

**Annual List of Rule-Making Activity**  
**Rules Adopted January 1, 2020 to December 31, 2020**  
*Prepared by the Secretary of State, pursuant to 5 MRS §8053-A sub-§5*

**Agency name:** **Maine Health Data Organization**  
**Umbrella-Unit:** **90-590**  
**Statutory authority:** 22 MRS §§ 8704 sub-§4, 8706 sub-§2; PL 2019 ch. 470  
**Chapter number/title:** **Ch. 10**, Determination of Assessments  
**Filing number:** **2020-018**  
**Effective date:** 2/4/2020  
**Type of rule:** Routine Technical  
**Emergency rule:** No

**Principal reason or purpose for rule:**

Pursuant to PL 2019 ch. 470, this adopted rule change adds prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers to the list of health care services entities required to pay annual assessments to support the operational costs of the Maine Health Data Organization.

**Basis statement:**

Ch. 10 identifies the health care providers, health insurance entities, carriers that provide only administrative services for a plan sponsor, third-party administrators, prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers required to pay annual assessments for the operational costs of the Maine Health Data Organization (MHDO). This chapter also establishes the process for determining the individual assessments for each entity and the time frame for payment.

**Fiscal impact of rule:**

*(No response)*

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**Agency name:** **Maine Health Data Organization**  
**Umbrella-Unit:** **90-590**  
**Statutory authority:** 22 MRS §§ 8705-A; PL 2019 ch. 470  
**Chapter number/title:** **Ch. 100**, Enforcement Procedures  
**Filing number:** **2020-134**  
**Effective date:** 7/3/2020  
**Type of rule:** Major Substantive  
**Emergency rule:** No

**Principal reason or purpose for rule:**

Pursuant to PL 2019 ch. 470, this rule change adds prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers to the list of health care services entities who may be fined for failure to file 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.

**Basis statement:**

Ch. 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 changes (except for corrections) are a result of the new requirements defined in PL 2019 ch. 470. "An Act to Further Expand Drug Price Transparency."

The MHDO Board met on May 23, 2019 and authorized the MHDO to initiate rulemaking to ch. 100, as required under 22 MRS §8705-A. A public hearing was held on November 21, 2019 with a 10-day public comment period of December 2, 2020. The following public comments were received and on January 16, 2020 the Board provisionally adopted this major substantive rule. The provisionally adopted rule was submitted to the Maine State Legislature for its review, in accordance with 5 MRS §8072. On March 10, 2020, the Maine State Legislature authorized final adoption of the rule, with an amendment in Section 2 of paragraph M to change the cross reference in the definition of "pharmacy benefits manager" to Title 24-A §4347 sub-§17.

**Fiscal impact of rule:**

*(No response)*

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**Agency name:** **Maine Health Data Organization**  
**Umbrella-Unit:** **90-590**  
**Statutory authority:** 22 MRS §§ 8703(1), 8704(4), 8708(6-A), 8712(2)  
**Chapter number/title:** **Ch. 243**, Uniform Reporting System for Health Care Claims  
Data Sets  
**Filing number:** **2020-217**  
**Effective date:** 10/12/2020  
**Type of rule:** Routine Technical  
**Emergency rule:** No

**Principal reason or purpose for rule:**

The rule change will update the current definitions of Pharmacy Benefit Manager (consistent with statutory revision made earlier this year), resume collection of race and ethnicity data, and add fields to indicate if a provider is in a payer's network.

**Basis statement:**

The Maine Health Data Organization is authorized by statute to collect health care data. The purpose of this chapter is to explain the provisions for filing health care claims data sets from all third-party payers, third-part administrators, Medicare health plan sponsors and pharmacy benefits managers.

**Fiscal impact of rule:**

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

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**Agency name:** **Maine Health Data Organization**  
**Umbrella-Unit:** **90-590**  
**Statutory authority:** 22 MRS §§ 8704 sub-§4, 8709  
**Chapter number/title:** **Ch. 300**, Uniform Reporting System for Hospital Financial Data  
**Filing number:** **2020-052**  
**Effective date:** 3/16/2020  
**Type of rule:** Routine Technical  
**Emergency rule:** No

**Principal reason or purpose for rule:**

This rule change will add the requirement that hospitals and parent entities be required to submit consolidated financial data along with organizational information. This change will provide greater transparency to the public into the finances of the hospital and parent entities.

**Basis statement:**

The Maine Health Data Organization is authorized by statute to collect health care data. This chapter governs the provisions for the identification of entities required to file financial data to the MHDO; including data content, format, medium, submission schedule, reporting standards; and compliance.

The MHDO Board met on May 23, 2019 and authorized the MHDO to initiate rulemaking to ch. 300. A public hearing was held on November 21, 2019 with a MHDO staff recommended comment (see below) to the amended rule. On March 5, 2020 the MHDO Board approved the amended rule as revised.

**Fiscal impact of rule:**

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

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**Umbrella-Unit:** **90-590**  
**Statutory authority:** 22 MRS §§ 8703(1), 8704(1), 8705-A and 8705-A(3), 8731, 8732, 8733, 8734, 8735, 8737  
**Chapter number/title:** **Ch. 570** (*New*), Uniform Reporting System for Prescription Drug Price Data Sets  
**Filing number:** **2020-019**  
**Effective date:** 2/4/2020  
**Type of rule:** Routine Technical  
**Emergency rule:** No

**Principal reason or purpose for rule:**

PL 2019 ch. 470, "An Act to Further Expand Drug Price Transparency" requires prescription drug manufacturers to report to the Maine Health Data Organization no later than January 30, 2020 and annually thereafter, on prescription drug prices when the manufacturer has during the prior calendar year increased the wholesale acquisition cost of a brand-name drug by more than 20% per pricing unit, increased the wholesale acquisition cost of a generic drug that costs at least \$10 per pricing unit by more than 20% per pricing unit or introduced a new drug for distribution in this State when the wholesale acquisition cost is greater than the amount that would cause the drug to be considered a specialty drug under the Medicare Part D program.

Prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers are also required to provide pricing component data per pricing unit of a drug within 60 days of a request by the Maine Health Data Organization. This rule defines "pricing component data" as data unique to each manufacturer, wholesale drug distributor or pharmacy benefit manager that evidences the cost to make a prescription drug available to consumers and the payments received by each manufacturer, wholesale drug distributor or pharmacy benefit manager to make a prescription drug available to consumers, taking into account any price concessions, that is measured uniformly among and between the entities.

**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 drug distributors and pharmacy benefits managers.

The MHDO Board met on May 23, 2019 and authorized the MHDO to initiate rulemaking to ch. 570 (22 MRS §8704 sub-§1; §8705-A; §8737). A public hearing was held on November 21, 2019 with a 10-day public comment period. This is a routine technical rule only until April 1, 2020 then it is a major substantive rule (PL 2019 ch.470 §10).

**Fiscal impact of rule:**

This bill requires prescription drug manufacturers to report to the Maine Health Data Organization (MHDO) on prescription drug information under certain situations or when requested by MHDO and requires MHDO to annually produce and post a report of this information on its website. Any costs to MHDO to carry out these provisions are expected to be minor and can be absorbed within budget resources. The bill also authorizes MHDO to collect an annual assessment on drug manufacturers of \$500. Additional revenues collected from these assessments are expected to increase Other Special Revenue Fund revenues by minor amounts.