TESTIMONY OF

Karynlee Harrington, Executive Director

Maine Health Data Organization

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

February 12, 2025

L.D. 310 "Resolve, Regarding Legislative Review of Portions of Chapter 100, Enforcement Procedures, a Major Substantive Rule of the Maine Health Data Organization"

Senator Bailey, Representative Mathieson, 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 LD 310, *Resolve, Regarding Legislative Review of Portions of Chapter 100, Enforcement Procedures*, and the proposed changes to MHDO's Rule Chapter 100.

Overview of MHDO

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 annual mandated reporting requirements.

The MHDO is governed by a board of directors which includes representatives from the following stakeholder groups: Payers, Hospitals, Providers, 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 specific health care data, failure to pay the annual assessment; and intentional or knowing failure to protect the disclosure of confidential or privileged data.

MHDO Board of Directors Public Hearing

The MHDO Board of Directors held a public hearing on September 5th, 2024, on the proposed changes to Chapter 100, *Enforcement Procedures.* No public comments were received at the public hearing or by the 10-day comment deadline of September 16th, 2024. The MHDO Board met on November 7th, 2024, and unanimously voted to provisionally adopt the rule as proposed and presented to you today.

Summary of Proposed Changes

The proposed substantive changes are necessary to align the enforcement requirements in Public Law 2023, Chapter 276 (LD 1395, *An Act to Increase Transparency Regarding Certain Drug Pricing Programs)* **and** Public Law 2023, Chapter 610 (LD 2282, *An Act to Provide Greater Transparency About the Cost of Insulin and to Promote the Availability of Low-cost Insulin in the State*), by adding provisions under Section 3. Penalties; fines, for hospitals participating in the 340B Drug Program that fail to file a 340B Drug Program data set and/or meet the standards for data as defined in 90-590 Chapter 340, *Uniform Reporting System for Reporting 340B Drug Program Data*

Sets; and prescription drug manufacturers that fail to file wholesale acquisition costs for insulin and/or meet the standards for data defined in 90-590 Chapter 800 (pending legislative action and final board action). The Attorney General's office signed off on the form and legality of the proposed changes under the Maine Administrative Procedures Act.

Attached to my testimony is a Basis Statement that includes a description and the rationale of the substantive proposed changes (*Attachment A*); along with 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.

MHDO Maine Health Data Organization

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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, organizational information, 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 rule changes are necessary to ensure compliance with new rules 90-590 C.M.R. Chapters 340 and 800.

The MHDO Board met on September 7th, 2023, and authorized the MHDO to initiate rulemaking to implement the new requirements of LD 1395 (PL 2023, c276); and on June 6th, 2024, and authorized the MHDO to initiate rulemaking to implement the new requirements of LD 2282 (PL 2023, c. 610). In anticipation of these new rules being adopted by the MHDO board of directors before the end of 2024, MHDO must update Chapter 100, Enforcement Procedures, with these new reporting requirements as required under 22 M.R.S. §8705-A. This is a major substantive rule that requires legislative approval prior to final adoption.

The MHDO Board held a public hearing on September 5, 2024, with a 10-day comment deadline of September 16, 2024. No comments were received at the public hearing or by the comment deadline.

The Attorney General's office signed off on the form and legality of the proposed changes under the Maine Administrative Procedure Act. The MHDO board of directors voted unanimously to provisionally adopt the changes proposed at the November 7, 2024 board meeting.

The following represent the proposed changes to Chapter 100 and the rationale for these changes:

Section 3. Penalties; fines. (page 3, H & K)

This proposed rule change is necessary to align the enforcement requirements in Public Law 2023, Chapter 276 and Public Law 2023, Chapter 610, and in 90-590 C.M.R. Chapters 340 and 800, with the provisions described in 90-590 C.M.R. Chapter 100: Enforcement Procedures.

These proposed changes add provisions under Section 3. Penalties; fines, for a hospital participating in the 340B Drug Program that fails to file a 340B Drug Program data set and/or meet the standard for data as defined in 90-590 Chapter 340; and a prescription drug manufacturer that fails to file wholesale acquisition costs for insulin and/or to meet the standards for data as defined in 90-590 Chapter 800.

Rationale: Alignment of PL 2023, c276 and PL 2023, c610 and C.M.R. Chapters 340, 800, and Chapter 100.

Statutory Authority: 22 M.R.S. §§ 1728, 8705-A, 8735 and 24-A M.R.S. §6951

Effective Date: TBD

Attachment B

90-590 MAINE HEALTH DATA ORGANIZATION

Chapter 100: ENFORCEMENT PROCEDURES

SUMMARY: As required under 22 M.R.S. §§8705-A and 8735, this Chapter establishes a schedule of fines and other enforcement actions for failure to file clinical, quality, financial, organizational information, 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.

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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 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.

B. 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.

~~A.~~C. 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.~~D. 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.~~E. 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.~~F. 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.~~G. A parent entity, health care facility, and/or hospital that fails to file financial data, organizational information, 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.

H. A hospital participating in the 340B Drug Program that fails to file a 340B Drug Program data set and/or to meet the standards for data and the provisions for compliance as set forth in 90-590 C.M.R Chapter 340, 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.~~I. 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.~~J. 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.

K. A prescription drug manufacturer that fails to file wholesale acquisition costs for insulin and/or to meet the standards for data and the provisions for compliance as set forth in 90-

590 C.M.R Chapter 800 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.

L. A prescription drug manufacturer that fails to file wholesale acquisition costs for insulin and/or to meet the standards for data and the provisions for compliance as set forth in 90-590 C.M.R Chapter 800 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 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. §§ 1728, 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)
October 14, 2023 – filing 2023-171 (Major substantive)
