

**Chapter 100: Enforcement Procedures** *(Major Substantive Rule)*

*Revised on DATE based on MHDO Board meeting DATE.*

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**Section I. 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 corrections) are a result of the new requirements defined in PL 2019, c470. “An Act to Further Expand Drug Price Transparency.”

The MHDO Board met on May 23, 2019 and authorized the MHDO to initiate rulemaking to Chapter 100, as required under 22 M.R.S. §8705-A. A public hearing was held on November 21, 2019 with a 10-day public comment period.

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

1. Prescription drug price data was added to the rule summary, per 22 M.R.S. §8704, sub-§1(A). (page 1)
2. Definitions were added for manufacturer, pharmacy benefits manager (PBM) and wholesale drug distributor. (page 2)
3. The language in section 3(D) pertaining to the submission of hospital financial data, as required under Chapter 300, was updated to be consistent with Sections 3(A)-(C). (page 4)
4. The text added in section 3(E) ensures that prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers (PBMs) file prescription drug price data, as required by 22 M.R.S. §8704, sub-§1 and 90-590 C.M.R. Chapter 570. (page 4)
5. The text regarding the submission of hospital restructuring data was deleted in section 3(E). 90-590 C.M.R. Enforcement of Chapter 630 was suspended on December 7, 2017 and it is expected to be repealed. (page 5)
6. Section 3(G) ensures that prescription drug manufacturers, wholesale drug distributors and PBMs that fail to pay the annual assessment levied for the operational costs of the MHDO as set forth in 90-590 C.M.R. Chapter 10 may be subject to a fine (22 M.R.S. §8705-A). (page 5)
7. Corrections (pages 1-6)

**Section II. Names of Individuals that Submitted Comments**

The following is a list of individuals and affiliations that submitted written comments to the Maine Health Data Organization (MHDO) regarding the proposed rule:

1. Ann Woloson, Executive Director, Consumers for Affordable Health Care
2. Lori Parham, State Director, AARP Maine

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

Below is a summary of the comments received by each submitter and the proposed Agency Response:

1. **Consumers for Affordable Health Care had the following comments:**

**Comment: Section 2(P) Wholesale Drug Distributor**

CAHC urges MHDO to revise the definition to “Wholesale drug distributor” means an entity licensed by the state to engage in the sale of prescription drugs to persons and/or entities other than a consumer or patient.”

**MHDO Staff Response:** Amend the definition of Wholesale Drug Distributor to include sales to non-person entities other than a consumer or patient.

**Recommended Board Action:** Amend Section 1 definition for “Wholesale drug distributor” as follows:

**Wholesale drug distributor.** “Wholesale drug distributor” means an entity licensed by the State to engage in the sale of prescription drugs, of which it is not the manufacturer, to persons and/or entities other than a consumer or patient.

**Comment: Section 3(E) – “Penalties”**

CAHC believes the penalties for failing to report the required data in this section of the proposed rules is insufficient in deterring required entities from not submitting the required data. We urge MHDO to align this section of the final rules with proposed section 3(F) ($30,000 per day).

**MHDO Staff Response:** Public Law Chapter 470 amends §8705-A, sub-§3, to include prescription drug manufactures, wholesale distributors and pharmacy benefit managers. Adding drug manufacturers, wholesale distributors and pharmacy benefit managers to this section makes the civil violations and penalties for failing to report data to the MHDO consistent with the civil violations and penalties for other reporting entities. The language in Section 3(E) in the proposed Rule Chapter 100 is consistent with the requirements in §8705-A, sub-§3.

**Recommended Board Action:** No further action required.

1. **AARP Maine had the following comments:**

**Comment: Section 3(E) – “Penalties”**

The penalties proposed in Section 3(E) are almost undoubtedly insufficient to persuade manufacturers, wholesale drug distributors, and PBMs to provide prescription drug information required under 90-590 - C.M.R. Chapter 570 Section 2. As proposed, the maximum fine for failure to report required price data would be $25,000 per any one occurrence. As a point of contrast, this fine is only somewhat higher than the average annual cost for just one prescription drug, which was nearly $20,000 in 2017.1 The proposed rule would further seek to institute a graduated fine scale that would result in a fine of $700 for failure to report in week one; $1,750 in week two; and $3,500 in week three; and $1,000 per day beginning in week 4.

Significantly, it should be noted that any entity that does not provide the required price data information outlined in 90-590 - C.M.R. Chapter 570 Section 2 for 17 total weeks would reach the proposed rule’s maximum fine amount of $25,000 for any one occurrence. Per that standard, there would not seem to be any additional recourse for MHDO’s enforcement of price data reporting related to Chapter 570 Section 2.

AARP urges that MDHO replace the inadequate graduated scale of penalties proposed in Chapter 100 Section 3 E with same penalty of $30,000 per day as contemplated in Chapter 100 - Section 3 F.

**MHDO Staff Response:** Public Law Chapter 470 amends §8705-A, sub-§3, to include prescription drug manufactures, wholesale distributors and pharmacy benefit managers. Adding drug manufacturers, wholesale distributors and pharmacy benefit managers to this section makes the civil violations and penalties for failing to report data to the MHDO consistent with the civil violations and penalties for other reporting entities. The language in Section 3(E) in the proposed Rule Chapter 100 is consistent with the requirements in §8705-A, sub-§3.

**Recommended Board Action:** No further action required.

**Comment: Section 3(F) – “Penalties”**

The proposed penalties for Section 3(F) are listed as being related to Chapter 570, Section 4. However, MHDO’s SUMMARY document for this proposed rule states that “Section 3(F) ensures that prescription drug manufacturers, wholesale drug distributors and PBMs that fail to pay the annual assessment levied for the operational costs of the MHDO as set forth in 90-590 C.M.R Chapter 10 may be subject to a fine (page 5)”. The rules that reference an annual assessment of $500 appear to be reflected in 90-590 CMR Chapter 10 2(F), not Chapter 570, Section 4 as currently written.

**MHDO Staff Response:** The language regarding civil violations and fines for non-payment of assessments is defined in Section 3(G).

**Recommended Board Action:** No further action required.

**Comment: Chapter 100 – Section 2(P) – “Wholesale Drug Distributor”**

The proposed definition of Wholesale Drug Distributor is:

“Wholesale drug distributor” means an entity licensed by the State to engage in the sale of prescription drugs to persons other than a consumer or patient.

AARP suggests that the word “persons” underlined above be changed to “entities” and defined as needed.

**MHDO Staff Response:** Amend the definition of Wholesale Drug Distributor to include sales to non-person entities other than a consumer or patient.

**Recommended Board Action:** Amend Section 1 definition for “Wholesale drug distributor” as follows:

**Wholesale drug distributor.** “Wholesale drug distributor” means an entity licensed by the State to engage in the sale of prescription drugs, of which it is not the manufacturer, to persons and/or entities other than a consumer or patient.

1. **MHDO Staff Recommendation:** Align definition of “Manufacturer” in this Chapter with the one in Chapter 570.

**Manufacturer.** “Manufacturer” means ~~a manufacturer~~ an entity that manufactures, and sets the wholesale acquisition cost for, ~~of~~ prescription drugs that are distributed in the State.