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

Background materials related to LD 41:

Rule-Making Fact Sheet

(5 MRSA §8057-A)

AGENCY: 90-590 Maine Health Data Organization

NAME, ADDRESS, PHONE NUMBER, E-MAIL OF AGENCY CONTACT PERSON:

Debra Dodge, Health Planner
Maine Health Data Organization
151 Capitol Street
102 State House Station
Augusta, ME 04333-0102
287-6724, debra.j.dodge@maine.gov

CHAPTER NUMBER AND RULE TITLE: Chapter 570: Uniform Reporting System for Prescription Drug Price Data Sets (Major Substantive)

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

DATE, TIME AND PLACE OF PUBLIC HEARING: September 3, 2020 – 9:00 A.M.
Maine Health Data Organization
151 Capitol Street
Augusta, ME 04333

COMMENT DEADLINE: September 14, 2020, at 5:00 P.M.

PRINCIPAL REASON(S) OR PURPOSE FOR PROPOSING THIS RULE: [*see* §8057-A(1)(A)&(C)]

The proposed revisions clarify the requirements for the reporting entities defined in Rule Chapter 570, which will ensure more uniform data submission, and streamline the data collection and validation process.

IS MATERIAL INCORPORATED BY REFERENCE IN THE RULE? ___YES _X_ NO [§8056(1)(B)]

ANALYSIS AND EXPECTED OPERATION OF THE RULE: [*see* §8057-A(1)(B)&(D)]

The proposed clarifications will reduce the number of questions from the reporting entities defined in Rule Chapter 570 regarding specific data elements that are required to be reported to the MHDO.

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE (including up to 3 primary sources relied upon) [*see* §§8057-A(1)(E) & 8063-B]

1. PL 2019, c 470, "An Act to Further Expand Drug Price Transparency".
2. Jim Jones, Consultant, Ten2Eleven Business Solutions, LLC
3. Feedback from Reporting Entities defined in Chapter 570

ESTIMATED FISCAL IMPACT OF THE RULE: [*see* §8057-A(1)(C)]
There is no fiscal impact on state municipalities, counties, or businesses.

FOR EXISTING RULES WITH FISCAL IMPACT OF $1 MILLION OR MORE, ALSO INCLUDE:

ECONOMIC IMPACT, WHETHER OR NOT QUANTIFIABLE IN MONETARY TERMS: [*see* §8057-A(2)(A)]

INDIVIDUALS, MAJOR INTEREST GROUPS AND TYPES OF BUSINESSES AFFECTED AND HOW THEY WILL BE AFFECTED: [*see* §8057-A(2)(B)]

BENEFITS OF THE RULE: [*see* §8057-A(2)(C)]

Note: If necessary, additional pages may be used.

Provisionally Adopted Rule w/changes noted

90-590 MAINE HEALTH DATA ORGANIZATION

Chapter 570: UNIFORM REPORTING SYSTEM FOR PRESCRIPTION DRUG PRICE DATA SETS

SUMMARY: This Chapter contains the provisions for filing pharmaceutical pricing data sets from prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers.

The provisions include:

Identification of the organizations required to register and report;

Establishment of requirements for the content, format, method, and time frame for filing prescription drug price data;

Establishment of standards for the data reported; and

Compliance provisions.

1. Definitions

Unless the context indicates otherwise, the following words and phrases shall have the following meanings:

A. **Acquisition date.** "Acquisition date" means the date that the manufacturer registered with the FDA as the labeler for the drug product.

B. **Brand-name drug.** "Brand-name drug" means a prescription drug, having a unique NDC, marketed under a proprietary name or registered trademark name, including a biological product, and approved under a New Drug Application or Biologics License Application.

~~B.~~C. **Drug product family**. "Drug product family" means a group of one or more prescription drugs that share a unique generic drug description (non-trade name) and drug form.

~~C.~~D. **Generic drug.** "Generic drug" means a prescription drug, having a unique NDC, whether identified by its chemical, proprietary or nonproprietary name, that is not a brand-name drug, is therapeutically equivalent to a brand-name drug in dosage, strength, method of consumption, performance and intended use, and approved under an Abbreviated New Drug Application. "Generic drug" includes a biosimilar product.

~~D.~~E. **Introduced to Market.** "Introduced to Market" means made available for purchase in the United States.

~~N.~~O. **Pricing unit.** "Pricing unit" means the smallest dispensable amount of a prescription drug product that could be dispensed.

~~O.~~P. **Proprietary name.** "Proprietary name" means the brand or trademark name of the drug reported to the FDA.

~~P.~~Q. **Rebate.** "Rebate" means a discount, chargeback, or other price concession that affects the price of a prescription drug product, regardless of whether conferred through regular aggregate payments, on a claim-by-claim basis at the point-of-sale, as part of retrospective financial reconciliations (including reconciliations that also reflect other contractual arrangements), or by any other method. "Rebate" does not mean a "bona fide service fee", as such term is defined in Section 447.502 of Title 42 of the Code of Federal Regulations, published October 1, 2019.

~~Q.~~R. **Reporting entity.** "Reporting entity" means any manufacturer, pharmacy benefits manager, wholesale drug distributor, or any other entity required to ~~report~~register and/or submit data pursuant to 22 M.R.S., Sections 8732, 8734, ~~and~~ 8735 and this rule.

~~R.~~S. **Specialty Drug Under Medicare Part D Program.** "Specialty Drug Under Medicare Part D Program" means a prescription drug product having a wholesale acquisition cost that exceeds the threshold set for a specialty drug by the Centers for Medicare and Medicaid Services under the Medicare Part D.

~~S.~~T. **Tax identification number (TIN).** "Tax identification number (TIN)" means the 9-digit Taxpayer Identification Number used by the Internal Revenue Service (IRS).

~~T.~~U. **Wholesale acquisition cost (WAC).** "Wholesale acquisition cost (WAC)" means a manufacturer's published list price for sale of a prescription drug product with a unique NDC to any wholesale drug distributor or other entity that purchases a prescription drug directly from the manufacturer, not including any price concessions.

V. **Wholesale drug distributor.** "Wholesale drug distributor" means an entity that

i. is licensed by the State to engage in the sale of prescription drugs~~, of which it is not the manufacturer~~, to persons and/or entities other than a consumer or patient; and~~.~~

~~i.~~ii. distributes prescription drugs, of which it is not the manufacturer, to persons and /or entities other than a consumer or patient in the State.

2. Registration and Submission Requirements

Reporting entities shall submit to the MHDO or its designee complete prescription drug price data sets in accordance with the requirements of this section. Data may be submitted by corporate entities or their subsidiaries. Reporting entities that engage subcontractors or other third parties to submit information on their behalf warrant the completeness and accuracy of all data submitted.

a) ~~Manufacturers: On or before April 10th, 2020, and February 15th of each year thereafter, the MHDO will notify, via e-mail, prescription drug~~ manufacturers that are required to report ~~new drug or price increase~~ pricing component data as detailed in sections 2(J)(1);~~(1) or 2(J)(2), respectively~~.

b) ~~Wholesale drug distributors: On or before April 10th, 2020, and February 15th of each year thereafter, the MHDO will notify, via e-mail,~~ wholesale drug distributors that are required to report pricing component data as detailed in section 2(J)(2)~~(3).~~; and

c) ~~Pharmacy Benefits Managers: On or before April 10th, 2020, and February 15th of each year thereafter, the MHDO will notify, via e-mail,~~ pharmacy benefits managers that are required to report pricing component data as detailed in section 2(J)(3)~~(4)~~.

~~2)~~4) Each reporting entity receiving such a notification shall submit their pricing component data to MHDO for each NDC in each drug product family included in the notice in accordance with the requirements below.

D. **Submission Method.** Data files must be submitted via the MHDO Prescription Drug Price Data Portal web interface (https://mhdo.maine.gov/pharma_portal/). E-mail attachments shall not be accepted.

E. **File Format.** The file format will be an MHDO-provided Excel template for each dataset submitted via a secure web upload interface. Submitters must use the current version of the appropriate template. The file format will contain the data elements found in the Reporting Specifications described in subsection 2(J). File naming conventions will be specified in the instructions included with each template.

F. **Codes.** Unless otherwise specified, only the code sources listed and described in the templated reports are to be utilized. Specific or unique coding systems shall not be permitted.

G. **Submission Deadline.** Prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers shall report no later than 60 days after notification from the MHDO, as described in section 2(C).

H. **Rejection of Submissions**. Failure to conform to the requirements of subsections D, E or F of this Section shall result in the rejection of the data file(s). All rejected files must be corrected and resubmitted to the MHDO or its designee within 30 days.

I. **Replacement of Data Files.** A ~~manufacturer~~ reporting entity may replace data submitted to the MHDO with updated data within 90 days of the updated information becoming available. Any replacements after this period must be approved by the MHDO.

J. **Reporting Specifications.** For each drug product NDC indicated in the MHDO notice, the reporting entity must report the following data. Data related to sales volume, acquisition volume, revenue, acquisition amount, and rebates ~~may~~ should be provided net of returns. ~~if all data elements for the NDC are provided net of returns.~~

1) Manufacturer Report ~~for Price Increase~~

Data Element Name	Description/Codes/Sources
NDC	The national drug code maintained by the FDA for the drug product that includes the labeler code, product code, and package code. A drug's NDC is typically expressed using 11 digits in a 5-4-2 format (xxxxx-yyyy-zz). The first five digits identify the manufacturer, the second four digits identify the product and strength, and the last two digits identify the package size and type. Do not leave blank.
Drug Indicator	1 = Brand Name; 2 = Generic
~~Introduced to Market Date~~	~~If the drug product was introduced to market during the previous calendar year, the date that the drug product was introduced to market. If not, leave blank.~~
~~WAC at Market Introduction~~	~~If the drug product was introduced to market during the previous calendar year, the wholesale acquisition cost of the drug product at market introduction. If not, leave blank.~~
Estimated Number of Patients	Estimated annual patient volume in the United States for this drug product during the current calendar year.
~~WAC Effective Date~~	~~The effective date of the wholesale acquisition cost increase for the drug product.~~
Baseline WAC Amount	The wholesale acquisition cost of the drug product on the later of the day prior to the first day of the prior calendar year, the introduced to market date, or the acquisition date.
Total WAC ~~Increase~~ Change Amount	The total amount of wholesale acquisition cost ~~increase~~ change for the drug product during the last calendar year. Indicate $0 if no change.
WAC After ~~Increase~~Change	The wholesale acquisition cost resulting from the reported wholesale acquisition cost ~~increase~~ change for the drug product. That is, the wholesale acquisition cost on the last day of the calendar year. If no change, this amount should be the same as the Baseline WAC Amount.
~~Baseline WAC Amount~~	~~The wholesale acquisition cost of the drug product on the later of the last day of the calendar year prior to the cost increase, the introduced to market date, or the acquisition date.~~
Unit Sales Volume in US	The number of units of the drug product sold in the United States during the prior calendar year ~~of the cost increase~~.
Revenue in US	~~R~~Gross revenue from sales in the United States for this drug product during the prior calendar year ~~of the cost increase~~.

Data Element Name	Description/Codes/Sources
	previous five years, the date the drug product was introduced to market. If not, leave blank.
WAC at ~~Introduction to~~ Market Introduction	If the drug product was introduced to market within the previous calendar year or acquired by the manufacturer within the previous five years, the wholesale acquisition cost of the drug product when it was introduced to market. If not, leave blank.
Acquisition Comments	Additional information related to the acquisition information provided, if applicable.
General Comments	Additional information related to the data submitted for this drug product, if applicable.

3) Pharmacy Benefits Manager Report

Data Element Name	Description/Codes/Sources
NDC	The national drug code maintained by the FDA for the drug product that includes the labeler code, product code, and package code. A drug's NDC is typically expressed using 11 digits in a 5-4-2 format (xxxxx-yyyy-zz). The first five digits identify the manufacturer, the second four digits identify the product and strength, and the last two digits identify the package size and type. Do not leave blank.
Pricing Units Administered in US	The number of pricing units of the drug product filled in the United States for which the PBM administered claims during the prior calendar year.
Total Pharmacy Reimbursement in US	Total reimbursement amount accrued and payable to pharmacies for pricing units of the drug product filled in the United States for which the PBM administered claims during the prior calendar year.
Total Payment Received in US	Total reimbursement and/or administrative fee amount accrued and receivable from payers for pricing units of the drug product filled in the United States for which the PBM administered claims during the prior calendar year.
Total Rebate Receivable Amount in US	Total rebate receivable amount accrued by the PBM for the drug product in the United States during the prior calendar year.
Total Rebate Payable Amount	Total rebate payable amount accrued by the PBM for the drug product during the prior calendar year.
General Comments	Additional information related to the data submitted for this drug product, if applicable.

5. Extensions to Data Submission Requirements

If a reporting entity, due to circumstances beyond its control, is temporarily unable to meet the terms and conditions of this Chapter, a written request must be made to the Compliance Officer of the MHDO as soon as it is practicable after the reporting entity has determined that an extension is required. The written extension request shall include the same elements as the corrective action plan in Section 4(C).

6. Confidentiality

Information provided to the MHDO as required by this chapter by a manufacturer, wholesale drug distributor or pharmacy benefits manager is confidential and not a public record under Title 1, chapter 13, except that the MHDO may share information:

A. **Bureau of Insurance.** With the Department of Professional and Financial Regulation, Bureau of Insurance, to the extent necessary for the bureau to enforce the provisions of Title 24-A, as long as prior notice is provided to reporting entities that information will be shared, and any information shared is kept confidential; and

B. **Aggregate.** In the aggregate, as long as it is not released in a manner that allows the identification of an individual drug or manufacturer, wholesale drug distributor or pharmacy benefits manager.

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: February 4, 2020

MHDO Maine Health Data Organization

Information | Insight | Improvement

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

Table of Contents

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.

The proposed revisions will clarify the requirements for reporting entities, which will ensure more uniform data submission, and streamline the data collection and validation process.

The MHDO Board met on June 4, 2020 and authorized the MHDO to initiate rulemaking to Chapter 570 (22 MRSA §8704, sub-§1; §8705-A; §8737). A public hearing was held on September 3, 2020 with a 10-day public comment period. The MHDO Board met on 10/1/2020 and *provisionally adopted* this rule. This major substantive rule (PL 2019 c470, Section 10) requires legislative approval prior to final adoption.

Section II. Names of Individuals that Submitted Comments

The following is a list of individuals and affiliations that submitted written comments to the Maine Health Data Organization (MHDO) regarding the proposed rule:

1. Sam Hallemeier, Pharmaceutical Care Management Association (PCMA)
2. William Dane, Healthcare Distribution Alliance (HDA)

3. Nicolas Doherty, PhRMA
4. Karynlee Harrington, Maine Health Data Organization (MHDO)

Section III. Summary of Comments Received by Submitter with Proposed Agency Response & Action.

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

1. **Pharmaceutical Care Management Association** submitted the following comments:

Comment 1 – (Statutory Authority (22 M.R.S. Chapter 1683, Sec. 8736)
The data request in the rulemaking is expanded to include the entire United States. We strongly believe that any data collection should be limited to just the state of Maine. The MHDO only has the right to data based on the utilization of drugs in Maine as the MHDO is clearly charged in the law with "providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the State." (See 22 M.R.S. Chapter 1683, Sec. 8736) Therefore, the requirement to broaden the data required beyond the borders of Maine goes well beyond that scope.

MHDO Staff Response: MHDO has an interest in understanding the extent to which rebates negotiated by reporting entities at a national level contribute to the cost of prescription drugs in the State. The updated language in Section 2(J)(3) is an administrative clarification that pricing component data elements submitted by Prescription Benefits Managers should be reported at a national level. This clarification provides consistency in the level of reporting across all reporting entities.

Recommended Board Action: Approve the proposed change.

Comment 2 - (Submission of Pricing Component Data by Reporting Entities, Section 2 (C) 3)
The proposed rules alter the notice date in which the MHDO will notify the PBM has been changed to an earlier time in the year. We request that it be kept to April as there can be a lag in reporting on reconciliation between PBMs and manufacturers. This information is crucial to be included in the report and the suggested new timeline could result in inaccurate information for the MHDO.

MHDO Staff Response: The proposed language in Section 2(C)(3) removes reference to dates that applied only to the first year of program implementation. Rule Chapter 570 currently

requires MHDO to notify reporting entities no later than February 15th of each year after April 10, 2020.

As proposed, Section 2(C)(2) introduces notice from MHDO to reporting entities, in the form of a public posting on its website, of a list of drug product families for which it intends to request pricing component data no later than February 15th. Section 2(C)(3) then further provides that MHDO may not notify reporting entities which are required to report until 30 days after such public posting. In effect, the proposed language gives the reporting entities an extra 30 days to prepare their data.

Recommended Board Action: Approve the proposed change.

Comment 3 – (Confidentiality, Section 6)
Under the rule, the MHDO is seeking to obtain proprietary and/or trade secret information, such as drug specific rebate information and reimbursement amounts to pharmacies. We remain concerned with the broad authority in the rule and the authorizing statute that permits the sharing of information among government agencies, which have different sets of confidentiality rules and rules around exemptions from public disclosure. Based on this, PCMA requests that reporting entities be notified in advance if such data is going to be shared with other agencies.

MHDO Staff Response: The proposed rule does not contemplate changes to Section 6 which became effective February 4, 2020. However, adding language to Rule Chapter 570 requiring notice to reporting entities prior to sharing data with the Department of Professional and Financial Regulation, Bureau of Insurance is not a substantive change and therefore our recommendation is to do so.

Recommended Board Action: Amend Section 6(A) as follows:

> **Bureau of Insurance.** With the Department of Professional and Financial Regulation, Bureau of Insurance, to the extent necessary for the bureau to enforce the provisions of Title 24-A, as long as <u>prior notice is provided to reporting entities that information will be shared, and</u> any information shared is kept confidential; and

2. Healthcare Distribution Alliance (HDA) submitted the following comments:

Comment 1 – (Definitions, Section 1(F))
Section 1.(F): "Manufacturer is defined as "an entity that manufactures or repackages, and sets the wholesale acquisition cost for, prescription drugs that are distributed in the State."

HDA respectfully requests MHDO strike any reference to repackagers from the definition of manufacturer. States throughout the country recognize the many differences between a drug manufacturer and repackager. For example, New Hampshire's definition of manufacturer in their

recently-passed legislation aimed at collecting drug pricing data, HB 1280, specifically excludes a repackager. It is imperative to note that including repackager threatens the accuracy and quality of data.

MHDO Staff Response: MHDO has an interest in understanding the impact of competitive pricing for multiple source prescription drug products within a drug product family. Excluding repackagers from the definition of a manufacturer precludes MHDO from performing an accurate analysis of both market share and cost influence of repackaged products in the State.

Recommended Board Action: Approve the proposed change.

Comment 2 – (Definitions, Section 1(Q))
Section 1.(Q): "Rebate is defined as a discount, chargeback, or other price concession that affects the price of a prescription drug product, regardless of whether conferred through regular aggregate payments, on a claim-by-claim basis at the point-of-sale, as part of retrospective financial reconciliations (including reconciliations that also reflect other contractual arrangements), or by any other method. "Rebate" does not mean a "bona fide service fee", as such term is defined in Section 447.502 of Title 42 of the Code of Federal Regulations, published October 1, 2019.

HDA asks that the MHDO replace this definition with the definition in Federal Statute 42 CFR § 1001.952(h)(4), stating "Rebate is any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale."

As previously stated, this definition is both overly complex and vague. Importantly, the inclusion of "chargebacks" does not fit with the definition of rebate. Chargebacks are the pharmaceutical wholesaler's reimbursement from the manufacturer following a sale to a customer that has directly negotiated a lower price with the manufacturer. The wholesaler sells the product to the customer at a loss and is then reimbursed the difference from the manufacturer. It is not in the interest of MHDO to include chargebacks in the definition of rebates as it will not lead to accurate data.

MHDO Staff Response: The proposed rule does not contemplate changes to Section 1(Q) which became effective February 4, 2020. Public Law Chapter 470, §8731(4) specifies that Pricing Component Data will take into account any price concessions when evidencing the cost to make a prescription drug available to consumers. This requires a broader scope definition of Rebate than what is provided in Federal Statute 42 CFR § 1001.952(h)(4) because MHDO cannot accurately calculate the cost of a drug product as it moves through the supply chain without accounting for discounts, chargebacks, or other price concessions provided to entities throughout.

Recommended Board Action: No further action needed.

Comment 3: (Registration and Submission Requirements, Section 2)
Registration and Submission Requirements Section 2(A) relating to Registration, which states "Each entity required to report shall complete an online registration form, or update an existing one, via the MHDO Prescription Drug Price Data Portal web interface by January 30th of each year. It is the responsibility of the reporting entity to complete, as needed, all company and contact information."

Because numerous supply chain entities meet the definition of "wholesaler" and "manufacturer," HDA asks for definitive criteria to determine if an entity is required to register. For example, Oregon's registration and reporting threshold for manufacturers requires an entity to satisfy three points; (1) Required to be registered with the Board of Pharmacy as drug manufacturers; (2) Engage in the "manufacture" of prescription drugs as defined by state statute; and (3) set or change the wholesale acquisition cost (WAC) of the drugs they manufacture. HDA would ask for a similar set of criteria to ensure wholesale distributors are compliant.

MHDO Staff Response: The proposed rule does not contemplate changes to Section 2(A) which became effective February 4, 2020. It is possible that a reporting entity may be required to report as both a Manufacturer and a Wholesale Drug Distributor. The definitive criteria for determining whether an entity meets the registration requirements for a Manufacturer and/or a Wholesale Drug Distributor are provided under Section 1, subsections (F) and (V) respectively.

Recommended Board Action: No further action needed.

Comment 4: (Manufacturer Report *for New Drugs (Struck from Rule),* **Section 2)**
Striking the Manufacturer Report for New Drugs conflicts with current statute and threatens to confuse which entities would be required to report this information. If this reporting requirement is struck from the regulations, other reporting entities should not be required to report similar data on new drugs.

MHDO Staff Response: All data elements from Manufacturer Report for New Drugs have been maintained and consolidated into Section 2(J)(1) Manufacturer Report. Further, the Manufacturer requirement to provide notice of new prescription drugs that exceed the WAC threshold identified in Section 2(B)(3) has not been updated or removed.

Recommended Board Action: Approve the proposed changes.

Comment 5: (Manufacturer Report, Section 2 – Estimated Number of Patients)
Estimated Number of Patients - Neither wholesale distributors nor repackages can access patient data. By leaving repackagers in the definition of a manufacturer, reporting entities will not be able to comply with MHDO's request. If repackager is to remain in the definition, HDA respectfully asks that repackagers and wholesale distributors abstain from reporting this data point since they do not have access to any patient information.

MHDO Staff Response: Wholesale Drug Distributors are not required to provide data regarding the Estimated Number of Patients. Repackagers should provide their best estimate of the annual number of patients for each NDC requested.

Recommended Board Action: Approve the proposed changes.

Comment 6: (Manufacturer Report, Section 2 – Cost Change Factors)
Cost Change Factors - If repackager remains in the definition of manufacturer, HDA asks that MHDO add a category for supplier price increase. The supplier, or the actual manufacturer of the product, is not likely to provide a specific reason for a price increase to subsequent entities like the repackager. However, the repackager will be forced to increase their price due to the price increase by a previous supply chain entity.

MHDO Staff Response: MHDO agrees to add a new Cost Change Factor option that allows manufacturers to indicate an increase in supplier price for repackaged products.

Recommended Board Action: Amend Section 2(J)(1), Cost Change Factors Description/Codes/Sources as follows:

Reasons for WAC change
0 – No change/not applicable
1 – Change in administrative expenses
2 – Scheduled price change
3 – Change in ingredient costs
4 – Change in manufacturing
5 – Change in marketing & advertising costs
6 – Change in financial assistance
7 – Change in R&D costs
8 – Change in rebates to PBMs/wholesalers
9 – Other rebate change
10 – Change in supply (shortage or surplus)
11 – Change in sales costs
12 – Change in state and federal taxes
13 – Change in profit targets

14 – Change in supplier price (repackaged NDC)
15 – Other/Specify

Comment 7: (Manufacturer Report, Section 2 – Acquisition Price)
Acquisition Price - Because repackagers are a separate entity from manufacturers, a repackager is not privy to this information and therefore unable to report this data to MHDO. Again, it is imperative to view repackagers under a different lens than manufacturers to receive adequate, accurate data.

MHDO Staff Response: Manufacturers (including repackagers) are not required to provide an Acquisition Price unless the manufacturer has acquired the product within the previous five-year period.

Recommended Board Action: No further action needed.

Comment 8: (Wholesale Drug Distributor Report, Section 2 – Total Rebate Receivable in the US)
Total Rebate Receivable in the U.S. - As previously stated, HDA recommends MHDO utilize the federal definition of "rebate" to provide uniformity in the reporting requirements. HDA respectfully asks that MHDO clarify if this applies to any entity, i.e., CMS. Please include if the total rebate receivable amount accrued represents the total amount of any rebates that will be paid to the wholesale drug distributor resulting from the purchase and/or sale of a drug product during the calendar year. Such data would appear to be irrelevant and could include proprietary data.

MHDO Staff Response: Total Rebate Receivable in the US includes any and all rebates, as defined in Section 1(Q), for the drug product including the total amount of any rebates that will be paid to the wholesale drug distributor resulting from the purchase and/or sale of a drug product during the calendar year. Rebate values must be included regardless of the entity from which the rebate is receivable. MHDO cannot accurately calculate the cost of a drug product as it moves through the supply chain without accounting for all rebates provided to entities throughout.

Recommended Board Action: No further action needed.

Comment 9: (Wholesale Drug Distributor Report, Section 2 – Revenue in the US)
Revenue in the U.S. - HDA asks for clarity around the term revenue as it pertains to wholesale distributors in this report. Further, HDA requests MHDO clarify if Revenue from Sales may be provided net of processed returns if all other data components are also provided net of returns.

MHDO Staff Response: Revenue in the US is the total amount invoiced and accrued as receivable, including amounts recognized at the time of sale, for the sale of the drug product during the prior calendar year. MHDO agrees to add clarifying language that data values should be provided net of returns.

Recommended Board Action: Amend Section 2(J) as follows:

> **Reporting Specifications.** For each drug product NDC indicated in the MHDO notice, the reporting entity must report the following data. Data related to sales volume, acquisition volume, revenue, acquisition amount, and rebates should be provided net of returns.

Comment 10: (Wholesale Drug Distributor Report, Section 2 – Total Rebate Payable Amount in US)
Total Rebate Payable Amount in U.S. - HDA requests MHDO include whether this value represents the prior calendar year aggregate value of WAC at the time of purchase, multiplied by units purchased. If a wholesaler contracts to acquire drug products using a different cost basis, the aggregate value of that cost basis, multiplied by units purchased would appear more appropriate.

MHDO Staff Response: Total Rebate Payable Amount in US represents the total amount of any rebates, as defined in Section 1(Q), that will be paid by the wholesale drug distributor to any entity resulting from the purchase and/or sale of a drug product during the calendar year.

HDA's comment appears to be oriented to the definition of Total Acquisition Amount in US. Total Acquisition Amount in US represents all amounts paid by the wholesale drug distributor to acquire the drug product during the calendar year. While MHDO anticipates that this value will represent the prior calendar year aggregate value of WAC at the time of purchase multiplied by units purchased, if a wholesaler contracts to acquire drug products using an alternative cost basis, the aggregate value of such alternative cost basis multiplied by units purchased should be provided.

Recommended Board Action: No further action needed.

3. **Nicolas Doherty, PhRMA** submitted the following comments:

Comment 1: Statutory Authority (22 MRSA c. 1683, sub-3 sections 8732(1) and section 8732(2)
The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. PhRMA respectfully submits these comments related to the August 2020 Proposed Rule

("Proposed Rule") for the reporting and notification requirements in Chapter 570, Uniform Reporting System for Prescription Drug Price Data Sets ("Ch. 570"). While we strongly disagree with MHDO's interpretation that reporting requirements are unfettered and that proposed amendments to Ch. 570 are merely a "clarification" as described during the public hearing, we have appreciated the opportunity to work collaboratively with MHDO at every stage of the legislative and regulatory process thus far.

As we have previously articulated, it was the understanding of manufacturers that 22 MRSA c. 1683, sub-3 sections 8732(1) and section 8732(2) worked together so that if a manufacturer meets any one of the three criteria in 8732(1), then MHDO would be able to use 8732(2) to gather more information from the manufacturer relative to the triggering drug after notice is provided. This is the most reasonable reading of the statute and an approach that was reflected throughout the initial rulemaking process for Ch. 570. The Proposed Rule, on the other hand, would render 8732(1) largely meaningless.

We maintain that requiring reporting related to drugs not captured by 8732(1) is beyond the legislative scope of LD 1162, and specifically identify two key areas where the Proposed Rule exceeds this authority – the addition of a reporting trigger tied to reports required by subsection 5 of 22 MRSA §8712 ("25-25-25 report") as well as reporting requirements for all drugs "in the same drug product family" as those identified in 8732(1) and the 25-25-25 report. We discuss these concerns in further detail below.

Eliminating unnecessary data collection is a key consideration underlying our comments, as the reporting requirements under Ch. 570 are significant and take time to compile. Manufacturers need predictability/notice and time to gather appropriate information, particularly when there are civil penalties which may be as high as $30,000/day for non-compliance.

MHDO Staff Response: MHDO's governing statute, Title 22, Chapter 1683 does not limit the MHDO to collecting pricing component data on drugs that meet one of the three triggers defined in 22 MRS §8732(1). There is no language in 8732 suggesting any such limitation. Furthermore, there is language in other sections of PL 2019, Ch. 470[LD 1162] *An Act to Further Expand Drug Price Transparency* ("the Act") that indicate otherwise. The Act states that an objective of the MHDO is to create and maintain a health system database used to issue the report required by section 8736; that a duty of the MHDO Board of Directors is to develop and implement policies for the collection, processing, storage and analysis of prescription drug price data; and that the MHDO shall produce and post each year a report "including information developed from the notifications and disclosures received pursuant to this subchapter on trends in the cost of prescription drugs, analysis of manufacturer prices and price increases, the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and cost sharing and any other information the organization determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the State." The Act at Sections 1 (8703), 2 (8704) and 8 (8736).

It was always the intent (stated in the January 16, 2020 MHDO Comment and Response document) to not only focus on the reporting of pricing component data for drugs that meet one of the triggers defined in statute (new drug or price increases) but to additionally seek information related to drugs identified as the most costly, most utilized, or having the highest year over year increases in the MHDO's annual pharmacy report as required in 22 MRS §8712(5). Further, it has become clear that where drugs of interest are available from multiple sources, understanding the impact of competitive pricing for drug products that fall within the same drug product family is relevant information to providing greater consumer awareness on the factors contributing to the costs of prescription drugs in the state.

MHDO is not adding any new reporting triggers (which are specific only to Section 2(B)), but is instead providing clarity and predictability regarding the pool of NDCs for which MHDO intends to request pricing component data.

MHDO is not interested in unnecessary data collection. As discussed with the MHDO board and during the work session on 1162, MHDO intends to focus the reporting of pricing component data on relevant drug pricing information and may not require manufacturers to produce pricing component data for every drug that meets one of the triggers that requires a notification to MHDO. To provide predictability, the proposed changes in Section 2. C. 1. (a-c), state the methodology MHDO will apply to identify NDCs of interest for pricing component data. In addition, Section 2. C. 2. requires MHDO to publicly post the drugs that MHDO will request pricing component data for in mid-February. Section 2. C. 3. states MHDO cannot ask for pricing component data for 30 days after the posting. Reporting entities then have 60 days from the date we officially notify them of the NDCs for which we are requesting pricing component data. These changes will give reporting entities 90 days effective notice to provide the required prescription drug pricing component data.

Recommended Board Action: Approve the proposed changes.

Comment 2: (Definitions, Section 1 – Drug Product Family)
Drug Product Family: We are unclear about the intent and impact of changes in the Proposed Rule that would require reporting of prescription drugs, but read this definition and the term's use throughout the regulation to require that products which do not meet the criteria in 8732(1) or appear on the 25-25-25 report nevertheless would be subject to reporting because the products are within the same drug product family of a drug that satisfies one of the triggers. This is a significant overreach of regulatory authority and operates well beyond the scope of LD 1162.

By requiring reporting by manufacturers of prescription drugs included in the same drug product family as those found in 8732(1) and 8712, but which do not actually meet either trigger, MHDO would be acting beyond the scope of its delegated legislative authority and penalizing a

manufacturer based on a pricing decision of another company or other factors completely beyond the manufacturer's control such as appearance of a product in the same drug product family on the 25-25-25 report. The Proposed Rule creates significant disjointedness between the triggering products and the scope of products for which reporting would be required, which is concerning given the significant penalties associated with these requirements.

We would respectfully request the definition of "drug product family" and all uses of the term be removed from the Proposed Rule.

MHDO Staff Response: MHDO's governing statute, Title 22, Chapter 1683 does not limit the MHDO to collecting pricing component data on drugs that meet one of the three triggers defined in 22 MRS §8732(1). There is no language in 8732 suggesting any such limitation. Furthermore, there is language in other sections of PL 2019, Ch. 470[LD 1162] *An Act to Further Expand Drug Price Transparency* ("the Act") that indicate otherwise. The Act states that an objective of the MHDO is to create and maintain a health system database used to issue the report required by section 8736; that a duty of the MHDO Board of Directors is to develop and implement policies for the collection, processing, storage and analysis of prescription drug price data; and that the MHDO shall produce and post each year a report "including information developed from the notifications and disclosures received pursuant to this subchapter on trends in the cost of prescription drugs, analysis of manufacturer prices and price increases, the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and cost sharing and any other information the organization determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the State." The Act at Sections 1 (8703), 2 (8704) and 8 (8736).

It was always the intent (stated in the January 16, 2020 MHDO Comment and Response document) to not only focus on the reporting of pricing component data for drugs that meet one of the triggers defined in statute (new drug or price increases) but to additionally seek information related to drugs identified as the most costly, most utilized, or having the highest year over year increases in the MHDO's annual pharmacy report as required in 22 MRS §8712(5). Further, it has become clear that where drugs of interest are available from multiple sources, understanding the impact of competitive pricing for drug products that fall within the same drug product family is relevant information to providing greater consumer awareness on the factors contributing to the costs of prescription drugs in the state.

MHDO is not adding any new reporting triggers (which are specific only to Section 2(B)), but is instead providing clarity and predictability regarding the pool of NDCs for which MHDO intends to request pricing component data.

MHDO is not interested in unnecessary data collection. As discussed with the MHDO board and during the work session on 1162, MHDO intends to focus the reporting of pricing component data on relevant drug pricing information and may not require manufacturers to produce pricing

component data for every drug that meets one of the triggers that requires a notification to MHDO. To provide predictability, the proposed changes in Section 2. C. 1. (a-c), state the methodology MHDO will apply to identify NDCs of interest for pricing component data. In addition, Section 2. C. 2. requires MHDO to publicly post the drugs that MHDO will request pricing component data for in mid-February. Section 2. C. 3. states MHDO cannot ask for pricing component data for 30 days after the posting. Reporting entities then have 60 days from the date we officially notify them of the NDCs for which we are requesting pricing component data. These changes will give reporting entities 90 days effective notice to provide the required prescription drug pricing component data.

Recommended Board Action: Approve the proposed changes.

Comment 3: (Definitions, Section 1 – Manufacturers)
Manufacturers: The Proposed Rule amends the definition of "manufacturers" to include repackagers and we understand this change was made at the request of reporting entities. However, to avoid NDCs being reported multiple times by entities in the same reporting entity category, we request guidelines that outline which scenarios each entity should report to avoid unnecessary duplication.

MHDO Staff Response: Manufacturers should provide information regarding NDCs that are manufactured or repackaged by the reporting entity and for which the reporting entity sets the WAC price. A repackager should provide pricing component data for NDCs that apply to repackaged products, whereas a source manufacturer for repackaged products should provide pricing component data for source product NDCs.

Recommended Board Action: Approve the proposed changes.

Comment 4: (MHDO Notification to Reporters, Section 2(C)(1)(b))
We recognize MHDO's attempt to address predictability concerns by defining a trigger for reporting requirements to include any specific drug included on the 25-25-25 report along with a drug that meets any one of the three criteria in 8732(1), but continue to disagree that MHDO has the authority to include the 25-25-25 report as a trigger when it is not contemplated by the statute. The 25-25-25 report is not a trigger authorized by LD1162 nor was it contemplated during the legislative process.

The 25-25-25 report is expansive and includes the most frequently prescribed drugs in the state, the costliest drugs as determined by total spend, and the drugs with the highest year over year cost increase as determined by total spend. By nature, this report includes drugs for reasons outside of a manufacturer's control such as prescribing patterns and how data are reported by

third parties. For example, the claims data relied upon by MHDO reflects the paid amount as contracted between payors and pharmacies, not the net cost of a drug. Rebate information is not available in claims data because the payor does not receive the rebate until after the prescription has been purchased by the patient.

The Proposed Rule would impose significant reporting requirements on manufacturers, including of confidential and proprietary data, and the specter of significant penalties based on actions and reports they have no control over or data that may not accurately reflect costs with no opportunity to correct or rebut the report.

We reiterate our concerns that MHDO's expansion of reporting requirements beyond the statute will result in the ground rules – such as who needs to report or what needs to be reported – changing with some frequency. Given the complexity and regulatory nature of developing pricing component data, which is unique nationally, there is concern among reporters that the requirements could change from one reporting cycle to another. Such uncertainty is not only burdensome for reporters, but undermines any longitudinal data analysis if reporting requirements are not consistent from year to year and raises due process concerns in light of the penalties attached to the reporting requirements.

MHDO Staff Response: MHDO's governing statute, Title 22, Chapter 1683 does not limit the MHDO to collecting pricing component data on drugs that meet one of the three triggers defined in 22 MRS §8732(1). There is no language in 8732 suggesting any such limitation. Furthermore, there is language in other sections of PL 2019, Ch. 470[LD 1162] *An Act to Further Expand Drug Price Transparency* ("the Act") that indicate otherwise. The Act states that an objective of the MHDO is to create and maintain a health system database used to issue the report required by section 8736; that a duty of the MHDO Board of Directors is to develop and implement policies for the collection, processing, storage and analysis of prescription drug price data; and that the MHDO shall produce and post each year a report "including information developed from the notifications and disclosures received pursuant to this subchapter on trends in the cost of prescription drugs, analysis of manufacturer prices and price increases, the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and cost sharing and any other information the organization determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the State." The Act at Sections 1 (8703), 2 (8704) and 8 (8736).

It was always the intent (stated in the January 16, 2020 MHDO Comment and Response document) to not only focus on the reporting of pricing component data for drugs that meet one of the triggers defined in statute (new drug or price increases) but to additionally seek information related to drugs identified as the most costly, most utilized, or having the highest year over year increases in the MHDO's annual pharmacy report as required in 22 MRS §8712(5). Further, it has become clear that where drugs of interest are available from multiple sources, understanding the impact of competitive pricing for drug products that fall within the same drug

product family is relevant information to providing greater consumer awareness on the factors contributing to the costs of prescription drugs in the state.

MHDO is not adding any new reporting triggers (which are specific only to Section 2(B)), but is instead providing clarity and predictability regarding the pool of NDCs for which MHDO intends to request pricing component data.

MHDO is not interested in unnecessary data collection. As discussed with the MHDO board and during the work session on 1162, MHDO intends to focus the reporting of pricing component data on relevant drug pricing information and may not require manufacturers to produce pricing component data for every drug that meets one of the triggers that requires a notification to MHDO. To provide predictability, the proposed changes in Section 2. C. 1. (a-c), state the methodology MHDO will apply to identify NDCs of interest for pricing component data. In addition, Section 2. C. 2. requires MHDO to publicly post the drugs that MHDO will request pricing component data for in mid-February. Section 2. C. 3. states MHDO cannot ask for pricing component data for 30 days after the posting. Reporting entities then have 60 days from the date we officially notify them of the NDCs for which we are requesting pricing component data. These changes will give reporting entities 90 days effective notice to provide the required prescription drug pricing component data.

Recommended Board Action: Approve proposed changes.

Comment 5: (Reporting Specifications, Section 2(J)(1))
We recognize MHDO's attempt to streamline the reporting forms, however, we are concerned this merger would result in confusion for a reporting entity and result in incomplete or unhelpful data. For example, the previous "New Drug" reporting form focused on information applicable to a new product – introduction date, estimated patient population, acquisition cost, etc. Now, that reporting is blended with more general reporting for existing products, and many items no longer make sense or will lead to inconsistent data (e.g., reporting elements focusing on "prior year" will capture a full year for some products and inconsistent partial year data for new products depending on launch date.). We recommend reverting to separate forms for new launches and increases/other products.

MHDO Staff Response: The consolidation of data elements into a single manufacturer report will streamline the reporting process and provide consistency in the pricing component data elements collected for all drugs. In an effort to minimize confusion, MHDO will take the date of market introduction into consideration for first year drug products when analyzing pricing component data for the following data elements:

- Baseline WAC Amount
- Total WAC Change Amount
- WAC After Change

- Unit Sales Volume in US
- Revenue in US
- Total Rebate Payable Amount in US
- Cost Change Factors

Recommended Board Action: Approve the proposed changes.

Comment 6: (Reporting Specifications, Section 2(J)(1) – Baseline WAC Amount)
We seek further clarification on the following reporting element categories:

"Baseline WAC Amount" – Although this element was also included in the previously finalized rules, an illustrative example of how to calculate this item in guidance would help to clarify how the amount is calculated.

MHDO Staff Response: Baseline WAC Amount provides MHDO with the starting point WAC price of an NDC during a reporting period. For a majority of NDCs the starting point price will be the WAC for the NDC on the last day of the prior calendar year. In some instances, however, a manufacturer may launch a new drug product or acquire a drug product during the reporting period. In such instances, the initial WAC price at market introduction or product acquisition is the Baseline WAC Amount. The difference between the Baseline WAC Amount and the WAC price on the last day of the reporting period will be the Total WAC Change Amount.

Recommended Board Action: No further action needed.

Comment 7: (Reporting Specifications, Section 2(J)(1) – Total Rebate Payable Amount)
We seek further clarification on the following reporting element categories:

"Total Rebate Payable Amount" - While a 'total rebate' amount must be provided by multiple reporters, neither the regulatory definition nor the form clarifies the scope of this requirement. To ensure consistency in reporting, we recommend clarifying the scope of this reporting is limited to the private, commercial market.

MHDO Staff Response: Total Rebate Payable Amount in US represents the total amount of any and all rebates, as defined in Section 1(Q), that will be paid to any entity, whether governmental, private, or commercial, resulting from the purchase and/or sale of a drug product during the calendar year.

Recommended Board Action: No further action needed.

Comment 8: (Reporting Specifications, Section 2(J)(1) – Estimated Number of Patients)
We seek further clarification on the following reporting element categories:

"Estimated Number of Patients" – In the Proposed Rule, other reporting elements specify the data be from the prior calendar year. We would recommend that this element be clarified to apply to the prior calendar year.

MHDO Staff Response: The Estimated Number of Patients data element is intended to provide MHDO a forward-looking estimate of drug demand in the market based on market conditions at the time of reporting. Manufacturers should provide their best estimate of the number of patients that will use the drug product during the current year.

Add clarifying language to the data element description to specify reporting for the current year.

Recommended Board Action: Amend Section 2(J)(1), Estimated Number of Patients Description/Codes/Sources as follows:

> Estimated annual patient volume in the United States for this drug product <u>during the current calendar year</u>.

Comment 9: (Confidentiality, Section 6)
In the event MHDO codifies new reporting requirements from subsection 5 of 22 MRSA §8712, MHDO should be clear that the same confidentiality protections in Sec. 8. 22 MRSA c. 1683, sub-c. 3, § 8733 apply to any new information submitted by manufacturers.

MHDO Staff Response: The confidentiality provisions in Sec. 8. 22 MRSA c. 1683, sub-c. 3, § 8733 apply to all pricing component data submitted to MHDO under Rule Chapter 570.

Recommended Board Action: No further action needed.

4. MHDO Staff submitted the following comments:

It has come to my attention that in the drafting of our proposed rule changes to Rule Chapter 570, Uniform Reporting System for Prescription Drug Price Data Sets, the Manufacturer Report includes two data elements *Introduced to Market Date* and *WAC at Market Introduction,* that were listed twice in the template. These data elements should only be listed once. Additionally, we would like to include the following revisions in the descriptions of these data elements to further clarify their definitions. (Underline and cross outs represent the proposed revisions):

Introduced to Market Date – If the drug product was introduced to market within the previous calendar year or acquired by the manufacturer within the previous five years, the date the drug product was introduced to market. If not, leave blank.

WAC at ~~Introduction to~~ Market Introduction –If the drug product was introduced to market during the previous calendar year or acquired by the manufacturer within the previous five years, the wholesale acquisition cost of the drug product when it was introduced to market. If not, leave blank.

MHDO Staff Response: Delete the data elements name and description for, Introduced to Market Date and WAC at Market Introduction (page 7). Revise the description for Introduced to Market Date and WAC at Market Introduction page 8 and 9 as described above.

Introduced to Market Date – If the drug product was introduced to market within the previous calendar year or acquired by the manufacturer within the previous five years, the date the drug product was introduced to market. If not, leave blank.

WAC at ~~Introduction to~~ Market Introduction –If the drug product was introduced to market during the previous calendar year or acquired by the manufacturer within the previous five years, the wholesale acquisition cost of the drug product when it was introduced to market. If not, leave blank.

Recommended Board Action: Revise the Manufacturer Report as described above.

APPROVED | CHAPTER
JUNE 24, 2019 | 470
BY GOVERNOR | PUBLIC LAW

STATE OF MAINE

IN THE YEAR OF OUR LORD

TWO THOUSAND NINETEEN

S.P. 350 - L.D. 1162

An Act To Further Expand Drug Price Transparency

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §8703, sub-§1, as amended by PL 2003, c. 469, Pt. C, §22, is further amended to read:

1. Objective. The purposes of the organization are to create and maintain a useful, objective, reliable and comprehensive health information database that is used to improve the health of Maine citizens and to issue reports, as provided in ~~section~~ sections 8712 and 8736. This database must be publicly accessible while protecting patient confidentiality and respecting providers of care. The organization shall collect, process, analyze and report clinical, financial, quality and restructuring data as defined in this chapter.

Sec. 2. 22 MRSA §8704, sub-§1, ¶A, as amended by PL 2003, c. 469, Pt. C, §23, is further amended to read:

A. The board shall develop and implement policies and procedures for the collection, processing, storage and analysis of clinical, financial, quality ~~and~~, restructuring and prescription drug price data in accordance with this subsection for the following purposes:

(1) To use, build and improve upon and coordinate existing data sources and measurement efforts through the integration of data systems and standardization of concepts;

(2) To coordinate the development of a linked public and private sector information system;

(3) To emphasize data that is useful, relevant and not duplicative of existing data;

(4) To minimize the burden on those providing data; and

(5) To preserve the reliability, accuracy and integrity of collected data while ensuring that the data is available in the public domain.

(27)

Sec. 3. 22 MRSA §8705-A, first ¶, as enacted by PL 2003, c. 659, §2 is further amended to read:

The board shall adopt rules to ensure that payors ~~and~~, providers, prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers file data as required by section 8704, subsection 1; that users that obtain health data and information from the organization safeguard the identification of patients and health care practitioners as required by section 8707, subsections 1 and 3; and that payors ~~and~~, providers, prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers pay all assessments as required by section 8706, subsection 2.

Sec. 4. 22 MRSA §8705-A, first ¶, as amended by PL 2013, c. 528, §6 and affected by §12, is further amended to read:

The board shall adopt rules to ensure that payors ~~and~~, providers, prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers file data as required by section 8704, subsection 1; that users that obtain health data and information from the organization safeguard the identification of patients and health care practitioners as required by section 8714, subsections 2, 3 and 4; and that payors ~~and~~, providers, prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers pay all assessments as required by section 8706, subsection 2.

Sec. 5. 22 MRSA §8705-A, sub-§3, ¶A, as amended by PL 2007, c. 136, §4, is further amended to read:

A. When a person or entity that is a health care facility ~~or~~, payor, prescription drug manufacturer, wholesale drug distributor or pharmacy benefits manager violates the requirements of this chapter, except for section 8707, that person or entity commits a civil violation for which a fine of not more than $1,000 per day may be adjudged. A fine imposed under this paragraph may not exceed $25,000 for any one occurrence.

Sec. 6. 22 MRSA §8705-A, sub-§3, ¶A, as amended by PL 2013, c. 528, §7 and affected by §12, is further amended to read:

A. When a person or entity that is a health care facility ~~or~~, payor, prescription drug manufacturer, wholesale drug distributor or pharmacy benefits manager violates the requirements of this chapter, except for section 8714, that person or entity commits a civil violation for which a fine of not more than $1,000 per day may be adjudged. A fine imposed under this paragraph may not exceed $25,000 for any one occurrence.

Sec. 7. 22 MRSA §8706, sub-§2, as amended by PL 2007, c. 136, §5, is further amended to read:

2. Permanent funding. Permanent funding for the organization is provided from reasonable costs, user fees and assessments according to this subsection and as provided by rules adopted by the board.

A. Fees may be charged for the reasonable costs of duplicating, mailing, publishing and supplies.

B. Reasonable user fees must be charged on a sliding scale for the right to access and use the health data and information available from the organization. Fees may be charged for services provided to the department on a contractual basis. Fees may be reduced or waived for users that demonstrate a plan to use the data or information in research of general value to the public health or inability to pay the scheduled fees, as provided by rules adopted by the board.

C. The operations of the organization must be supported from ~~3~~ 4 sources as provided in this paragraph:

(1) Fees collected pursuant to paragraphs A and B;

(2) Annual assessments of not less than $100 assessed against the following entities licensed under Titles 24 and 24-A: nonprofit hospital and medical service organizations, health insurance carriers and health maintenance organizations on the basis of the total annual health care premium; and 3rd-party administrators, carriers that provide only administrative services for a plan sponsor and pharmacy benefits managers that process and pay claims on the basis of claims processed or paid for each plan sponsor. The assessments are to be determined on an annual basis by the board. Health care policies issued for specified disease, accident, injury, hospital indemnity, disability, long-term care or other limited benefit health insurance policies are not subject to assessment under this subparagraph. For purposes of this subparagraph, policies issued for dental services are not considered to be limited benefit health insurance policies. The total dollar amount of assessments under this subparagraph must equal the assessments under subparagraph (3); ~~and~~

(3) Annual assessments of not less than $100 assessed by the organization against providers. The assessments are to be determined on an annual basis by the board. The total dollar amount of assessments under this subparagraph must equal the assessments under subparagraph (2)~~.~~; and

(4) Annual assessments of $500 assessed by the organization against prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers.

The aggregate level of annual assessments under subparagraphs (2) ~~and~~, (3) and (4) must be an amount sufficient to meet the organization's expenditures authorized in the state budget established under Title 5, chapter 149. ~~The annual assessment may not exceed $1,346,904 in fiscal year 2002-03. In subsequent fiscal years, the annual assessment may increase above $1,346,904 by an amount not to exceed 5% per fiscal year.~~ The board may waive assessments otherwise due under subparagraphs (2) ~~and~~, (3) and (4) when a waiver is determined to be in the interests of the organization and the parties to be assessed.

Sec. 8. 22 MRSA c. 1683, sub-c. 3 is enacted to read:

SUBCHAPTER 3

PRESCRIPTION DRUG PRICING FOR PURCHASERS

§8731. Definitions

As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

1. Brand-name drug. "Brand-name drug" means a prescription drug marketed under a proprietary name or registered trademark name, including a biological product.

2. Generic drug. "Generic drug" means a prescription drug, whether identified by its chemical, proprietary or nonproprietary name, that is not a brand-name drug and is therapeutically equivalent to a brand-name drug in dosage, safety, strength, method of consumption, quality, performance and intended use. "Generic drug" includes a biosimilar product.

3. Manufacturer. "Manufacturer" means a manufacturer of prescription drugs that are distributed in the State.

4. Pricing component data. "Pricing component data" means data unique to each manufacturer, wholesale drug distributor or pharmacy benefits manager subject to this subchapter that evidences the cost to each manufacturer, wholesale drug distributor or pharmacy benefits manager to make a prescription drug available to consumers and the payments received by each manufacturer, wholesale drug distributor or pharmacy benefits manager to make a prescription drug available to consumers, taking into account any price concessions, and that is measured uniformly among the entities, as determined by rules adopted by the organization pursuant to section 8737.

5. Pricing unit. "Pricing unit" means the smallest dispensable amount of a prescription drug that could be dispensed.

6. Wholesale acquisition cost. "Wholesale acquisition cost" means a manufacturer's listed price for sale to a wholesale drug distributor or other entity that purchases a prescription drug directly from the manufacturer, not including any price concessions.

§8732. Drug price notifications and disclosures

1. Notifications by manufacturers. No later than January 30, 2020 and annually thereafter, a manufacturer shall notify the organization when the manufacturer has during the prior calendar year:

A. Increased the wholesale acquisition cost of a brand-name drug by more than 20% per pricing unit;

B. Increased the wholesale acquisition cost of a generic drug that costs at least $10 per pricing unit by more than 20% per pricing unit; or

C. Introduced a new drug for distribution in this State when the wholesale acquisition cost is greater than the amount that would cause the drug to be considered a specialty drug under the Medicare Part D program. For the purposes of this

subsection, "Medicare Part D" has the same meaning as in section 254-D, subsection 1, paragraph F.

2. Disclosures by manufacturers, wholesale drug distributors and pharmacy benefits managers. Within 60 days of a request from the organization relating to a specific prescription drug, a manufacturer, wholesale drug distributor or pharmacy benefits manager shall notify the organization of pricing component data per pricing unit of a drug.

§8733. Confidentiality

Information provided to the organization as required by this subchapter by a manufacturer, wholesale drug distributor or pharmacy benefits manager is confidential and not a public record under Title 1, chapter 13, except that the organization may share information:

1. Bureau of Insurance. With the Department of Professional and Financial Regulation, Bureau of Insurance, to the extent necessary for the bureau to enforce the provisions of Title 24-A, as long as any information shared is kept confidential; and

2. Aggregate. In the aggregate, as long as it is not released in a manner that allows the identification of an individual drug or manufacturer, wholesale drug distributor or pharmacy benefits manager.

§8734. Registration requirements

Beginning January 1, 2020, a manufacturer and wholesale drug distributor subject to this subchapter shall register annually with the organization in a manner prescribed by the organization.

§8735. Compliance

1. Certification of accuracy. A manufacturer, wholesale drug distributor or pharmacy benefits manager that submits a notification or report to the organization pursuant to this subchapter shall submit with the notification or report a signed written certification of the notification's or report's accuracy.

2. Civil penalty. A manufacturer, wholesale drug distributor or pharmacy benefits manager that violates this subchapter commits a civil violation for which a fine of $30,000 may be adjudged for each day of the violation.

3. Audit. The organization may audit the data submitted by a manufacturer, wholesale drug distributor or pharmacy benefits manager pursuant to this subchapter. The manufacturer, wholesale drug distributor or pharmacy benefits manager shall pay for the costs of the audit.

4. Corrective action plan. The organization may require a manufacturer, wholesale drug distributor or pharmacy benefits manager subject to this subchapter to develop a corrective action plan to correct any deficiencies the organization finds with the

manufacturer's, wholesale drug distributor's or pharmacy benefits manager's compliance with this subchapter.

§8736. Public report

Beginning November 1, 2020 and annually thereafter, the organization shall produce and post on its publicly accessible website an annual report, including information developed from the notifications and disclosures received pursuant to this subchapter on trends in the cost of prescription drugs, analysis of manufacturer prices and price increases, the major components of prescription drug pricing along the supply chain and the impacts on insurance premiums and cost sharing and any other information the organization determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the State. The report may not disclose information attributable to any particular manufacturer, wholesale drug distributor or pharmacy benefits manager subject to this subchapter and may not make public any information that is confidential pursuant to section 8733. The organization shall submit the report required by this section to the joint standing committee of the Legislature having jurisdiction over health data reporting and prescription drug matters and the committee may report out legislation to the first regular or second regular session of the Legislature, depending on the year in which the report is submitted.

§8737. Rulemaking

The organization may adopt rules to implement this subchapter. Rules adopted pursuant to this section are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 9. Maine Revised Statutes headnote amended; revision clause. In the Maine Revised Statutes, Title 22, chapter 1683, before section 8701, the headnote "subchapter 1, general provisions" is enacted and the Revisor of Statutes shall implement this revision when updating, publishing or republishing the statutes.

Sec. 10. Initial rulemaking. Notwithstanding the Maine Revised Statutes, Title 22, section 8737, the Maine Health Data Organization may adopt emergency rules that are otherwise in accordance with section 8737 to implement the provisions of Title 22, chapter 1683, subchapter 3 and may adopt routine technical rules to implement that subchapter before April 1, 2020.