OPLA Bill Analysis
Joint Standing Committee on Health Coverage, Insurance and Financial Services
Legislative Analyst: Colleen McCarthy Reid, Esq.
February 3, 2021

LD 41, Resolve, Regarding Legislative Review of Portions of Chapter 570: Uniform Reporting System for Prescription Drug Price Data Sets, a Major Substantive Rule of the Maine Health Data Organization

This resolve provides for legislative review of portions of Chapter 570: Uniform Reporting System for Prescription Drug Price Data Sets, a major substantive rule of the Maine Health Data Organization (MHDO).

Statutory Cite to Rulemaking Authority: 22 MRSA §8737 and Public Law 2019, c. 470

Summary of the Rule: Rule Chapter 570 explains the provisions for filing prescription drug price sets from prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers. These amendments to Rule Chapter 570 have been provisionally adopted to clarify the requirements for reporting entities, which is intended by MHDO to ensure more uniform data submission and to streamline the data collection and validation process.

History of the Rule: This rule was originally authorized by P.L. 2019, c.470 to implement the reporting of prescription drug pricing data to MHDO. The law directed MHDO to adopt emergency routine technical rules to implement the provisions of Title 22, chapter 1683, subchapter 3 before April 1, 2020. Those rules went into effect February 4, 2020. The law requires that any subsequent changes to the rules are subject to the major substantive rule process.

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Brief Summary of Amendments to Rule Chapter 570:

1. Changes to definitions:

- Adds new definition of "drug product family";
- Includes re-packagers in definition of "manufacturer";
- Revises definition of "pharmacy benefits manager" to align with statutory definition; and
- Clarifies that "wholesale drug distributor" does not include wholesalers who do not actively distribute product in the State

2. Changes to registration and submission requirements:

- Removes reporting dates for first year reporting and clarifies scope and due dates for how MHDO provides notice to reporting entities for requested pricing component data
- Requires MHDO to post list of drug product families for which data may be requested on its website by February 15th annually and provides that MHDO may not request data any sooner than 30 days after listing on website
- Consolidates manufacturers report into one consolidated report and makes changes to clarify data elements in reports made by manufacturers, wholesale drug distributors and pharmacy benefits managers

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ISSUES FOR CONSIDERATION:

1. The Pharmaceutical Care Management Association (PCMA) reiterated concerns previously raised during the rulemaking process related to:

- The authority for MHDO to request national level data rather than state level data related to pharmacy benefits managers; and
- Maintaining the reporting date of April used for the first year of reporting (rather than February)

2. The Association for Accessible Medicines (AAM) and Pharmaceutical Research and Manufacturers of America (PhRMA) expressed concerns that the added definition of "drug product family" captures drug manufacturers that do not independently trigger any statutory reporting requirements. They noted that by requiring reporting from manufacturers of prescription drugs included in the same "drug product family" but which do not actually meet either trigger, MHDO would be penalizing a manufacturer based on a pricing decision of another company or other factors completely beyond the manufacturer's control.

FISCAL INFORMATION:

Not yet determined

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STATUTORY CRITERIA WHEN REVIEWING THE RULE:

- Has the agency exceeded the scope of its authority in approving the rule?
- Does the rule conform to the legislative intent of the statute it implements?
- Does the rule conflict with other rules or laws?
- Is the rule necessary to accomplish the objectives of the law?
- Is the rule reasonable?
- Could the rule be made less complex or easier to understand?
- Was the rule proposed in compliance with requirements of Administrative Procedures Act and other law?
- If a rule significantly reduces property value, is the reduction necessary or appropriate and does the rule avoid an unconstitutional taking?

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COMMITTEE'S OPTIONS FOR VOTING AFTER REVIEWING THE RULE:

- **OTP** to authorize adoption of the rule with no changes

- **OTP-A**
  - To authorize adoption of the rule if changes are made to the rule; or
  - Not to authorize adoption of the rule

Remember that the Legislature's *failure to act* on a properly-filed rule authorizes adoption. Voting ONTP on the resolve is considered a failure to act on the rule so it would have the effect of allowing the agency to finally adopt the rule. An affirmative action of the Legislature is recommended instead of an ONTP vote. If the committee wants to authorize the rule, an OTP vote is generally recommended. If the committee does not want to authorize the rule, an OTP-A vote is required.