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**90-590 MAINE HEALTH DATA ORGANIZATION****Chapter 800: UNIFORM REPORTING OF WHOLESALE ACQUISITION COSTS FOR INSULIN.**

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**SUMMARY:** This Chapter provides for the reporting of acquisition costs of insulin from manufacturers of insulin to the Maine Health Data Organization, pursuant to Public Law 2023, Chapter 610.

The provisions include:

Identification of the manufacturers required to report;

Establishment of requirements for the content, format, method, and time frame for filing insulin wholesale acquisition cost 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. **Category of Insulin.** “Category of Insulin” means rapid-acting, short-acting, immediate- acting, long-acting and premixed insulin for which at least 2 licenses have been issued by the federal Food and Drug Administration and are actively marketed pursuant to such licensure in a category.
- B. **Insulin.** “Insulin” has the same meaning as in Title 32, section 13786-D, subsection 1, paragraph A and includes insulin or an insulin pen that is licensed under the federal Public Health Service Act, 42 United States Code, Section 262(a) or 262(k).
- C. **Manufacturer.** “Manufacturer” means an entity that manufactures or repackages, and sets the wholesale acquisition cost for, prescription drugs that are distributed in the State.
- D. **MHDO.** “MHDO” means the Maine Health Data Organization.
- E. **M.R.S.** “M.R.S.” means *Maine Revised Statutes*.
- F. **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.

- G. **Pricing unit.** “Pricing unit” means the smallest dispensable amount of a prescription drug product that could be dispensed or administered.
- H. **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.

## 2. Submission Requirements

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

- A. **Submission.** Each manufacturer required to report shall complete an online form, or update an existing one, via the MHDO Prescription Drug Price Data Portal web interface ([https://mhdo.maine.gov/pharma\\_portal/](https://mhdo.maine.gov/pharma_portal/)) by February 15<sup>th</sup> of each year. It is the responsibility of the manufacturer to complete, as needed, all company and contact information.
- B. **Submission Method.** Data files must be submitted via the MHDO Prescription Drug Price Data Portal web interface ([https://mhdo.maine.gov/pharma\\_portal/](https://mhdo.maine.gov/pharma_portal/)). E-mail attachments shall not be accepted.
- C. **File Format.** The file format will be an MHDO standardized template submitted via an online form in the MHDO Prescription Drug Price Portal web interface. Submitters must use the current version of the appropriate template. The online form format will contain the data elements found in the Reporting Specifications described in subsection 2(H).
- D. **Codes.** Unless otherwise specified, only the code sources listed and described in the templated form are to be utilized. Specific or unique coding systems shall not be permitted.
- E. **Submission Deadline.** Manufacturers of Insulin, shall report by February 15<sup>th</sup> of each year, as described in subsection 2(A).
- F. **Rejection of Submissions.** Failure to conform to the requirements of subsections B, C, or D 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.
- G. **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.

H. **Reporting Specifications.** For each insulin drug product NDC produced by the manufacturer in each category of insulin, the manufacturer must report the following data. If an insulin product does not meet one of the defined categories it is not subject to reporting.

**1) Wholesale Acquisition Costs of Insulin Data**

<b>Data Element Name</b>	<b>Description/Codes/Sources</b>
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.
Category of Insulin	Category of Insulin Codes: 1 – Rapid-acting 2 – Short-acting 3 – Intermediate-acting 4 – Long-acting 5 – Premixed
WAC Amount per NDC	The wholesale acquisition cost of the drug product per NDC on the first day of the calendar year for which data is reported.
WAC Amount per Pricing Unit	The wholesale acquisition cost of the drug product per pricing unit on the first day of the calendar year for which data is reported.

### 3. Evaluation; Notification; Response

- A. **Evaluation.** The MHDO or its vendor shall evaluate each submission 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 manufacturer 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 manufacturer 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 manufacturer 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 manufacturer, and that entity shall pay for the costs of the audit. The MHDO will consider recommendations from the manufacturer as to the scope of the audit and the selection of the independent auditor.
- C. **Corrective action plan.** The MHDO may require a manufacturer 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 wholesale acquisition costs of insulin 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, 8735, and Code of Maine Rules 90-590, Chapter 100: *Enforcement Procedures*.

## **5. Extensions to Data Submission Requirements**

If a manufacturer, 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 manufacturer 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 rule by a manufacturer 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.

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

EFFECTIVE DATE: TBD