

**Chapter 570: Uniform Reporting System for Prescription Drug Price Data Sets**

*Revised on DATE based on MHDO Board meeting DATE*.

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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.

The MHDO Board met on May 23, 2019 and authorized the MHDO to initiate rulemaking to Chapter 570 (22 MRSA §8704, sub-§1; §8705-A; §8737). A public hearing was held on November 21, 2019 with a 10-day public comment period. This is a routine technical rule only until April 1, 2020 then it is a major substantive rule (PL 2019 c470, Section 10).

The following represent the contents and the rationale for this new rule:

1. **Definitions** (22 M.R.S, c. 1683, sub-c. 1 § 8731)
2. **Registration and Submission Requirements** (22 MRSA, c. 1683, sub-c. 1 § 8732)

This section includes the requirements for the registration of reporting entities; conditions under which manufacturers must notify the MHDO; conditions under which the MDHO would require pricing component data from a reporting entity; the data elements contained in the various reports (data specifications); proper coding, formatting and submission of data; and submission deadlines and resubmission of rejected files.

1. **Evaluation; Notification; Response**

This section describes the evaluation or validation of data, failure notification to the submitting entity, and the time frame for correction and resubmission of data.

1. **Compliance** requirements**,** including certificate of accuracy, audit, corrective action plan and enforcement. (22 M.R.S, c. 1683, sub-c. 1 § 8735)
2. **Extensions** to deadlines for data submission requirements.
3. **Confidentiality** (22 M.R.S, c. 1683, sub-c. 1 § 8733)

Information provided to the MHDO by a reporting entity under this Chapter is confidential and not a public record under 1 M.R.S., Chapter 13.

**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 new proposed rule:

1. April C. Alexander, VP State Legislative and Regulatory Affairs, Pharmaceutical Care Management Association (PCMA)
2. Kelly A. Ryan, Deputy Vice President, State Policy, The Pharmaceutical Research and Manufacturers of America (PhRMA)
3. Tara Ryan, VP, State Government Affairs, The Association for Accessible Medicines (AAM)
4. Roxolana Kozyckyj, Director, State Government Affairs, Healthcare Distributors Alliance (HDA)
5. Lori Parham, State Director, AARP
6. Ann Woloson, Executive Director, Consumers for Affordable Health Care (CAHC)

**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 -Statute applicability to PBM’s**

LD 1162 requires certain entities to, upon request, report to MHDO specified data related to making a prescription drug available to consumers. PBMs, as subcontractors to health insurance carriers administering prescription drug coverage, do not take any physical control over drugs that are provided to patients, unlike manufacturers and wholesale distributors. PBMs do not set prices for pharmaceutical products. Manufacturers, wholesalers, and pharmacies are the only entities in the supply chain that control the physical supply of drugs and affect the actual prices of the products. Thus, it is unclear whether this statute actually applies to the administrative functions of PBMs.

**MHDO Staff Response:** Public Law Chapter 470, “An Act To Further Expand Drug Price Transparency”, identifies in §8732. *Drug price notifications and disclosures, those entities that are impacted by this new mandate which include manufacturers, wholesale drug distributors and pharmacy benefit managers. In addition, in* §8736. *Public report, MHDO is required to produce an annual report that includes information developed from the notifications and disclosures as defined in* §8732 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.

**Recommended Board Action:** No further action required.

**Comment - Data volume is cost prohibitive**

The data request does not make practical sense given how PBMs operate as administrators of the benefit on behalf of carriers. Drug manufacturers develop and/or manufacture a limited number of drugs, so their reporting would be somewhat limited. A single PBM could process claims for millions of drugs each month, and there are over a hundred thousand active National Drug Codes (NDCs). The amount of data that this rule seeks to be reported is cost prohibitive for the PBM to provide and likely, for MHDO to process. In addition, it is unclear what value this massive amount of information provides to the state.

**MHDO Staff Response:** It is MHDO’s intent to focus the reporting by wholesale distributors and pharmacy benefit managers to the top 25 most costly, most utilized and with the highest year over year increases as identified in the MHDO’s annual pharmacy report as required in §8712(5) Prescription drug information. *The organization shall provide a report containing the following information about prescription drugs, both brand name and generic: A. The 25 most frequently prescribed drugs in the State; B. The 25 costliest drugs as determined by the total amount spent on those drugs in the State; and C. The 25 drugs with the highest year-over-year cost increases as determined by the total amount spent on those drugs in the State.* To minimize the administrative aspect of reporting data to the MHDO, the MHDO has proposed the adoption of a subset of the data elements defined in the National Academy for State Health Policy’s Pharmacy Benefit Managers reporting template.

**Recommended Board Action:** No further action required.

**Comment - Proprietary Nature of Rebate and Reimbursement data and Confidentiality Provisions**

The proposed rule appears to give MHDO authority to obtain proprietary and/or trade secret information, such as drug specific rebate information and reimbursement amounts to pharmacies. There are significant concerns regarding sharing such sensitive information outside of the business. In the rebate context, in the current marketplace, contract negotiations between PBMs and manufacturers are like sealed-bid auctions: manufacturers are encouraged to offer aggressive price concessions since they don’t know what’s being offered by their competitors. Government agencies—including the Congressional Budget Office (CBO) and the Federal Trade Commission (FTC)—have long cautioned that PBM disclosure mandates could raise costs. The CBO has noted that disclosure requirements could allow firms to “observe the prices charged by their rivals, which could lead to reduced competition.” According to CBO, the “disclosure of rebate data would probably cause the variation in rebates among purchasers to decline” leading to a “compression in rebates.”

Similarly, the FTC has noted concern about rebate transparency and its impact on pricing. The FTC has warned that “whenever competitors know the actual prices charged by other firms, tacit collusion—and thus higher prices—may be more likely." FTC concluded that PBM disclosure mandates could “undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford.” Estimates of disclosure mandates from research firm Visante quantify these potential additional costs at a 4.3% increase over the next ten years, or $228 million just in Maine. Although there are confidentiality protections built into the proposal, it is unclear whether they would apply, since in the statute those protections seem to focus on patient and provider protections. Additionally, there is broad authority in the proposed rule to allow sharing of information among government agencies, which have different sets of confidentiality rules and rules around exemptions from public disclosure. PCMA is concerned for these reasons, and suggests striking the collection of detailed rebate data and sharing among agencies.

**MHDO Staff Response:**  Public Law Chapter 470, requires the Maine Health Data Organization to collect prescription drug price data from manufacturers, wholesale drug distributors and pharmacy benefits managers in order to produce an annual report that includes information from these data submissions on trends in the costs 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 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.  Neither Public Law Chapter 470 or MHDO’s proposed rule Chapter 570 provides the MHDO with the broad authority to share the data submitted by manufactures, wholesale drug distributors or pharmacy benefits managers with other government agencies and or the public.  In fact, Public Law Chapter 470 contains the following confidentiality provision:

**§8733. Confidentiality**

Information provided to the organization as required by this subchapter by amanufacturer, 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.

The data that the MHDO collects under this proposed rule will remain confidential and not be released to the public or to other state or federal agencies except for as described above.

In response to the comments regarding the submission of rebate data.   Rebate data is a major component of prescription drug pricing along the supply chain and is a required data element in Rule Chapter 570 for MHDO to produce the annual report as described in §8736 Public report.

As stated in §8736, the annual 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.

Given the requirements in the mandate specific to the confidentiality of this data and the fact that the annual report as described in §8736  will not disclose information attributable to any particular manufacturer, wholesale drug distributor or pharmacy benefits manager, we do not recommend any revisions to the data submission requirements as we believe that the provisions in the law provide adequate protection to the reporting entities from the disclosure of what they believe is proprietary and/or trade secret information.

**Recommended Board Action:**  No further action required.

1. **The Pharmaceutical Research and Manufacturers of America (PhRMA)**

**submitted the following comments:**

**Comment- Section 1. Definitions- “Manufacturer”**

*Manufacturer:* In order to streamline reporting and compliance burden for both manufacturers and MHDO, PhRMA would recommend a clarification that manufacturers may report at the corporate, as opposed to subsidiary, level.

**MHDO Staff Response:** MHDO agrees that reporting entities may report at a corporate or subsidiary level and recommends incorporating clarifying language into Section 2 – Registration and Submission Requirements.

**Recommended Board Action:** Amend Section 2 – Registration and Submission Requirements as follows:

~~Prescription drug manufacturers, wholesale drug distributors and PBMs~~ 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 ~~are also responsible for the submission of all data by any sub-contractor on their behalf~~.

**Comment Section 1. Definitions – “National Drug Code (NDC)”**

*National Drug Code (NDC)*: We are concerned that the use of the 11-digit NDC code as a reporting requirement will result in significant over-reporting of information that does not align with the pricing of products and will be burdensome to both reporters and MHDO. Requiring reporting for each unique 11- digit NDC would result in data files for every package size and type of package for the same product. Instead, reporting should be standardized to occur at the 9-digit product-level NDC, which will focus on manufacturer and product/strength, but not require unnecessarily duplicative information for every packaging variation of the same product. This will result in more meaningful and manageable data submissions to MHDO.

**MHDO Staff Response:** Section 8732 specifies that a manufacturer must provide notice when during the prior calendar year, the manufacturer increases the wholesale acquisition cost of a) a brand-name drug or, b) a generic drug with a wholesale acquisition cost of at least $10 per pricing unit, by more than 20% per pricing unit. The wholesale acquisition cost of a drug product is applied at an NDC-11 level with variation by package size and, by extension, pricing unit. As such we disagree that reporting should be standardized to occur at the 9-digit product-level NDC.

**Recommended Board Action:** No further action required.

**Comment Section 1. Definitions – “New Prescription Drug”**

*New Prescription Drug*: The definition of “new prescription drug” indicates that “each product listed on the application shall be considered a new prescription drug.” The term “new prescription drug” is only used to define a “new drug” for reporting purposes under 2.B.3. Like the concern raised above regarding the definition of national drug code, this approach will result in multiple, duplicative “Manufacturer Report for New Drugs” submissions.

**MHDO Staff Response:** Section 8732 specifies that a manufacturer must provide notice when during the prior calendar year, the manufacturer has introduced a new prescription drug with a wholesale acquisition cost greater than the amount that would cause the drug to be considered a specialty drug under the Medicare Part D program. The wholesale acquisition cost of a drug product is applied at an NDC-11 level with variation by package size. As such we disagree that reporting may occur at a level other than NDC-11.

**Recommended Board Action:** No further action required.

**Comment - Section 2. Registration and Submission Requirements-Narrative/Supplemental Information**

Submission of reporting information through the MHDO web portal, as contemplated by the proposed rule (2.D), is preferred over other methods such as encrypted emails. However, many of the reporting requirements may not lend themselves clearly to single data points and could require narrative explanations (as is the standard in other state transparency laws) or allow reporters to voluntarily provide supplemental information. The proposed report seems to contemplate this with comment fields. However, the comment fields in the manufacturer reports appear limited to acquisition comments and do not clearly allow for narrative submissions more generally.

We urge MHDO to permit reporters to provide context for their submissions more generally in a field that allows for a narrative supplement. To the extent reporting will require multiple submissions (see NDC discussion above), the narrative supplement should be applicable across a product to ease reporting burden.

**MHDO Staff Response:** Add an additional data element to all Reporting Specifications sections for General Comments. This data element will provide reporting entities with the option to include additional narrative descriptive information related to data submissions including any additional explanations or supplemental information that they wish to provide. MHDO requires uniform data submission across all records; optional General Comments should be included for each data record to which the commentary applies.

**Recommended Board Action:** Amend Sections 2(~~I~~J)(1), (2), (3), (4) to include an additional data element with Data Element Name “General Comments” and Description “Additional information related to the data submitted for this drug product, if applicable”.

**Comment-Section 2. Registration and Submission Requirements – Multiple Cost Increase Factors**

We would like to confirm that reporting entities will be permitted to identify multiple cost increase factors in the Price Increase report.

**MHDO Staff Response:** Confirmed. Manufacturers are permitted to identify multiple cost increase factors in the Manufacturer Report for Price Increases.

**Recommended Board Action:** No further action required.

**Comment-Section 2. Registration and Submission Requirements – Timeframe for Deficiency Correction**

The proposed rule includes a timeframe for deficiency correction of 10 days that is far too short and inconsistent with existing requirements imposed on other reporters. Other MHDO regulations require file format deficiency corrections within 15 days (e.g. Chapters 241, 243) and more substantive corrections include windows up to 30 days (e.g. Chapter 300(4)(C). Challenges faced by reporters under this proposed rule are likely to be more complex than file formatting issues, especially in the first few reporting cycles, so the 30 days afforded other reporters should be included in this proposed rule. The window to correct deficiencies should not be shorter for reporters under this rule than it is for other reporters to MHDO.

**MHDO Staff Response:** Revise the timeframe for deficiency as requested from 10 days to 30 days.

**Recommended Board Action**: Revise Sections 2.H. and 3.C. as follows:

**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 ~~10~~-30 days.

**3.C. Response**. Each reporting entity notified under subsection 3(B) will respond within ~~10~~ 30 days of the notification by making and reporting the changes necessary to satisfy the standards.

**Comment-Section 2. Registration and Submission Requirements – Clarification that Acquisition Data pertains to drugs on the market when acquired.**

Both the Manufacturer Report for New Drugs and the Manufacturer Report for Price Increase request information related to acquisition if the drug product was acquired in the previous five years. While “drug product” is not defined in either the proposed rule or the statute, every other instance in which it is used contemplates a product that is on the market. To avoid confusion, especially because reporting entities are not permitted to use “data not available” or “data unknown” in reporting fields, all report fields related to acquisition should clarify they are only applicable to drugs that were on the market when acquired. This is important to ensure meaningful and consistent reporting. Quantifying information for a single product as it relates to a pipeline or whole company acquisition that may eventually lead to a future product is imprecise at best and implicates highly confidential information.

**MHDO Staff Response:** MHDO agrees that drug product acquisition data related to wholesale acquisition cost on or prior to the date of acquisition, specifically Section 2(I),(2) “WAC at Acquisition”, and “WAC One Year Prior to Acquisition”, need only be provided for drug products that were available for distribution in the State of Maine at the time of acquisition and suggests incorporating clarifying language into Section 2 – Registration and Submission Requirements. All other data elements related to drug product acquisition must be reported.

**Recommended Board Action:** Amend the Descriptions provided in Section 2(~~I~~J)(2) as follows:

**WAC at Acquisition** to read “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** to read “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.”

**Comment-Section 2. Registration and Submission Requirements – Estimated Patient Volume**

The Manufacturer Report for New Drugs requests the “estimated patient volume in the United States for this drug product.” We recommend amending this data point to read “Estimated prevalence of patients with the condition or conditions for which the drug product is indicated, as designated by the federal FDA” to establish reporting consistency.

**MHDO Staff Response:** The prevalence of patients with a condition or conditions for which a drug is indicated does not provide MHDO information adequate to determine the number of persons that the manufacturer estimates will use its drug product after it is introduced to market.

**Recommended Board Action:** No further action required.

**Comment-Section 2. Registration and Submission Requirements – Data not available by reporting deadline**

The Manufacturer Report for Price Increases requires the submission of “Unit Sales Volume in US” and “Total Rebate Payable Amount.” While estimates may be available by the reporting deadline, final data are often not available for these items until after the reporting deadline. For example, volume-based rebate data for a calendar year may not be finalized and audited until after the reporting deadline. Manufacturers should be permitted to submit a reasonable estimate for these data points, or be permitted to provide updated information at such time as data are finalized.

**MHDO Staff Response:** Allow for the submission of updated information within 90 days of the information being finalized and audited.

**Recommended Board Action:** Add a new provision to Section 2. Registration and Submission Requirements:

**2. ~~J~~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.

**Comment-Section 3. Evaluation; Notification; Response**

As discussed above, the 10-day timeframe for deficiency correction (2.H.) is far too short and inconsistent with requirements imposed on other MHDO reporters.

**MHDO Staff Response:** Revise the timeframe for deficiency as requested from 10 days to 30 days.

**Recommended Board Action:** Revise Sections 2.H. and 3.C. as follows:

**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 ~~10~~ 30 days.

**3.C. Response.** Each reporting entity notified under subsection 3(B) will respond within ~~10~~ 30 days of the notification by making and reporting the changes necessary to satisfy the standards.

**Comment- Section 4. Compliance- Certification of Accuracy**

We request clarification regarding how reporting entities should submit the required “certification of accuracy” given that it must be a signed, written document and email attachments are not permitted with submissions.

**MHDO Staff Response:** Clarify Section 4.A. Certification of Accuracy by adding language that reporting entities will be allowed to attest to the accuracy of their notification or report through the MHDO Pharmacy Portal web interface. Confirmation will be documented electronically and will count as the written certification.

**Recommended Board Action:** Amend Section 4.A as follows:

**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 Pharmacy Portal web interface. Confirmation will be documented electronically and will count as the written certification.

**Comment-Section 4. Compliance – Language regarding scope of the audit and independent auditor.**

The proposed rule incorporates a statutory provision that permits MHDO to audit finalized data submitted by reporting entities and that the reporting entity is responsible for the costs of the audit. The rule should include language that the parties agree to the scope of the audit and jointly agree to an independent auditor.

**MHDO Staff Response:** Add language to Section 4.B. that states that the MHDO will consider recommendations from the reporting entity as to the scope of the audit and the selection of the independent auditor.

**Recommended Board Action:** Amend Section 4.B. Audit as follows

**Section 4.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.

**Comment-Retroactivity of Proposed Rules**

The proposed rules do not indicate whether Chapter 470 (LD 1162) applies retroactively by taking into account price increases made before the statute’s effective date of September 19, 2019. If the implementing regulations either make the statute retroactive in application, or fail to clarify this important issue, the potential retroactive application would raise serious constitutional problems with Chapter 470.

Section 8732(1) requires manufacturers to provide notice on January 30, 2020, and annually thereafter based on price increases made “during the prior calendar year.” The statute does not define the phrase “during the prior calendar year,” nor does it otherwise indicate whether price increases made before the law’s September 19, 2019 effective date count toward the price-increase thresholds set forth in Section 8732(1). Under the “deeply rooted” “presumption against retroactive legislation,” the fact that Section 8732(1) does not expressly cover price increases made before its effective date means that it does not include those price increases. Landgraf v. USI Film Prods., 511 U.S. 244, 265 (1994). The rules should thus make clear that only price increases taken on or after September 19, 2019 count toward Section 8372(1)’s thresholds.

Without such clarification, the statute would be impermissibly vague. Statutes must provide regulated entities “fair notice of what is prohibited.” FCC v. Fox Television Stations, Inc., 567 U.S. 239, 253 (2012). Although the presumption against retroactivity requires that Section 8732(1) cover only prospective price increases, PhRMA’s members currently have no assurance that MHDO will not interpret the law to cover price increases undertaken prior to its effective date. A federal district court in California has held that a similar law raised due process concerns where the statute “d[id] not articulate, and California w[ould] not clarify,” whether the thresholds for price-increase notifications “will be applied retroactively.” Order at 2, PhRMA v. David, No. 2:17-cv-2573, ECF No. 55 (E.D. Cal. July 31, 2019).

The proposed rules should therefore be amended to clarify that only price increases taken on or after September 19, 2019, count toward the price increase thresholds set forth in Section 8372(1).

**MHDO Staff Response:** Amend the proposed rule to clarify that price increases on or after September 19, 2019 count toward the price increase thresholds set forth in Section 2.B. Notifications by Manufacturers**.**

**Recommended Board Action:** Amend Section 2.B. Notifications by Manufacturers as follows:

**2.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 Pharmacy 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. **The Association for Accessible Medicines (AAM) submitted the following comments:**

**Comment- Section 1 – Definitions – “Brand-name Drug” and “Generic Drug”**

# *Brand-name drug and Generic drug*. The proposed rule incorporates the statutory definitions but does not address those instances where a drug approved by FDA as a generic under the Abbreviated New Drug Application pathway is marketed using a proprietary name. As such, it is unclear whether branded generics should be reported as Brand-name or Generic drugs. We suggest MHDO clarify that brand-name drugs are those drugs approved under FDA' s brand drug approval pathways (New Drug Application or Biologics License Application) and that generic drugs are those drugs approved by FDA under an Abbreviated New Drug Application.

**MHDO Staff Response:** Amend the definition of Brand-name drug in order to limit the scope of drug products to those receiving approval under an original New Drug Application or Biologics License Application. Also amend the definition of Generic Drug to limit the scope of drug products to those receiving approval under an Abbreviated New Drug Application.

**Recommended Board Action:** Amend Section 1 Definitions of “Brand-name Drug” and “Generic Drug” as follows:

**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.

**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, ~~and~~ 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.

**Comment-Section 1 – Definitions – “Manufacturer”**

While the proposed definition of "Manufacturer" follows that included in L.D.1162, we suggest that MHDO clarify that the definition applies to manufacturers with responsibility for setting a drug's price. As you know, a contract manufacturer is not responsible for setting the price and would therefore be unable to comply with the requirements of this proposal. We suggest the following language:

# "Manufacturer" means the entity that sets or changes the wholesale acquisition cost of prescription drugs that are distributed in the states.

**MHDO Staff Response:** Amend the definition of Manufacturer to exclude entities that do not set the wholesale acquisition cost of the drugs they manufacture.

**Recommended Board Action:** Amend Section 1 Definition of a Manufacturer as follows:

**Manufacturer.** “Manufacturer” means ~~a manufacturer of~~ an entity that manufactures, and sets the wholesale acquisition cost for, prescription drugs that are distributed in the State.

**Comment-Section 1 – Definitions – “New Prescription Drug”**

# *New Prescription Drug.* The statute does not define new drug. The intent of the statute appears to be mandating reporting for novel therapies that have never before been available to patients. Therefore, we propose defining "new prescription drug" with reference to the Food and Drug Administration's list of New Molecular Entities and New Therapeutic Biological Products as follows:

# "New Prescription Drug" means a drug or biological that appears on the Food and Drug Administration's Center for Drug Evaluation and Research list of New Molecular Entities and New Therapeutic Biological Products.

**MHDO Staff Response**: To streamline and use consistent definitions across states with similar pharmacy reporting requirements, the definition of New Prescription Drug that is defined in the proposed rule is the same definition adopted by the State of California.

**Recommended Board Action:** No further action required.

**Comment-Section 1 – Definitions – “Pricing Unit”**

# *Pricing unit.* The proposed rule defines "pricing unit" consistent with the statute. As you know, L.D.1162 defines "pricing unit" in the same manner as the federal Medicaid Drug Rebate Program. To avoid confusion, we suggest the following language to clarify that the terms are identical.

# "Pricing Unit" means the smallest dispensable amount of prescription drug product that could be dispensed, consistent with how the manufacturer reports under the Medicaid Drug Rebate Program.

**MHDO Staff Response** –Section 1.N. defines *Pricing unit* exactly how it is defined in Section 8731 of the governing statute.

**Recommended Board Action:** No further action required.

**Comment-Section 1 – Definitions – “Wholesale acquisition cost”**

# *Wholesale acquisition cost (WAC)*. The federal law definition of WAC serves as the basis for manufacturer compliance activities. To avoid confusion over potentially varying definitions, we suggest the following language:

# "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, consistent with the meaning given in 42 U.S.C. 1395w-3a.

**MHDO Staff Response**: Section 1.T. defines Wholesale acquisition cost (WAC) exactly how it is defined in Section 8731 of the governing statute.

**Recommended Board Action:** No further action required.

**Comment-Section 1 – Definitions – “Wholesale drug distributor”**

# *Wholesale drug distributor*. Some manufacturers may also hold distributor licenses in the state to ship their own products. In order to avoid duplicative and confusing reporting requirements, we request that any such manufacturers be excluded from the definition of wholesale drug distributor as follows:

# "Wholesale drug distributor" means an entity (other than the manufacturer) that engages in the sale of prescription drugs to persons other than a consumer or patient.

**MHDO Staff Response:** Amend the definition of Wholesale Drug Distributor to exclude manufacturers who hold distributor licenses to ship their own products.

**Recommended Board Action:** Amend Section 1 Definition of “Wholesale drug distributor” as follows:

**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.

## Comment-Section 2 – Registration and Submission Requirements

We also suggest greater clarity in this section. Specifically, we recommend the following language: "Reporting entities are also responsible for the collection of all data by any sub-contractor that may be required as part of reporting entities submission. " This would provide for the reporting entity to be responsible for obtaining the necessary data from its own subcontractors for the report.

**MHDO Staff Response:** Amend Section 2 to provide greater clarity that reporting entities warrant the completeness and accuracy of any information provided by a third party on their behalf.

**Recommended Board Action:** Amend Section 2 to read:

~~Prescription drug manufacturers, wholesale drug distributors and PBMs~~ 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 ~~are also responsible for the submission of all data by any sub-contractor on their behalf~~.

Comment-Sections 2(I)(1), (2) – Exclude Acquisition Data for drug products acquired through company acquisition.

The proposed rule provides that manufacturers report the "Acquisition Date" if the drug product was acquired by the manufacturer within the previous five years. We recommend this be amended to exclude products that are part of an overall company acquisition. When a product is acquired as part of a company merger or acquisition, the reporting liability for that product will pass to the new company. We recommend this reporting specification apply only to individual drugs that are purchased by a company.

MHDO Staff Response: As the state agency responsible for carrying out the mandates applicable to Public Law Chapter 470, An Act To Further Expand Drug Price Transparency, it is important to understand the impact to market pricing when drug products are acquired either as a product line or as part of an overall company acquisition. Reporting entities may provide additional information related to drug product acquisitions by populating the Acquisition Comments data element.

**Recommended Board Action:** No further action required.

**Comment- Retroactivity of Proposed Rules**

The first manufacturer reports are due March 31, 2020 for drugs that have had pricing increases of 20% over the prior calendar year. Because the law was not effective until September 1, 2019, we request that MHDO clarify if the report would cover price increases from January 1 through December 31, 2019 or September 1 through December 31, 2019.

**MHDO Staff Response:** Amend the proposed rule to clarify that price increases on or after September 19, 2019 count toward the price increase thresholds set forth in Section 2. B. Notifications by Manufacturers

**Recommended Board Action:** Amend Section 2.B. Notifications by Manufacturers as follows:

**2.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 Pharmacy 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.)

**Comment- Compliance / Audit**

While L.D.1162 provides MHDO with authority to perform audits, it does not provide clarity on when such audits may be appropriate. In order to steward MHDO funding and not create an undue burden on reporting entities, we recommend that this language be amended to articulate when an audit would be appropriate (e.g., if MHDO reasonably determines that a material quality issue exists with respect to the submitted report).

**MHDO Staff Response:** Add language to Section 4.B. that states that the MHDO will consider recommendations from the reporting entity as to the scope of the audit and the selection of the independent auditor.

**Recommended Board Action:** Amend Section 4.B. Audit as follows:

**Section 4.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.

1. **Healthcare Distributors Alliance submitted the following comments:**

**Comment-Proposed Rules, Chapter 570, Uniform Reporting System for Prescription Drug Price Data Sets**

HDA believes that given the availability of [existing pricing] information to the state, it would be cumbersome and redundant to have it be reported again. We ask that the MHDO take these factors into consideration before requiring pricing component data to be reported by wholesale distributors.

**MHDO Staff Response:** It is MHDO’s intent to focus the reporting by wholesale distributors and pharmacy benefit managers to the top 25 most costly, most utilized and with the highest year over year increases as identified in the MHDO’s annual pharmacy report as required in §8712 5. Pricing component data required by Wholesale Drug Distributors in Section 2(I)(3) seeks aggregate product acquisition volume and cost, rebate receivable and payable amounts, and sales volume and revenue amounts for each individual reporting entity during the calendar year. These data values are not publicly available and are necessary to fulfill the requirements of §8736; specifically, information developed from disclosures received on the major components of prescription drug pricing along the supply chain.

**Recommended Board Action:** No further action required.

**5. AARP submitted the following comments:**

**Comment-Section 2 (page 6)** **“Baseline WAC Amount”**

The proposed rules contain the following definition for 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”.

AARP urges MHDO to also request the wholesale acquisition cost at the earliest of these dates so MHDO may see how much the price has grown while it has been on the market.

**MHDO Staff Response:** Section 8732 specifies that a manufacturer must provide notice when during the prior calendar year, the manufacturer increases the wholesale acquisition cost of a) a brand-name drug or, b) a generic drug with a wholesale acquisition cost of at least $10 per pricing unit, by more than 20% per pricing unit. As defined, the Baseline WAC Amount provides insight to the WAC Amount value used by a manufacturer to determine the price increase percentage for which notice is provided. MHDO will have access to the last 5 years of price increases through our data managers license with Analysource. MHDO will include information in its annual report on increases in drug pricing over time. The determination of how much the WAC amount per pricing unit has increased since a drug was introduced to market is not a trigger or a requirement defined in Public Law Chapter 470.

**Recommended Board Action:** No further action required.

**Comment -Section 2 (page 6) “Cost Increase Factors”**

It is unclear if the cost increase listed in Section 2 requires a reporting narrative to explain the reasons for a cost increase. A simple selection of a reason without explanation will not provide sufficient information to allow the MHDO to understand factors that contribute to high drug costs, and subsequent identification of possible solutions to mitigate large price increases.

AARP urges Maine to modify this section to read “Reasons and Explanations for WAC increase”, and provide a reporting mechanism for manufacturers to provide a detailed explanation of the elements that contributed to a price increase.

**MHDO Staff Response**: Add an additional data element to all Reporting Specifications sections for General Comments. This data element will provide reporting entities with the option to include additional narrative descriptive information related to data submissions including any additional reasons or explanations for the cost increase that they wish to provide.

**Recommended Board Action:** Amend Sections 2(~~I~~J)(1), (2), (3), (4) to include an additional data element with Data Element Name “General Comments” and Description “Additional information related to the data submitted for this drug product, if applicable”.

**6. Consumers for Affordable Health Care submitted the following comments:**

**Comment- Section 2(I)(2) Manufacturer Report for Price Increase**

We urge MHDO to require detailed information regarding the reason for a cost increase be included as part of the cost increase factor reporting requirements. Requiring entities to select factors for increases without an explanation of those factors could be contrary to the intent of the law – that is to provide greater transparency (clarity) as to the reason drug prices/costs are increasing. The provision of unambiguous information is critical to fully understanding factors contributing to cost increases and to the development of explicit steps that may be taken to address such factors. Please include that details regarding this reporting requirement are required and include a mechanism for reporting detailed and clear explanation of the factors indicated as contributing to price increases.

**MHDO Staff Response**: Add an additional data element to all Reporting Specifications sections for General Comments. This data element will provide reporting entities with the option to include additional narrative descriptive information related to data submissions including any additional reasons or explanations for the cost increase that they wish to provide.

**Recommended Board Action**: Amend Sections 2(~~I~~J)(1), (2), (3), (4) to include an additional data element with Data Element Name “General Comments” and Description “Additional information related to the data submitted for this drug product, if applicable.”

**Comment-Section 5 - Extensions to Data Submission Requirements**

The proposed rules provide opportunity for reporting entities to request an extension of reporting requirements if the entity is temporarily unable to meet the terms and conditions of the rules “due to circumstances beyond its control.” The proposed rules do not specify what action MHDO will take in response to such a request or how it will respond to requests that are not sincere in nature regarding circumstances that may be out of an entity’s control. We urge MHDO to be more specific in terms of how it will respond to such requests including requests for which a reporting entity actually does have control over but may, perhaps, instead be unnecessarily working to delay the submission of the required data.

**MHDO Staff Response:** Similar language is included in the uniform reporting systems for hospital inpatient/outpatient data sets (Maine Rule 90-590 Chapter 241) and health care claims data sets (Maine Rule 90-590 Chapter 243). Our experience over the last ten years working with reporting entities is that they do not take advantage of the ability to occasionally request an extension, when circumstances require one. Approval of reasonable extension requests ultimately leads to increased compliance and improved data quality without delaying MHDO reporting requirements or resorting prematurely to enforcement action. Finally, the MHDO is under no obligation to approve extension requests that are considered unreasonable or seek to avoid timely submission of compliant data.

**Recommended Board Action:** Amend Sections 4.C. and 5 as follows:

**4.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.

**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). ~~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.~~