

**Annual List of Rule-Making Activity**  
**Rules Adopted January 1, 2023 to December 31, 2023**  
*Prepared by the Secretary of State, pursuant to 5 MRS §8053-A(5)*

**Agency name:** **Maine Health Data Organization**  
**Umbrella-Unit:** **90-590**  
**Statutory authority:** 22 M.R.S. Section 8705-A and 24-A M.R.S. §6951  
**Chapter number/title:** **Ch. 100**, Enforcement Procedures  
**Filing number:** **2023-171**  
**Effective date:** 10/14/2023  
**Type of rule:** Major Substantive  
**Emergency rule:** No

**Principal reason or purpose for rule:**

This proposed rule change is necessary to align the enforcement requirements in Public Law 2021, Chapter 603 and in 90-590 C.M.R. Chapter 247, with the enforcement provisions described in 90-590 C.M.R. Chapter 100: Enforcement Procedures. These proposed changes add a new provision under Section 3. Penalties; fines, for a payor that fails to file supplemental health care data sets and/or to meet the standards for data as defined in 90-590 Chapter 247. Additionally, the definitions for manufacturer and wholesale drug distributor have been updated to align the definitions in 22 MRS Chapter 1683 and 90-590 C.M.R. Chapter 570.

**Basis statement:**

Chapter 100 establishes a schedule of fines and other enforcement actions for failure to file clinical, quality, financial, restructuring, health care claims and prescription drug price data; failure to pay the annual assessment; and for intentional or knowing failure to protect the disclosure of confidential or privileged data.

The proposed changes summarized below (except for updates to two definitions in Section 2) are a result of the new requirements in 24-A M.R.S. §6951, including those in PL 2021, c603, "An Act Regarding Reporting on Spending for Behavioral Health Care Services and To Clarify Requirements for Credentialing by Health Insurance Carriers".

The MHDO Board met on April 7, 2022, and authorized the MHDO to initiate rulemaking to Chapter 100, as required under 22 M.R.S. §8705-A. The proposed rule was publicly noticed on September 14, 2022, and a public hearing was held on October 6, 2022. No public comments were received at the public hearing or by the 10-day comment period deadline of October 17, 2022. The Board provisionally adopted the major substantive rule on December 1, 2022. Subsequently, the Board submitted the provisionally adopted rule to the Maine State Legislature for its review, in accordance with 5 MRS Sec. 8072.

**Fiscal impact of rule:**

N/A

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**Umbrella-Unit:** **90-590**  
**Statutory authority:** 22 MRSA, §§8703(1), 8704(4), 8708(6-A) and 8712(2)  
**Chapter number/title:** **Ch. 243**, Uniform Reporting System for Health Care Claim Data Sets  
**Filing number:** **2023-249**  
**Effective date:** 12/17/2023  
**Type of rule:** Routine Technical  
**Emergency rule:** No

**Principal reason or purpose for rule:**

Given the public health crisis the opioid epidemic has created and the need for comprehensive data to assist with identifying outbreaks, responding to overdoses and providing care in Maine's communities, this proposed rule adds fields to the data layout that will be needed to collect de-identified substance use disorder (SUD) data. We intend to prepare the data collection files so that when the federal government adopts the clarification that they have provided regarding 42 CFR Part 2, specifically related to the submission of deidentified SUD data, MHDO will be ready to respond with its payors in a timely manner. Additionally, we are adding fields for the collection of prescription drug rebate data, and dental claims information. The proposed changes modify fields in the medical claims file to better account for the payment arrangement type at the claim level and remove obsolete requirements, definitions, and sources.

**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).

**Fiscal impact of rule:**

There is no fiscal impact on state municipalities, counties or small businesses.

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**Umbrella-Unit:** **90-590**  
**Statutory authority:** 22 M.R.S. §§8703(1); 8704(1)&(4); and 24-A M.R.S. §6951  
**Chapter number/title:** **Ch. 247**, Uniform Reporting System for Non-Claims Based Primary Care Payments and Other Supplemental Health Care Data Sets  
**Filing number:** **2023-250**  
**Effective date:** 12/17/2023  
**Type of rule:** Routine Technical  
**Emergency rule:** No

**Principal reason or purpose for rule:**

This proposed rule adds new data fields and updates others to ensure collection of aggregated dollar amounts paid in relation to substance use disorder (SUD) and non-claims-based prescription drug rebate data.

**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).

**Fiscal impact of rule:**

There rule will not have a fiscal impact on municipalities or counties, or any adverse economic impact of small businesses.

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**Umbrella-Unit:** **90-590**  
**Statutory authority:** 22 M.R.S. §§ 8703(1), 8704(1), 8705-A and 8705-A(3), 8731, 8732, 8733, 8734, 8735 and 8737.  
**Chapter number/title:** **Ch. 570**, Uniform Reporting System for Prescription Drug Price Data Sets  
**Filing number:** **2023-083**  
**Effective date:** 7/8/2023  
**Type of rule:** Major Substantive  
**Emergency rule:** No

**Principal reason or purpose for rule:**

This rule change is necessary to align the requirements in PL 2021, c 305, "An Act To Increase Prescription Drug Pricing Transparency", with the requirements in 90-590 C.M.R. Ch. 570.

**Basis statement:**

The Maine Health Data Organization (MHDO) is authorized by statute to collect health care data, including prescription drug price data. The purpose of this Chapter is to explain the provisions for filing prescription drug price sets from prescription drug manufacturers, wholesale distributors and pharmacy benefits managers. The MHDO Board met on April 7, 2022 and authorized the MHDO to initiate rulemaking to Chapter 570 (22 MRSA §8704, sub-§1; §8705-A; §8737), for the primary purpose of aligning Chapter 570 with PL 2021, c. 305. The proposed rule was publicly noticed on September 14, 2022, and a public hearing was held on October 6, 2022 with a 10 comment period deadline of October 17, 2022. The Board met on December 1, 2022, to discuss comments received and unanimously voted to provisionally adopt the rule changes as outlined. This rule was reviewed by the legislature and approved by the MHDO Board on June 1, 2023 for final adoption, with an amendment to Section 2(C)(1)(a) to correct a cross-reference. The following represent the proposed changes to the rule and the rationale for these changes:

**Section 1. Definitions**

Non-substantive typographical and wording changes are included.

**Rationale:** The proposed changes clean up the typos and improve uniformity and consistency in language between MHDO statute and rules.

Amends current Section 1(C) as follows:

Drug Product Family. "Drug product family" means a group of one or more prescription drugs that share a unique non-proprietary name and dosage form.

Adds a definition to current Section I for Dosage Form

Dosage Form means the physical form in which a prescription drug is produced and dispensed, such as a tablet, a capsule, or an injectable.

**Section 2. Registration and Submission Requirements**

-Section 2(B) Public Notice of Substantial Drug Price Change or Introduction has revised language.

**Rationale:** PL 2021, c. 305 Sec. 5 and 22 MRSA §8732, sub-§1-A

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Section 2(C) Disclosures by Manufacturers, Wholesale Drug Distributors and Pharmacy Benefits Managers has revised language.

**Rationale:** PL 2021, c. 305 Sec. 6 and 22 MRSA §8732, sub-§2

-Section 2(J)(3) Pharmacy Benefits Manager Report has revised language for several data elements regarding reporting for the State of Maine rather than the United States.

**Rationale:** The issue regarding the level of reporting for Pharmacy Benefit Managers was agreed to in the HCIFS committee work session in the 130th Maine Legislature, but inadvertently not included in the final version of the rule that the legislature voted on earlier this year.

**Section 6. Confidentiality**

-Sections 6(B) and 6(C) have revised language.

**Rationale:** PL 2021, c. 305 Sec. 7 and 22 MRSA §8733

**Fiscal impact of rule:**

There is no fiscal impact on state municipalities, counties, or small businesses.