

**Chapter 570: Uniform Reporting System for Prescription Drug Price Data Sets (Major Substantive Rule).** *This rule requires legislative approval prior to final adoption***.**

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**Section I. Basis Statement**

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 drug distributors and pharmacy benefits managers.

This rule change is necessary to align the requirements in PL 2021, c305, “An Act To Increase Prescription Drug Price Transparency”, with the requirements in 90-590 C.M.R. Ch. 570.

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). A public hearing was held on October 6, 2022, with a 10-day public comment period. This major substantive rule requires legislative approval prior to final adoption.

**Section II. Names of Individuals that Submitted Comments**

The following individual and affiliation submitted written comments to the Maine Health Data Organization (MHDO) regarding the proposed rule change:

1. Ashlie Van Meter, Senior Director, State Government Affairs, Association for Accessible Medicines

**Section III. Summary of Comments Received by Submitter with Agency Response & Recommended Board Action.**

Below is a summary of the comments received by the submitter and the proposed Agency Response and Board Action:

**Comments:**

**Definition of “Drug Product Family” Should be Modified to Reference “Non-Proprietary Name” and “Dosage Form”**

*We recommend the definition of “drug product family” be modified in the following two ways:*

*1. Replace “generic drug description” with “non-proprietary name.” This amendment is consistent with the terminology used by the U.S. Adopted Names Council, as well as other healthcare regulatory agencies, stakeholders, and organizations. This non-substantive change would streamline the language by removing the use of a vague term (“generic drug description”) which has no formal meaning and replacing it with a formal, legally defined term.*

**MHDO Staff Response:**

The proposed Rule does not contemplate changes to the definition of Drug Product Family in Section 1(C) which became effective December 10, 2021.  However, the recommendation to modify the definition to specify “non-proprietary name” in place of “generic drug description (non-trade name)” for clarity is not a substantive change and therefore our recommendation is to do so.

*2. Add “dosage form” descriptor for specificity. Under the current definition for “drug product family,” reporting requirements may be triggered for all dosage forms that use the same active pharmaceutical ingredient(s) (API). However, there can be and are multiple dosage forms that use the same API. For example, lisinopril has at least two different dosage forms (oral tablets and solution). Further, the oral tablets are available in six strengths, ranging from 2.5 mg to 40 mg, however, the solution is only available as 1 mg/mL. After a drug goes off patent, multiple manufacturers make certain dosage forms, and strengths, but not others, leading to price fluctuations within the API or even unique dosage forms. It is important that reporting requirements are limited to the specific dosage form of interest to allow the MHDO to implement substantive reporting requirements that increase the applicability of the data collected.*

**MHDO Staff Response:**

MHDO is interested in evaluating drug costs for all strengths within a drug product family. For example, MHDO may examine whether there may be potential savings achieved in prescribing two units of a 250MG tablet instead of one unit of a 500MG tablet. However, for clarity, we do recommend replacing “drug form” with “dosage form” in our definition of Drug Product Family, defined as the physical form in which a prescription drug is produced and dispensed, such as a tablet, a capsule, or injectable.

We also recommend adding the definition for “dosage form” in Section 1. The proposed definition for “dosage form” is adapted from the FDA Glossary of Terms.

**Recommended Board Action:**

1. Amend 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 ~~generic drug description (non-trade name)~~ and ~~drug~~ dosage form.

1. Add a definition to current Section 1 for Dosage Form as follows:

**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.

**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:** TBD