331 Payment
Arrangement
Type Indicator

2/1/2022 Text

2 Indicates the payment methodology. Valid codes are: 01=Capitation (If used, MC064 must contain a non-zero

amount.) Unused/Retired

02=Fee for Service 03=Percent of Charges

04=DRG

05=Pay for Performance 06=Global Payment 07=Bundled PaymentAPC

08=Other Claims-based Payment

09= Capitation contract per member per month (PMPM)

3) Retirement of data element MC064, page 41

MC064 Prepaid
AmountPlaceholder

1/1/20032/1/2025 N/ANumber 10 The prepaid amount is the total permember-per-month (PMPM) capitated

amount. For claims related to noncapitated services, leave blank. For

capitated services, the fee for service equivalent amount. Use MC331 = '01' to indicate capitation.

Do not code decimal point. Two decimal places implied. Prepaid amount retired.

8. The proposed changes to Rule Chapter 243 include a requirement to submit two new files with respect to Substance Abuse Disorder (SUD). These files are essentially subsets of the standard claim files.

**MHDO Staff Response:** The MHDO agrees with the commentor and therefore proposes to eliminate the new files and collect de-identified SUD data within the existing medical and pharmacy claim files.

Recommended Board Action: Adopt the revisions detailed above in items 6-9. In the revised draft of the proposed rule, these changes are reflected in the elimination of proposed subsections 2(B)(4)(e,f) (page 7), portions Appendix A (pages 12-18), and Appendices G-1, G-2, H-1, and H-2 (pages 101-139), as well as the addition of data elements and the modification of data element descriptions in the medical claims (Appendices D-1 and D-2) (pages 33-35, 40-42, 45-46, 48-55, 61-63, 66, 74-75) and pharmacy claims (Appendices E-1 and E-2) files (pages 76-78, 79, 81-82, 85).

9. It is our understanding that the MHDO is seeking to eliminate the 18 specific data fields outlined in the HIPAA de-identification safe harbor (164.514(b)(2)(i)(A)-(R)). We would note, however, that more is required under HIPAA to meet the HIPAA safe harbor. The proposed rule also provides that the Covered Entity does not have actual knowledge that the information could be used in combination with other information available to the recipient to identify an individual. This is a very difficult standard to meet. For the following reasons, we believe it is unlikely that the data would be considered to be de-identified and, therefore, would remain subject to the SUD data sharing restrictions set forth in the rules adopted under 42 CFR Part 2:

MHDO Staff Response: MHDO is proposing to eliminate the submission of data elements which map to the 18 specific data fields outlined in the HIPAA de-identification safe harbor regulation specifically for the submission of claims data covered under 42 CFR Part 2 and 42 USC § 290dd-2(b)(2)(D). The guidance from the U.S. Department of Health and Human Services (HHS), states that "actual knowledge" means "clear and direct knowledge that the remaining information could be used...to identify an individual" (<a href="https://www.hhs.gov/hipaa/forprofessionals/privacy/special-topics/de-identification/index.html#actualknowledge">https://www.hhs.gov/hipaa/forprofessionals/privacy/special-topics/de-identification/index.html#actualknowledge</a>). Thus, HIPAA's de-identification safe harbor applies as long as the covered entity has made a good faith effort to remove all

identifying information and is unaware of any way that the data could be used to reidentify an individual.

The definition of patient identifying information in 42 CFR Part 2 is "name, address, fingerprint, photograph, or similar information by which the identity of a patient...can be determined with reasonable accuracy either directly or by reference to other information" (<a href="https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-2">https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-2</a>).

The proposed changes to Chapter 243 removes all such identifying information from claim lines for 42 CFR Part 2 data, including the removal of any external cause of injury codes that could be used to impute the identification of an individual.

Recommended Board Action: See recommended action in item #10 below.

- 10. We would be providing an identifiable data set identifying the individuals who may be subject of the SUD data is being provided, and that data set is relatively small form a statistical perspective (about 200,000 individuals) which could then be further subdivided based on:
  - a. birth years up to 90 which would subdivide that group into some very small segments;
  - b. further age at date of service could allow birthdates to be more precisely or even exactly identified where multiple dates of service occur for the same individual;
  - c. individuals would be identified as subscribers or dependents further dividing those segments;
  - d. identification of plan/product types, some with limited membership;
  - e. identification of insurer code;
  - f. Gender divides by 2, and may more precisely ID non-binary indicated members;
  - g. Identification of providers could be used to identify individuals who may live outside of Maine (e.g., college students) or seek care across a border;
  - h. External cause of injury could identify certain individuals in certain cases.

Based on the foregoing concerns, at this time do not believe we can provide such data and be compliant with 42 CFR Part 2; therefore, we would be unable to submit the data.

**MHDO Staff Response:** In response to this feedback, MHDO staff is recommending that date of birth, relationship identifiers, payor group numbers, gender, and external cause of injury codes should be left blank, and service dates should contain only the year in which the service was provided for 42 CFR Part 2 SUD data.

Provider location, payer identification, and plan/product types should be populated because these alone do not provide information that would allow the identification of a patient. The MHDO believes that the data being requested with these revisions meets the safe harbor provisions outlined in the HIPAA privacy rule and thus would not reasonably be considered identifiable.

**Recommended Board Action:** Adopt the revisions detailed in the summary of proposed changes items 7-9, which include the addition of data elements and the modification of data element descriptions in the medical claims (Appendices D-1 and D-2) (pages 33-35, 40-42, 45-46, 48-55, 61-63, 66, 74-75) and pharmacy claims (Appendices E-1 and E-2) files (pages 76-78, 79, 81-82, 85).

11. 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.

12. 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, especially the SUD data at the claim line level continues to be a significant priority for those using the MHDO data for analyses specific to the opioid epidemic and other behavioral health matters.

However, MHDO 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.

# Maine Association of Health Plans submitted the following 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 pharmacies dispense. The 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 provides greater transparency into prescription drug pricing along the highly complex pharmaceutical supply chain.

# Recommended Board Action: None

2. Claims-based pricing is some of the most propitiatory information in the PBM business and information reported to a health data agency should not surpass the level of detail available to clients. If MHDO does move forward with collecting PBM activity, any data disclosed must be aggregated to protect sensitive information.

MHDO Staff Response: Both Pharmacy Rebate and PBM compensation data reported under 90-590, Chapter 243, Uniform Reporting System for Health Care Claims 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 MHDO reports on CompareMaine, MHDO does 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.

# Recommended Board Action: None

3. <u>PBM Compensation Definition</u>: 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 proposed 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

4. 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:** Rebate values proposed under Rule Chapter 243 should reflect amounts accrued at the point of sale. As defined, PBM compensation is the total value of payments, including administrative costs, made by the payor to its pharmacy benefits manager that is not paid to the pharmacy. There is no limitation on the type or value of payments made to the pharmacy benefits manager except that the total amount paid to the PBM by the payor must be reduced by any amounts paid by the pharmacy benefits manager to the pharmacy.

# Recommended Board Action: None

5. 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, MHDO looks to other states that have developed similar definitions. In fact, most of the new data elements and definitions added to Chapter 243 over the last several

years align with the All-Payor 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 over the years, transparency fosters a competitive market.

#### Recommended Board Action: None

6. Rebates: Not all plans in Maine include prescription drug point-of-sale rebates.

**MHDO Staff Response:** If there is no rebate at the point of sale for a claim reported under Rule Chapter 243, data elements PC1143 and PC1154 should be populated as \$0.

# **Recommended Board Action:** None

7. Health insurers in Maine must file an annual report with the Superintendent of Insurance demonstrating how compensation from a pharmaceutical manufacturer or others was used to benefit plan members. The 2021 report details \$97.3 million carriers received and how it was remitted to benefit the member.1

MHDO Staff Response: Title 22, Chapter 1683, §8736, requires MHDO to produce an annual report 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 data collected per the requirements of Chapter 570, Uniform Reporting System for Prescription Drug Price Data Sets, the existing and proposed requirements in 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, provides MHDO the granular data needed to produce a comprehensive analysis that the annual report requires.

Recommended Board Action: None

8. When POS rebates are provided, they are not a dollar-for-dollar reduction in patient obligation. The rebate amount discounts the reference price of the drug from which the cost share is calculated.

**MHDO Staff Response:** When POS rebates exist, the amount of reduction that is applied to actual payment amounts should be reported as the value for Total POS Rebate Amount (PC1143) and Member POS Rebate Amount (PC1154). If there is no point-of-sale rebate paid for a claim reported under Rule Chapter 243, data elements PC1143 and PC1154 should be populated as \$0.

Recommended Board Action: For the purpose of clarification, accept the modification of the description for data element PC1143 in Appendix E-1 to reflect: "The total dollar amount of all reductions to amounts paid by the health plan or an individual member resulting from POS (point-of-sale) rebates. The total POS rebate amount should be reported in full and should not be deducted from either plan paid or member copay, deductible, or coinsurance amounts. The dollar amount of the total POS (point-of-sale) rebate. The total POS rebate amount should be reported in full and should not be deducted from either plan paid or member copay, deductible, or coinsurance amounts.

For the purpose of clarification, accept the modification of the description for data element PC1154 in Appendix E-1 to reflect: "The dollar amount of all reductions to amounts paid by an individual member resulting from POS rebates. The member POS rebate amount should not be deducted from member copay, deductible, or coinsurance amounts. The dollar amount of the total POS rebate that was received by the member. The member POS rebate amount should not be deducted from member copay, deductible, or coinsurance amounts."

9. 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 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

10. 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 Chapters 243 should reflect amounts accrued whether payment for the rebate was paid or received in the reported time-period.

# Recommended Board Action: None

11. <u>Substance Abuse Disorder Pharmacy Claim File Specifications:</u> MHDO should adhere to a national standard format for identification of SUD products to ensure consistency. A carrier subject matter expert asks, *for example, if the American Hospital Formulary System designation codes included on the PAL file should be used.* 

MHDO Staff Response: MHDO is not aware of a national standard that would be suitable for the purpose of reporting SUD data as defined in Chapter 243. While information such as American Hospital Formulary System (AFHS) designation codes can be useful for some purposes such as determining drug classes and whether a drug is brand or generic, they do not provide the comprehensive coverage of all codes that are in use or address issues such as the use of non-standard codes. Thus, reliance on a source like this for payor-level filtering or flagging could contribute to a gap in reporting. At this time we believe the current practices of data submitters identifying 42 CFR Part 2 SUD claims based upon their internal processes helps ensure that their data submissions reflect the full range of variation in the identification of these claims.

# Recommended Board Action: None

12. We expect technical issues and questions involving Appendix H-1 will be identified in comments from the carriers and ask the MHDO to collaborate with plans and their subject matter experts to clarify these items.

**MHDO Staff Response:** To minimize the administrative burden and technical issues/questions MHDO is proposing to eliminate Appendix H-1 and collect de-identified SUD data within the existing medical and pharmacy claim files.

**Recommended Board Action:** Adopt the revisions detailed in the Summary of Changes items 6-9. In the revised draft of the proposed rule, these changes are reflected in the elimination of proposed subsections 2(B)(4)(e,f) (page 7), portions Appendix A (pages 12-18), and Appendices G-1, G-2, H-1, and H-2 (pages 101-139), as well as the addition of data elements and the modification of data element descriptions in the medical claims (Appendices D-1 and D-2) (pages 33-35, 40-42, 45-46, 48-55, 61-63, 66, 74-75) and pharmacy claims (Appendices E-1 and E-2) files (pages 76-78, 79, 81-82, 85).

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

1. As a follow-up from the recent public hearing on proposed MHDO rule changes, here are the questions Community Health Options has. A handful of these questions are similarly stated, in terms of specific language around blank/null vs. 000. We poked around the existing specifications and wondered how similarly some of these elements might end up being to PC043: "Amount that is calculated by the payor and returned to the pharmacy as the total amount to be paid by the patient to the pharmacy. \$0 is acceptable, if 'data not available' leave blank. Do not include decimal point. Two decimal places implied."

**MHDO Staff Response:** The intent of the guidance being offered for PC043 is to ensure that submitters leave this field blank when a patient pay amount is not available and only provide a value of zero when the data were available, but there was no payment. This field, like the other payment fields, has two implied decimal places, so the value of '000' will be interpreted as a payment of \$0.00. MHDO expects that not all data submitters will have access to patient pay information in contrast to the other payment fields. We are making it clear that submitters should leave this field blank in this situation.

#### Recommended Board Action: None

- 2. <u>Substance Abuse Disorder Pharmacy Claims File specifications Appendix H-</u>MHDO does not define the National Standard format for identification of SUD products to include to ensure consistency among carriers. Example: Should the American Hospital Formulary System (AHFS) designation codes be used?
  - 280812 Opiate Partial Agonists
  - 281000 Opiate Antagonists
  - 289200 Central Nervous System Agents Misc
  - 920400 Alcohol Deterrents

MHDO Staff Response: As outlined in a response above, MHDO is not aware of a national standard that would be suitable for the purpose of reporting SUD data as defined in Chapter 243. While information such as American Hospital Formulary System (AFHS) designation codes can be useful for some purposes such as determining drug classes and whether a drug is brand or generic, they do not provide the comprehensive coverage of all codes that are in use or address issues such as the use of non-standard codes. Thus, reliance on a source like this for payor-level filtering or flagging could contribute to a gap in reporting. At this time, we believe allowing data submitters to flag 42 CFR Part 2 SUD claims based upon their internal processes helps ensure that their data submissions reflect the full range of variation in the identification of these claims.

Recommended Board Action: None

3. SP018 – Pharmacy Number (page 127). Description states "Payer assigned pharmacy number" – If a Payer doesn't assign a pharmacy number, should the field be left blank or use the same number as SP021 – NPI number?

**MHDO Staff Response:** If the MHDO Board adopts items 6-9 above in the summary/justification section of this document, data element SP018 will not exist. However, the question is relevant to data element PC018. If a payor does not assign pharmacy numbers and data element PC021 contains the NPI, then data element PC018 should be left blank.

# Recommended Board Action: None

4. Description states the "AHFS number is acceptable which is the American Hospital Formulary System" which doesn't assign pharmacy numbers. Did MHDO mean the National Association of Boards of Pharmacy (NABP) 7-digit number? Note: the NCPDP D.0 version uses the pharmacy NPI number in the transmission and not the NABP.

**MHDO Staff Response:** If the MHDO Board adopts items 6-9 above in the summary/justification section of this document, data element SP018 will not exist. However, the question is relevant to data element PC018. If a payor does not assign pharmacy numbers and data element PC021 contains the NPI, then data element PC018 should be left blank.

#### **Recommended Board Action**: None

5. SP038 – Postage Amount – if postage fees are not charged, would field be left blank or fill with "000"?

**MHDO Staff Response:** If the MHDO Board adopts items 6-9 above in the summary/justification section of this document, data element SP038 will not exist. However, the question is relevant to PC038\_Postage Amount. Since this field, like all of the payment fields, has two implied decimal places, the value '000' will be interpreted as a postage amount of \$0.00. This would be appropriate if there were no postage fees.

#### Recommended Board Action: None

5. Pharmaceutical Care Management Association (PCMA) submitted the following 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.

**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, for clarification purposes, staff supports including language in the description of data element PC1165, 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:** For the purpose of clarification, accept the additional language in the description for data element PC1165: "...PBM compensation does not include any compensation paid by a manufacturer, developer, or labeler for the performance of services." (Appendix E-1, page 83)

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.

A PBM client is not privy to specific pharmacy reimbursement amounts for individual claims. These clients hire a PBM for its expertise in handling these reimbursement amounts to lower drug costs.

**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. 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 90-590, Chapter 243, Uniform Reporting System for Health Care Claims 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

# 4. Rebate

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 arraignments." 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 243 and 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. When there is a rebate at the point of sale, the data elements in Chapter 243 specific to POS rebate, PC1143 and PC1154 must be populated. If there is no point-of-sale rebate paid for a claim reported under Rule Chapter 243, data elements PC1143 and PC1154 should be populated as \$0.

# Recommended Board Action: None

5. Next, the language misunderstands point-of-sale ("PoS") rebates. PoS rebates are not a dollar-for-dollar reduction in patient obligation. Rather, the rebate amount discounts the reference price of the drug from which the cost share is calculated. Thus, the current language in the Proposed Rules does not appear to properly contemplate how rebates work.

MHDO Staff Response: When POS rebates exist, the amount of reduction that is applied to actual payment amounts should be reported as the value for Total POS Rebate Amount (PC1143) and Member POS Rebate Amount (PC1154). If there is no point-of-sale rebate paid for a claim reported under Rule Chapter 243, data elements PC1143 and PC1154 should be populated as \$0.

Recommended Board Action: For the purpose of clarification, accept the modification of the description for data element PC1143 in Appendix E-1 to reflect: "The total dollar amount of all reductions to amounts paid by the health plan or an individual member resulting from POS (point-of-sale) rebates. The total POS rebate amount should be reported in full and should not be deducted from either plan paid or member copay, deductible, or coinsurance amounts. The dollar amount of the total POS (point-of-sale) rebate. The total POS rebate amount should be reported in full and should not be deducted from either plan paid or member copay, deductible, or coinsurance amounts.

For the purpose of clarification, accept the modification of the description for data element PC1154 in Appendix E-1 to reflect: "The dollar amount of all reductions to amounts paid by an individual member resulting from POS rebates. The member POS rebate amount should not be deducted from member copay, deductible, or coinsurance amounts. The dollar amount of the total POS rebate that was received by the member. The member POS rebate amount should not be deducted from member copay, deductible, or coinsurance amounts."

6. Again, PCMA also respectfully requests that any data reporting for this language be reported in the aggregate.

MHDO Staff Response: Pharmacy Rebate data and PBM compensation data reported under 90-590, Chapter 243, Uniform Reporting System for Health Care Claims 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. 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

8. 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 <u>advance</u> 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 90-590, Chapter 243, Uniform Reporting System for Health Care Claims 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

9. 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:** 90-590, Chapter 243 Uniform Reporting System for Health Care Claims Data Sets, Section 2 - Health Care Claims Data Set Filing Description specifies that "Health care claims processors shall submit to the MHDO or its designee a completed health care claims data set for all members **who are Maine residents** in accordance with the requirements of this section."

#### **Recommended Board Action:** None

10. 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:** Pharmacy Rebate data reported under 90-590, Chapter 243, Uniform Reporting System for Health Care Claims Data Sets, relates only to rebates provided at the point of sale and applied on a claim-by-claim basis. Annual reporting of rebate data is described in Chapter 247, Uniform Reporting System for Non-Claims Based Payments, and Other Supplemental Health Care Data Sets. Data reported under Chapter 247 are due in August of each year.

# Recommended Board Action: None

11. 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 90-590, Chapter 243, Uniform Reporting System for Health Care Claims 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

6. The MHDO submitted the following correction comment:

**Comment:** A typo correction should be made to page 7 of the proposed rule changing Section 2(B)(4)(f)(ii), to read, "Substance Abuse Disorder *Pharmacy* Claims Filing Mapping to National Standard Formats – Appendix H-2."

MHDO Staff Response: The proposed recommendations eliminate Appendix H-2.

**Recommended Board Action:** Adopt the revisions detailed in the summary of proposed changes item 6.

**Statutory Authority:** 22 M.R.S.A., §§8703(1), 8704(4), 8708(6-A) and 8712(2)

Effective Date: TBD