

TESTIMONY OF

Karynlee Harrington, Executive Director

Maine Health Data Organization

Before the Joint Standing Committee on Health Coverage, Insurance & Financial Services

Public Hearing Date: February 16, 2023

L.D. 418

**"Resolve, Regarding Legislative Review of Portions of Chapter 100, Enforcement Procedures,
a Major Substantive Rule of the Maine Health Data Organization"**

Senator Bailey and Representative Perry and members of the Joint Standing Committee on Health Coverage, Insurance & Financial Services. My name is Karynlee Harrington; I am the Executive Director of the Maine Health Data Organization (MHDO) and the Maine Quality Forum (MQF). I am here today to present testimony in support of the proposed changes to MHDO's Rule Chapter 100, *Enforcement Procedures*.

Role of MHDO

The Maine Health Data Organization (MHDO) is authorized by statute to collect health care data, including prescription drug price data. The purpose of the MHDO as defined in Title 22, Chapter 1683, is to create and maintain a useful, objective, reliable, and comprehensive health information database that is accessed by a broad group of authorized users to improve the health care quality and costs for Maine people; and to promote the transparency of the cost and quality of health care services and prescription drugs in the State through a publicly accessible website.

The Maine Health Data Organization is governed by a board of directors which includes representatives from the following stakeholder groups: Payers, Hospitals, Providers, Home Health Care, Consumers, Employers, and Government.

MHDO's governing statute includes a provision regarding fines and enforcement actions for when a person or entity violates the requirements of this chapter.

MHDO Rule Chapter 100, *Enforcement Procedures*, establishes the schedule of fines and other enforcement actions for failure to file clinical, quality, financial, health care claims and now prescription drug price data. Failure to pay the annual assessment; and intentional or knowing failure to protect the disclosure of confidential or privileged data is a violation of this chapter.

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.

MHDO Board of Directors Public Hearing

The MHDO Board of Directors (the board) met on April 7, 2022, and authorized MHDO to initiate major substantive rulemaking for Chapter 100. 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 met on December 1, 2022, and unanimously voted to provisionally adopt the rule changes presented to you today.

Summary of Proposed Changes

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. Attached to my testimony is a Basis Statement that includes a description of each proposed change and the rationale for the change (Attachment A); and a copy of Rule Chapter 100 with the proposed changes identified in track changes (Attachment B).

This concludes my testimony. I would be happy to answer questions now or at the work session.

Attachment A

Basis Statement and Summary of Changes

Chapter 100: Enforcement Procedures *(Major Substantive) This rule requires legislative approval prior to final adoption.*

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. A public hearing was held on October 6, 2022, with a 10-day comment period. No public comments were received.

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

Section 2. Definitions (page 2)

Revised definitions for manufacturer and wholesale drug distributor to align with definitions in 22 MRS Chapter 1683 and 90-590 C.M.R. Chapter 570, Uniform Reporting System for Prescription Drug Price Data Sets.

Rationale: Uniformity in definitions across various agency rules.

Section 3. Penalties; fines. (page 3)

This proposed rule change is necessary in order 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.

Rationale: Alignment of PL 2021, Chapter 603 with 90-590 C.M.R. Chapter 247 & Chapter 100.

Statutory Authority: 22 M.R.S. Section 8705-A and 24-A M.R.S. §6951

Effective Date: TBD

Chapter 100: ENFORCEMENT PROCEDURES

SUMMARY: As required under 22 M.R.S. §8705-A, this Chapter establishes a schedule of fines and other enforcement actions for failure to file clinical, quality, financial, 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.

1. **Applicability.** This rule is applicable to all activities and processes described under 22 M.R.S. Chapter 1683 including but not limited to the activities required of health care providers, payors, other persons and/or data users in the filing, acquisition, and use of Maine Health Data Organization data.

2. **Definitions.**
 - A. **Carrier.** "Carrier" means an insurance company licensed in accordance with 24-A M.R.S., including a health maintenance organization, a multiple employer welfare arrangement licensed pursuant to Title 24-A, chapter 81, a preferred provider organization, a fraternal benefit society, or a nonprofit hospital or medical service organization or health plan licensed pursuant to 24 M.R.S. An employer exempted from the applicability of 24-A M.R.S., chapter 56-A under the federal Employee Retirement Income Security Act of 1974, 29 United States Code, Sections 1001 to 1461 (1988) is not considered a carrier.

 - B. **Entity.** "Entity" means an assessed, commercial, educational, or non-profit entity as defined by the MHDO Prices for Data Sets, Fees for Programming and Report Generation, and Duplication Rates Rule (90-590 C.M.R. Chapter 50).

 - C. **Health care facility.** "Health care facility" means a public or private, proprietary or not-for-profit entity or institution providing health services including, but not limited to an independent radiological services center licensed under 22 M.R.S., chapter 160, a health care facility licensed under 22 M.R.S., chapter 405 or certified under chapter 405-D, a rural health clinic certified by the Division of Licensing and Certification within the Department of Human Services, a home health care provider licensed under 22 M.R.S., chapter 419, a hospice provider licensed under 22 M.R.S., chapter 1681, a community rehabilitation program licensed under 20-A M.R.S., chapter 701, a state institution as defined under 34-B M.R.S., chapter 1 and a mental health facility licensed under 34-B M.R.S., chapter 1.

 - D. **Health care practitioner.** "Health care practitioner" means physicians and all others certified, registered or licensed in the healing arts, including but not limited to, nurses, podiatrists, optometrists, chiropractors, physical therapists, dentists, psychologists and physicians' assistants as defined in 24 M.R.S., chapter 21. "Health care practitioner" also includes licensed clinical social workers as defined in 32 M.R.S., chapter 83 and marriage and family therapists and licensed clinical professional counselors as defined in 32 M.R.S., chapter 119.

- E. **Health care provider.** "Health care provider" means a health care facility, health care practitioner, health product manufacturer, health product vendor or pharmacy.
- F. **Hospital.** "Hospital" means any acute care institution required to be licensed pursuant to 22 M.R.S., chapter 405.
- G. **Manufacturer.** "Manufacturer" means an entity that manufactures or repackages, and sets the wholesale acquisition cost for, prescription drugs that are distributed in the State.
- H. **MHDO.** "MHDO" means the Maine Health Data Organization.
- I. **M.R.S.** "M.R.S." means *Maine Revised Statutes*.
- J. **Parent entity.** "Parent entity" means the organization or corporation that has control, directly or indirectly through majority ownership, affiliation, contract or membership of a hospital and/or any affiliated health care facility. A parent entity may be an individual hospital or, as a parent of a health care facility, considered a health care facility.
- K. **Payor.** "Payor" means a third-party payor or third-party administrator.
- L. **Person.** "Person" means an individual, trust, estate, partnership, corporation including associations, joint stock companies and insurance companies, the State or any political subdivision or instrumentality, including a municipal corporation of the State, or any other legal entity recognized by State law.
- M. **Pharmacy Benefits Manager (PBM).** "Pharmacy benefits manager (PBM)" means an entity that performs pharmacy benefits management, as defined in 24-A M.R.S. §4347, sub-section 17.
- N. **Third-party administrator.** "Third-party administrator" means any person who, on behalf of a plan sponsor, health care service plan, nonprofit hospital or medical service organization, health maintenance organization or insurer, receives or collects charges, contributions or premiums for, or adjusts or settles claims on residents of this State.
- O. **Third-party payor.** "Third-party payor" means a health insurance carrier, nonprofit hospital, medical services organization, or managed care organization licensed in the State of Maine. "Third-party payor" does not include carriers licensed to issue limited benefit health policies or accident, specified disease, vision, disability, long-term care or nursing home care policies.
- P. **Wholesale drug distributor.** "Wholesale drug distributor" means an entity that
- i. is licensed by the State to engage in the sale of prescription drugs to persons and/or entities other than a consumer or patient; and
 - ii. distributes prescription drugs, of which it is not the manufacturer, to persons and /or entities other than a consumer or patient in the State.

3. Penalties; fines.

The MHDO Board may assess fines pursuant to 22 M.R.S. § 8705-A in accordance with the following schedules:

- A. A hospital that fails to file inpatient and outpatient service data and/or to meet the standards for data and the provisions for compliance as set forth in 90-590 C.M.R Chapter 241 is considered in civil violation under 22 M.R.S. §8705-A for which fines may be adjudged as follows:
 - 1. \$100 per day for the first week of non-compliance;
 - 2. \$250 per day for the second week of non-compliance;
 - 3. \$500 per day for the third week of non-compliance; and
 - 4. \$1,000 per day for the fourth week of non-compliance and each week thereafter, not to exceed a maximum of \$25,000 per any one occurrence.

- B. A payor that fails to file health care claims data and/or to meet the standards for data and the provisions for compliance as set forth in 90-590 C.M.R Chapter 243 is considered in civil violation under 22 M.R.S. §8705-A for which fines may be adjudged as follows:
 - 1. \$100 per day for the first week of non-compliance;
 - 2. \$250 per day for the second week of non-compliance;
 - 3. \$500 per day for the third week of non-compliance; and
 - 4. \$1,000 per day for the fourth week of non-compliance and each week thereafter, not to exceed a maximum of \$25,000 per any one occurrence.

- C. A payor that fails to file supplemental health care data sets and/or to meet the standards for data and the provisions for compliance as set forth in 90-590 C.M.R Chapter 247 is considered in civil violation under 22 M.R.S. §8705-A for which fines may be adjudged as follows:
 - 1. \$100 per day for the first week of non-compliance;
 - 2. \$250 per day for the second week of non-compliance;
 - 3. \$500 per day for the third week of non-compliance; and
 - 4. \$1,000 per day for the fourth week of non-compliance and each week thereafter, not to exceed a maximum of \$25,000 per any one occurrence.

- D. A payor or health care provider, excluding health care practitioners, that fails to file quality data and/or to meet the standards for data and the provisions for compliance as set forth in 90-590 C.M.R Chapter 270 is considered in civil violation under 22 M.R.S. §8705-A for which fines may be adjudged as follows:

1. \$100 per day for the first week of non-compliance;
2. \$250 per day for the second week of non-compliance;
3. \$500 per day for the third week of non-compliance; and
4. \$1,000 per day for the fourth week of non-compliance and each week thereafter, not to exceed a maximum of \$25,000 per any one occurrence.

A health care practitioner that fails to file quality data and/or to meet the standards for data and the provisions for compliance as set forth in 90-590 C.M.R Chapter 270 is considered in civil violation under 22 M.R.S. §8705-A for which fines may be adjudged as follows:

1. \$50 per day for the first week of non-compliance;
2. \$75 per day for the second week of non-compliance;
3. \$100 per day for the third week of non-compliance; and each week thereafter, not to exceed a maximum of \$2,500 per any one occurrence.

E. A parent entity, health care facility, and/or hospital that fails to file financial data and/or to meet the standards for data and the provisions for compliance as set forth in 90-590 C.M.R Chapter 300, is considered in civil violation under 22 M.R.S. Sec. 8705-A for which fines may be adjudged as follows:

1. \$100 per day for the first week of non-compliance;
2. \$250 per day for the second week of non-compliance;
3. \$500 per day for the third week of non-compliance; and
4. \$1,000 per day for the fourth week of non-compliance and each week thereafter, not to exceed a maximum of \$25,000 per any one occurrence.

F. A prescription drug manufacturer, wholesale drug distributor or PBM that fails to file prescription drug price data and/or to meet the standards for data and the provisions for compliance as set forth in 90-590 C.M.R Chapter 570 Section 2 is considered in civil violation under 22 M.R.S. §8705-A for which fines may be adjudged as follows:

1. \$100 per day for the first week of non-compliance;
2. \$250 per day for the second week of non-compliance;
3. \$500 per day for the third week of non-compliance; and
4. \$1,000 per day for the fourth week of non-compliance and each week thereafter, not to exceed a maximum of \$25,000 per any one occurrence.

G. A prescription drug manufacturer, wholesale drug distributor or PBM that fails to file prescription drug price data and/or to meet the standards for data and the provisions for

compliance as set forth in 90-590 C.M.R Chapter 570 Section 4 is considered in civil violation under 22 M.R.S. §8735 for which a fine of \$30,000 may be adjudged for each day of the violation.

1. **Certification of Accuracy.** A notification or report to the MHDO by a reporting entity shall include a signed, written certification of the notification or report's accuracy.
 2. **Audit.** With a 30-day notice, the MHDO may audit the finalized data submitted by a reporting entity, and that entity shall pay for the costs of the audit.
 3. **Corrective Action Plan.** The MHDO may require a reporting entity to develop a corrective action plan to correct any deficiencies in compliance discovered during an audit.
- H. A health care facility, payor, prescription drug manufacturer, wholesale drug distributor or PBM that fails to pay the annual assessment levied for the operational costs of the MHDO as set forth in 90-590 C.M.R Chapter 10, is considered in civil violation under 22 M.R.S. §8705-A for which fines may be adjudged at \$1,000 per day of non-compliance, not to exceed a maximum of \$25,000 per any one occurrence.
- I. Any person or entity, as defined under section 2, that receives data or information pursuant to 90-590 C.M.R Chapter 120, and intentionally or knowingly uses, sells or transfers the data in violation of the rules for commercial advantage, pecuniary gain, personal gain or malicious harm is considered in civil violation under 22 M.R.S., §8705-A for which a fine not to exceed \$500,000 may be adjudged.

The MHDO Board may, in its discretion, suspend, in whole or in part, any of the above-mentioned fines.

4. **Additional disciplinary action.**

Upon a finding that a person or entity has failed to comply with the requirements of 22 M.R.S., Chapter 1683 and any rules adopted by the MHDO Board, the Board may undertake any or all of the following:

- A. Refer the matter to the department or board that issued a license to the provider for such action as the department or board considers appropriate.
- B. Refer the matter to the Department of Professional and Financial Regulation, Bureau of Insurance for such action against the payor as the bureau considers appropriate.
- C. File a complaint with the Superior Court in the county in which the person resides or the entity is located, or in Kennebec County, seeking an order to require that person or entity in non-compliance to comply with the requirements for which adjudication is being sought, and for the enforcement of any fine determined by the Board or for other relief from the court.

5. **Injunctive relief.**

In the event of any violation of 22 M.R.S., Chapter 1683 and any rules adopted by the MHDO Board, the Attorney General may seek to enjoin a further violation and seek any other appropriate remedy provided by this Chapter.

6. Petition for review; fair hearing; judicial review.

Any person affected by any determination made under this rule by the MHDO may petition the MHDO Board for review of the decision. The petition must be filed within fifteen business days, in accordance with 5 M.R.S. Chapter 375.

STATUTORY AUTHORITY: 22 M.R.S. §8705-A, §8735, and 24-A M.R.S. §6951

EFFECTIVE DATE:
May 1, 2000

NON-SUBSTANTIVE CORRECTIONS:
November 26, 2000 - Sections 5 and 6 renumbered to 4 and 5

AMENDED:
August 6, 2005 – filing 2005-277
July 29, 2007 - filing 2007-277, (Major substantive)
July 3, 2020 – filing 2020-134 (Major substantive)