TESTIMONY OF

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Maine Health Data Organization

Before the Joint Standing Committee on Health Coverage, Insurance & Financial Services

Public Hearing Date: February 16, 2023

L.D. 375

"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"

Senator Bailey and Representative Perry and members of the Joint Standing Committee on Health Coverage, Insurance & Financial Services. My name is Karynlee Harrington; I am the Executive Director of the Maine Health Data Organization (MHDO) and the Maine Quality Forum (MQF). I am here today to present testimony in support of LD 375, the proposed changes to MHDO's Rule Chapter 570, *Uniform Reporting System for Prescription Drug Price Data Sets*.

Role of MHDO

The Maine Health Data Organization (MHDO) is authorized by statute to collect health care data, including prescription drug price data. The purpose of Chapter 570 is to explain the provisions for filing prescription drug price sets from prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers. The primary purpose for this rule change is 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.

MHDO Board of Directors Public Hearing

The MHDO Board of Directors (the board) met on April 7, 2022, and authorized MHDO to initiate rulemaking for Chapter 570. The proposed rule was publicly noticed on September 14, 2022, and a public hearing was held on October 6, 2022. Public comments were received at the public hearing and by the 10-day comment period deadline of October 17, 2022. The Board met on December 1, 2022, where they reviewed and discussed the public comments received and considered staff's recommendations regarding how to address each comment. At the end of the process the board unanimously voted to provisionally adopt the rule changes presented to you today.

Summary of Proposed Changes

Attached to my testimony is a description of each proposed rule change and rationale for the change (Attachment A). A copy of the Basis Statement which includes the Public Comments and Response Document (Attachment B); and a copy of Rule Chapter 570 with the proposed changes identified in track changes (Attachment C). Lastly, I would like to bring to the Committees' attention a reference correction that should be made in Section 2. C. 1. a.

The current language is as follows:

Included in the public notice of substantial drug price change or introduction under subsection 2(C); and;

The correction is as follows:

Included in the public notice of substantial drug price change or introduction under subsection 2(~~C~~ B); and;

This concludes my testimony. I would be happy to answer questions now or at the work session.

90-590 Maine Health Data Organization

Planning for Public Hearing – October 6, 2022

Attachment A

Proposed Rule Summary of Changes and Basis Statement Chapter 570: Uniform Reporting System for Prescription Drug Price Data Sets

(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 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 following represent the proposed 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.

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: TBD

MHDO Maine Health Data Organization

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Attachment B

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.

2. 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

Proposed Responses to Written Comments-Rule 570. Discussed with MHDO Board 12/01/2022-unanimously approved.

Attachment C

90-590 C.M.R. Chapter 570

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.

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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.

C. **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.

D. **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.

E. **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.

F. **Introduced to Market.** "Introduced to Market" means made available for purchase in the United States.

G. **Manufacturer.** "Manufacturer" means an entity that manufactures or repackages, and sets the wholesale acquisition cost for, prescription drugs that are distributed in the State.

H. **MHDO.** "MHDO" means the Maine Health Data Organization.

I. **M.R.S.** "M.R.S." means *Maine Revised Statutes*.

J. **National Drug Code (NDC).** "National Drug Code (NDC)" means the three-segment code maintained by the federal Food and Drug Administration that includes a labeler code, a product code, and a package code for a drug product and that has been converted to an 11-digit format consisting of five digits in the first segment, four digits in the second segment, and two digits in the third segment. A three-segment code shall be considered converted to an 11-digit format when, as necessary, at least one "0" has been added to the front of each segment containing less than the specified number of digits such that each segment contains the specified number of digits.

K. **New Prescription Drug.** "New prescription drug" means a drug receiving initial approval under an original new drug application under 21 United States Code, Section 355(b), under an abbreviated new drug application under 21 United States Code, Section 355(j), or under a biologics license application under 42 United States Code, Section 262. Each product listed on the application shall be considered a new prescription drug.

L. **Nonproprietary name.** "Nonproprietary name" means the generic name assigned by the United States Adopted Names (USAN) Council.

M. **Pharmacy Benefits Manager (PBM).** "Pharmacy Benefits Manager (PBM)" means an entity that performs pharmacy benefits management, as defined in 24-A M.R.S. §4347, sub-section 17.

N. **Prescription drug.** "Prescription drug" means a drug, as defined in 21 United States Code, Section 321(g) or a biological product as defined in 42 United States Code, Section 262(i)(1) that:

   i. Is intended for human use;

   ii. Is not a device within the meaning of 21 United States Code, Section 321(h); and

   iii. By federal or state law, can be lawfully dispensed or administered only on prescription by a licensed health care professional.

O. **Pricing component data.** "Pricing component data" means data unique to each reporting entity subject to this rule that evidences the cost to each reporting entity to make a prescription drug product available to consumers and the payments received by each reporting entity to make a prescription drug product available to consumers, taking into account any price concessions, and that is measured uniformly among and between the

entities, as detailed by this rule adopted by the organization pursuant to 22 M.R.S. § 8737.

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

Q. **Proprietary name.** "Proprietary name" means the brand or trademark name of the drug reported to the FDA.

R. **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 42 Code of Federal Regulations, Section 447.502, published October 1, 2019.

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

T. **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.

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

V. **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.

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

i. is licensed by the State to engage in the sale of prescription drugs to persons and/or entities other than a consumer or patient; and

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. **Registration.** 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 (https://mhdo.maine.gov/pharma_portal/) by January 30th of each year. It is the responsibility of the reporting entity to complete, as needed, all company and contact information.

B. **Public Notice of Substantial Drug Price Change or Introduction.** No later than January 30th of each year, the MHDO shall produce and post on its publicly accessible website a list of prescription drugs for which the manufacturer has during the prior calendar year:

1) Increased the wholesale acquisition cost of a brand-name drug by more than 20% per pricing unit;
2) 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
3) Introduced a new prescription 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 (hereinafter "new drug"). For the purposes of this paragraph, "Medicare Part D" has the same meaning as in 22 M.R.S. § 254-D(1)(F).

C. **Disclosures by manufacturers, wholesale drug distributors and pharmacy benefits managers.** The following disclosures apply to manufacturers, wholesale drug distributors and pharmacy benefits managers.

1) On or before February 15th of each year, the MHDO shall produce and post on its publicly accessible website a list of drug product families for which it intends to request pricing component data from manufacturers, wholesale drug distributors and pharmacy benefits managers. The MHDO will base its inclusion of drug product families on any information the MHDO determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the State, and the MHDO will consider drug product families of prescription drugs:
    a) Included in the public notice of substantial drug price change or introduction under subsection 2(B); and ;
    b) For which the MHDO is required to produce an annual report pursuant to 22 M.R.S. § 8712(5), including, but not limited to, the 25 costliest drugs (determined by the total amount spent in the State), the 25 most frequently prescribed drugs in the State, and the 25 drugs with the highest year-over-year cost increases (determined by the total amount spent in the State).
    c)
2) Not sooner than 30 days after publicly posting the list of drug product families pursuant to subsection C(1), the MHDO will notify, via e-mail:

a) manufacturers that are required to report pricing component data as detailed in section 2(J)(1);

b) wholesale drug distributors that are required to report pricing component data as detailed in section 2(J)(2); and

c) pharmacy benefits managers that are required to report pricing component data as detailed in section 2(J)(3).

3) Each reporting entity receiving such a notification shall submit their pricing component data to the 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 subsection 2(C)(2).

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 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 should be provided net of returns.

1) Manufacturer 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.
Drug Indicator	1 = Brand Name; 2 = Generic
Estimated Number of Patients	Estimated annual patient volume in the United States for this drug product during the current calendar year.
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 Change Amount	The total amount of wholesale acquisition cost change for the drug product during the last calendar year. Indicate $0 if no change.
WAC After Change	The wholesale acquisition cost resulting from the reported wholesale acquisition cost 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.
Unit Sales Volume in US	The number of units of the drug product sold in the United States during the prior calendar year.
Revenue in US	Gross revenue from sales in the United States for this drug product during the prior calendar year.
Total Rebate Payable Amount in US	Total rebate payable amount accrued for the drug product in the United States during the prior calendar year.
Cost Change Factors	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

Data Element Name	Description/Codes/Sources
	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
Acquisition Date	If the drug product was acquired by the manufacturer within the previous five years, the date of acquisition. If not, leave blank.
Company Acquired from Name	If the drug product was acquired by the manufacturer within the previous five years, the name of the company from which the drug was acquired. If not, leave blank.
Company Acquired from Tax ID Number	If the drug product was acquired by the manufacturer within the previous five years, the TIN of the company from which the drug was acquired. If not, leave blank.
Acquisition Price	If the drug product was acquired by the manufacturer within the previous five years, the purchase price of acquisition. If not, leave blank.
WAC at Acquisition	If the drug product was acquired by the manufacturer within the previous five years, and the acquisition date falls after the introduced to market date, the wholesale acquisition cost of the drug product at the time of acquisition. If not, leave blank.
WAC One Year Prior to Acquisition	If the drug product was acquired by the manufacturer within the previous five years, and the acquisition date falls more than 365 days after the introduced to market date, the wholesale acquisition cost of the drug product one year prior to the date of acquisition. If not, leave blank.
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 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.

2) Wholesale Drug Distributor 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.
Unit Acquisition Volume in US	The number of units of the drug product acquired in the United States by the wholesale drug distributor during the prior calendar year.
Total Acquisition Amount in US	Total spent before rebates by the wholesale drug distributor to acquire the drug product in the United States during the prior calendar year.
Total Rebate Receivable Amount in US	Total rebate receivable amount accrued by the wholesale drug distributor for the drug product in the United States during the prior calendar year.
Unit Sales Volume in US	Number of units of the drug product sold by the wholesale drug distributor in the United States during the prior calendar year.
Revenue in US	Gross revenue from sales in the United States generated by the wholesale drug distributor for this drug product during the prior calendar year.
Total Rebate Payable Amount in US	Total rebate payable amount accrued by the wholesale drug distributor for the drug product in the United States during the prior calendar year.
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 Maine	The number of pricing units of the drug product filled in Maine for which the PBM administered claims during the prior calendar year.
Total Pharmacy Reimbursement in Maine	Total reimbursement amount accrued and payable to pharmacies for pricing units of the drug product filled in Maine for which the PBM administered claims during the prior calendar year.
Total Payment Received in Maine	Total reimbursement and/or administrative fee amount accrued and receivable from payers for pricing units of the drug product filled in Maine for which the PBM administered claims during the prior calendar year.
Total Rebate Receivable Amount in Maine	Total rebate receivable amount accrued by the PBM for the drug product in Maine during the prior calendar year.
Total Rebate Payable Amount in Maine	Total rebate payable amount accrued by the PBM for the drug product in Maine during the prior calendar year.
General Comments	Additional information related to the data submitted for this drug product, if applicable.

3. Evaluation; Notification; Response

A. **Evaluation.** The MHDO or its vendor shall evaluate each file in accordance with the following standards:

1) When applicable, only an eligible code value for a specified data element shall be accepted;

2) Coding values indicating "data not available", "data unknown", or the equivalent shall not be used for individual data elements unless specified as an eligible value for the element.

B. **Notification.** Upon completion of the data evaluation, the MHDO or its designee will promptly notify each reporting entity whose data submissions do not satisfy the standards for any filing period. This notification will identify the specific file and the data elements within them that do not satisfy the standards.

C. **Response.** Each reporting entity notified under subsection 3(B) will respond within 30 days of the notification by making and reporting the changes necessary to satisfy the standards.

4. Compliance

A. **Certification of accuracy.** A notification or report to the MHDO by a reporting entity shall include a signed, written certification of the notification or report's accuracy. Reporting entities will be allowed to attest to the accuracy of their notification or report through the MHDO Prescription Drug Price Data Portal web interface. Confirmation will be documented electronically and will count as the written certification.

B. **Audit.** With a 30-day notice, the MHDO may audit the finalized data submitted by a reporting entity, and that entity shall pay for the costs of the audit. The MHDO will consider recommendations from the reporting entity as to the scope of the audit and the selection of the independent auditor.

C. **Corrective action plan.** The MHDO may require a reporting entity to develop a corrective action plan to correct any deficiencies in compliance discovered during an audit. The corrective action plan shall include, in writing: the specific requirement to be extended; an explanation of the cause; the methodology proposed to eliminate the necessity of the extension; and the time frame required to come into compliance.

D. **Enforcement.** The failure to file, report, or correct prescription drug price data sets when required in accordance with the provisions of this Chapter may be considered a civil violation under 22 M.R.S. § 8705-A and Code of Maine Rules 90-590, Chapter 100: *Enforcement Procedures*.

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;

B. **Aggregate.** In the aggregate, as long as it is not released in a manner that allows the determination of individual prescription drug pricing contract terms covering a manufacturer, wholesale drug distributor or pharmacy benefits manager; and

C. **Publicly Available.** That is available, for purchase or otherwise, to the public.

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
December 10, 2021