90-590 Maine Health Data Organization

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

Proposed Rule Summary of Changes and Basis Statement
Chapter 570: Uniform Reporting System for Prescription Drug Price Data Sets

*(Routine Technical/Major Substantive)*

The Maine Health Data Organization (MHDO) is authorized by statute to collect health care data, including prescription drug price data. The purpose of this Chapter is to explain the provisions for filing prescription drug price sets from prescription drug manufacturers, wholesale distributors and pharmacy benefits managers.

The MHDO Board met on May 23, 2019 and authorized the MHDO to initiate rulemaking to Chapter 570 (22 MRSA §8704, sub-§1; §8705-A; §8737). This is a routine technical rule only until April 1, 2020 then it is a major substantive rule (PL 2019 c470, Section 10).

The following represent the contents and the rationale for this new rule:

1. **Definitions** (22 M.R.S, c. 1683, sub-c. 1 § 8731)
2. **Registration and Submission Requirements** (22 MRSA, c. 1683, sub-c. 1 § 8732)

This section includes the requirements for the registration of reporting entities; conditions under which manufacturers must notify the MHDO; conditions under which the MDHO would require pricing component data from a reporting entity; the data elements contained in the various reports (data specifications); proper coding, formatting and submission of data; and submission deadlines and resubmission of rejected files.

1. **Evaluation; Notification; Response**

This section describes the evaluation or validation of data, failure notification to the submitting entity, and the time frame for correction and resubmission of data.

1. **Compliance** requirements**,** including certificate of accuracy, audit, corrective action plan and enforcement. (22 M.R.S, c. 1683, sub-c. 1 § 8735)
2. **Extensions** to deadlines for data submission requirements.
3. **Confidentiality** (22 M.R.S, c. 1683, sub-c. 1 § 8733)

Information provided to the MHDO by a reporting entity under this Chapter is confidential and not a public record under 1 M.R.S., Chapter 13.