

**90-590 Maine Health Data Organization**

**Chapter 570: Uniform Reporting System for Prescription Drug Price Data Sets** *(Major substantive)*

Basis Statement & Summary of Changes

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 April 7, 2022 and authorized the MHDO to initiate rulemaking to Chapter 570 (22 MRSA §8704, sub-§1; §8705-A; §8737), for the primary purpose of aligning Chapter 570 with PL 2021, c. 305. The proposed rule was publicly noticed on September 14, 2022, and a public hearing was held on October 6, 2022 with a 10 comment period deadline of October 17, 2022. The Board met on December 1, 2022, to discuss comments received and unanimously voted to provisionally adopt the rule changes as outlined. This rule was reviewed by the legislature and approved by the MHDO Board on June 1, 2023 for final adoption, with an amendment to Section 2(C)(1)(a) to correct a cross-reference.

The following represent the changes to the rule and the rationale for these changes:

**Section 1. Definitions**

Non-substantive typographical and wording changes are included.

**Rationale:** The proposed changes clean up the typos and improve uniformity and consistency in language between MHDO statute and rules.

Amends current Section 1(C) as follows:

Drug Product Family. “Drug product family” means a group of one or more prescription drugs that share a unique non-proprietary name and dosage form.

Adds a definition to current Section I for Dosage Form

Dosage Form means the physical form in which a prescription drug is produced and dispensed, such as a tablet, a capsule, or an injectable.

**Section 2. Registration and Submission Requirements**

-Section 2(B) Public Notice of Substantial Drug Price Change or Introduction has revised language.

**Rationale:** PL 2021, c. 305 Sec. 5 and 22 MRSA §8732, sub-§1-A

-Section 2(C) Disclosures by Manufacturers, Wholesale Drug Distributors and Pharmacy Benefits Managers has revised language.

**Rationale**: PL 2021, c. 305 Sec. 6 and 22 MRSA §8732, sub-§2

-Section 2(J)(3) Pharmacy Benefits Manager Report has revised language for several data elements regarding reporting for the State of Maine rather than the United States.

**Rationale:** The issue regarding the level of reporting for Pharmacy Benefit Managers was agreed to in the HCIFS committee work session in the 130th Maine Legislature, but inadvertently not included in the final version of the rule that the legislature voted on earlier this year.

**Section 6. Confidentiality**

-Sections 6(B) and 6(C) have revised language.

**Rationale**: PL 2021, c. 305 Sec. 7 and 22 MRSA §8733

**Statutory Authority:** 22 M.R.S. §§ 8703(1), 8704(1), 8705-A and 8705-A(3), 8731, 8732, 8733, 8734, 8735 and 8737.

**Effective Date:** July 8, 2023