| 90-590 Maine Health Data Organization |
| :---: |
| **Planning for Public Hearing – September 5, 2024** |

## Proposed Rule Basis Statement

### Chapter 800:  Uniform Reporting of Wholesale Acquisition Costs for Insulin
*(New rule:  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 new rule Chapter is to explain the provisions for reporting the acquisition costs of insulin from drug manufacturers to the MHDO.  It includes identification of the manufacturers, establishment of the requirements for content, format, method, time frame for filing, establishment of standards for the data, and compliance provisions.

The MHDO Board met on June 6, 2024, and authorized the MHDO to initiate rulemaking to implement the requirements in Public Law 2023, chapter 610, specifically Title 22, MRSA § 8732, sub-section 3.  This is a major substantive rule that requires legislative approval prior to final adoption.

The following represent the contents of this new rule:

I.   **Definitions**
     This section provides definitions of words and phrases outlined in the rule.

II.  **Submission Requirements**
     This section includes the submission requirements for reporting entities; submission method, file format, codes, submission deadline, rejection of submissions, replacement of data files and reporting specifications.

III. **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.

IV.  **Compliance**
     This section outlines the compliance requirements, including certificate of accuracy, audit, corrective action plan and enforcement.

V.   **Extensions**
     This section includes the process for requesting an extension to deadlines for data submission requirements.

**Statutory Authority:** 22 M.R.S. §§8703(1), 8704(1),8705-A, 8731, 8732, 8733, 8734, 8735 and 8737.

**Effective Date:** TBD