90-590 Maine Health Data Organization

**Planning for Public Hearing November 21, 2019**

Proposed Rule Summary of Changes and Basis Statement
Chapter 100: Enforcement Procedures *(Major Substantive)*

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.

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. (pages 2-3)
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in section 3(E). 90-590 C.M.R. Enforcement of Chapter 630 was suspended on December 7, 2017 and it is expected to be repealed.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 4)
6. 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)
7. Corrections (pages 1-6)