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.

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

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

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

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

H. **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.

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

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

K. **Pharmacy Benefits Manager (PBM).** "Pharmacy Benefits Manager (PBM)" means an entity that performs pharmacy benefits management, as defined in 24A M.R.S. §1913.

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

   i. is intended for human use;

   ii. is not a device within the meaning of Section 321(h) of Title 21 of the United States Code;

   iii. by federal or state law, can be lawfully dispensed only on prescription by a licensed healthcare professional.

M. **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., Chapter 1683, Section 8737.

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

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

P. **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. **Reporting entity.** "Reporting entity" means any manufacturer, pharmacy benefits manager, wholesale drug distributor, or any other entity required to report pursuant to 22 M.R.S., Sections 8732, 8734 and 8735.

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

T. **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.

U. **Wholesale drug distributor.** "Wholesale drug distributor" means an entity 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.

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. **Notifications by Manufacturers.** No later than March 31st, 2020 and January 30th of each year thereafter, a manufacturer shall notify the MHDO via the MHDO Prescription Drug Price Data Portal web interface when the manufacturer has during the prior calendar year:

(Note: Only those price increases taken on or after September 19, 2019 count toward the thresholds defined below.)

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").

C. **MHDO Notification to Manufacturers, Wholesale Distributors and Pharmacy Benefit Managers.**

1) **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) or 2(J)(2), respectively.

2) **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)(3).

3) **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)(4).

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 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.

1) Manufacturer Report for New Drugs

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	The date that the drug product was introduced to market.
WAC at Market Introduction	Wholesale acquisition cost of the drug product at market introduction.
Estimated Number of Patients	Estimated patient volume in the United States for this drug product
Acquisition Date	If the drug product was acquired by the manufacturer within the previous five years, the date of that acquisition.
Acquisition Price	If the drug product was acquired by the manufacturer within the previous five years, the purchase price of acquisition.
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) 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
WAC Effective Date	The effective date of the wholesale acquisition cost increase for the drug product.
WAC Increase Amount	The amount of wholesale acquisition cost increase for the drug product.
WAC After Increase	The wholesale acquisition cost resulting from the reported cost increase for the drug product.
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 calendar year of the cost increase.
Revenue in US	Revenue from sales in the United States for this drug product during the calendar year of the cost increase.
Total Rebate Payable Amount	Total rebate payable amount accrued for the drug product during the prior calendar year.
Cost Increase Factors	Reasons for WAC increase. 1 – Administrative expenses 2 – Scheduled price increase 3 – Changes in ingredient costs 4 – Changes in manufacturing 5 – Increased marketing & advertising costs 6 – Financial assistance 7 – R&D costs 8 – Rebates to PBMs/wholesalers 9 – Other rebates 10 – Supply shortage 11 – Sales costs 12 – State and Federal taxes 13 – Increase in profit targets 14 - Other/Specify

Data Element Name	Description/Codes/Sources
Acquisition Date	If the drug product was acquired by the manufacturer within the previous five years, the date of acquisition.
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.
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.
Acquisition Price	If the drug product was acquired by the manufacturer within the previous five years, the purchase price of acquisition.
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.
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.
Introduced to Market Date	If the drug product was acquired by the manufacturer within the previous five years, the date the drug product was introduced to market.
WAC at Introduction to Market	If the drug product was acquired by the manufacturer within the previous five years, the wholesale acquisition cost of the drug product when it was introduced to market.
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) 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	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	Total rebate receivable amount accrued by the wholesale drug distributor for the drug product 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	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	Total rebate payable amount accrued by the wholesale drug distributor for the drug product during the prior calendar year.
General Comments	Additional information related to the data submitted for this drug product, if applicable.

4) 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	The number of pricing units of the drug product filled for which the PBM administered claims during the prior calendar year.
Total Pharmacy Reimbursement	Total reimbursement amount accrued and payable to pharmacies for pricing units of the drug product filled for which the PBM administered claims during the prior calendar year.
Total Payment Received	Total reimbursement and/or administrative fee amount accrued and receivable from payers for pricing units of the drug product filled for which the PBM administered claims during the prior calendar year.
Total Rebate Receivable Amount	Total rebate receivable amount accrued by the PBM for the drug product 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.

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. Sec. 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 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