

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 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 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.

The MHDO Board met on 11/7/2024 and voted unanimously to provisionally adopt the rule as proposed.

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

The MHDO Board met on 11/7/2024 and voted unanimously to provisionally adopt the rule as proposed.