

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

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

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

**Section II. Names of Individuals that Submitted Comments**

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

1. Sam Hallemeier, Pharmaceutical Care Management Association (PCMA)
2. William Dane, Healthcare Distribution Alliance (HDA)
3. Nicolas Doherty, PhRMA
4. Karynlee Harrington, Maine Health Data Organization (MHDO)

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

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

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

**Comment 1 – (Statutory Authority (22 M.R.S. Chapter 1683, Sec. 8736)**

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

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

**Recommended Board Action:** Approve the proposed change.

**Comment 2 - (Submission of Pricing Component Data by Reporting Entities, Section 2 (C) 3)**

The proposed rules alter the notice date in which the MHDO will notify the PBM has been changed to an earlier time in the year. We request that it be kept to April as there can be a lag in reporting on reconciliation between PBMs and manufacturers. This information is crucial to be included in the report and the suggested new timeline could result in inaccurate information for the MHDO.

**MHDO Staff Response:** The proposed language in Section 2(C)(3) removes reference to dates that applied only to the first year of program implementation. Rule Chapter 570 currently requires MHDO to notify reporting entities no later than February 15th of each year after April 10, 2020.

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

**Recommended Board Action:** Approve the proposed change.

**Comment 3** – (**Confidentiality, Section 6)**

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

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

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

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

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

**Comment 1 – (Definitions, Section 1(F))**

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

HDA respectfully requests MHDO strike any reference to repackagers from the definition of manufacturer. States throughout the country recognize the many differences between a drug manufacturer and repackager. For example, New Hampshire’s definition of manufacturer in their recently-passed legislation aimed at collecting drug pricing data, HB 1280, specifically excludes a repackager. It is imperative to note that including repackager threatens the accuracy and quality of data.

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

**Recommended Board Action:** Approve the proposed change.

**Comment 2 – (Definitions, Section 1(Q))**

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

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

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

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

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

**Comment 3: (Registration and Submission Requirements, Section 2)**

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

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

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

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

**Comment 4: (Manufacturer Report** *for New Drugs (Struck from Rule),* **Section 2)**

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

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

**Recommended Board Action:** Approve the proposed changes.

**Comment 5: (Manufacturer Report, Section 2 – Estimated Number of Patients)**

Estimated Number of Patients - Neither wholesale distributors nor repackages can access patient data. By leaving repackagers in the definition of a manufacturer, reporting entities will not be able to comply with MHDO’s request. If repackager is to remain in the

definition, HDA respectfully asks that repackagers and wholesale distributors abstain from reporting this data point since they do not have access to any patient information.

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

**Recommended Board Action:** Approve the proposed changes.

**Comment 6: (Manufacturer Report, Section 2 – Cost Change Factors)**

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

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

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

Reasons for WAC change

0 – No change/not applicable

1 – Change in administrative expenses

2 – Scheduled price change

3 – Change in ingredient costs

4 – Change in manufacturing

5 – Change in marketing & advertising costs

6 – Change in financial assistance

7 – Change in R&D costs

8 – Change in rebates to PBMs/wholesalers

9 – Other rebate change

10 – Change in supply (shortage or surplus)

11 – Change in sales costs

12 – Change in state and federal taxes

13 – Change in profit targets

14 – Change in supplier price (repackaged NDC)

15 – Other/Specify

**Comment 7: (Manufacturer Report, Section 2 – Acquisition Price)**

Acquisition Price - Because repackagers are a separate entity from manufacturers, a repackager is not privy to this information and therefore unable to report this data to MHDO. Again, it is imperative to view repackagers under a different lens than manufacturers to receive adequate, accurate data.

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

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

**Comment 8: (Wholesale Drug Distributor Report, Section 2 – Total Rebate Receivable in the US)**

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

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

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

**Comment 9: (Wholesale Drug Distributor Report, Section 2 – Revenue in the US)**

Revenue in the U.S. - HDA asks for clarity around the term revenue as it pertains to wholesale distributors in this report. Further, HDA requests MHDO clarify if Revenue from Sales may be provided net of processed returns if all other data components are also provided net of returns.

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

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

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

**Comment 10: (Wholesale Drug Distributor Report, Section 2 – Total Rebate Payable Amount in US)**

Total Rebate Payable Amount in U.S. - HDA requests MHDO include whether this value represents the prior calendar year aggregate value of WAC at the time of purchase, multiplied by units purchased. If a wholesaler contracts to acquire drug products using a different cost basis, the aggregate value of that cost basis, multiplied by units purchased would appear more appropriate.

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

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

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

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

**Comment 1:** **Statutory Authority (22 MRSA c. 1683, sub-3 sections 8732(1) and section 8732(2)**

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) represents the country’s leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. PhRMA respectfully submits these comments related to the August 2020 Proposed Rule (“Proposed Rule”) for the reporting and notification requirements in Chapter 570, Uniform Reporting System for Prescription Drug Price Data Sets (“Ch. 570”). While we strongly disagree with MHDO’s interpretation that reporting requirements are unfettered and that proposed amendments to Ch. 570 are merely a “clarification” as described during the public hearing, we have appreciated the opportunity to work collaboratively with MHDO at every stage of the legislative and regulatory process thus far.

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

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

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

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

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

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

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

**Recommended Board Action:** Approve the proposed changes.

**Comment 2: (Definitions, Section 1 – Drug Product Family)**

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

By requiring reporting by manufacturers of prescription drugs included in the same drug product family as those found in 8732(1) and 8712, but which do not actually meet either trigger, MHDO would be acting beyond the scope of its delegated legislative authority and penalizing a manufacturer based on a pricing decision of another company or other factors completely beyond the manufacturer’s control such as appearance of a product in the same drug product family on the 25-25-25 report. The Proposed Rule creates significant disjointedness between the triggering products and the scope of products for which reporting would be required, which is concerning given the significant penalties associated with these requirements.

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

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

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

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

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

**Recommended Board Action:** Approve the proposed changes.

**Comment 3: (Definitions, Section 1 – Manufacturers)**

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

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

**Recommended Board Action:** Approve the proposed changes.

**Comment 4: (MHDO Notification to Reporters, Section 2(C)(1)(b))**

We recognize MHDO’s attempt to address predictability concerns by defining a trigger for reporting requirements to include any specific drug included on the 25-25-25 report along with a drug that meets any one of the three criteria in 8732(1), but continue to disagree that MHDO has the authority to include the 25-25-25 report as a trigger when it is not contemplated by the

statute. The 25-25-25 report is not a trigger authorized by LD1162 nor was it contemplated during the legislative process.

The 25-25-25 report is expansive and includes the most frequently prescribed drugs in the state, the costliest drugs as determined by total spend, and the drugs with the highest year over year cost increase as determined by total spend. By nature, this report includes drugs for reasons outside of a manufacturer’s control such as prescribing patterns and how data are reported by third parties. For example, the claims data relied upon by MHDO reflects the paid amount as contracted between payors and pharmacies, not the net cost of a drug. Rebate information is not available in claims data because the payor does not receive the rebate until after the prescription has been purchased by the patient.

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

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

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

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

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

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

**Recommended Board Action:** Approve proposed changes.

**Comment 5: (Reporting Specifications, Section 2(J)(1))**

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

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

* Baseline WAC Amount
* Total WAC Change Amount
* WAC After Change
* Unit Sales Volume in US
* Revenue in US
* Total Rebate Payable Amount in US
* Cost Change Factors

**Recommended Board Action:** Approve the proposed changes.

**Comment 6: (Reporting Specifications, Section 2(J)(1) – Baseline WAC Amount)**

We seek further clarification on the following reporting element categories:

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

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

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

**Comment 7: (Reporting Specifications, Section 2(J)(1) – Total Rebate Payable Amount)**

 We seek further clarification on the following reporting element categories:

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

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

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

**Comment 8: (Reporting Specifications, Section 2(J)(1) – Estimated Number of Patients)**

 We seek further clarification on the following reporting element categories:

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

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

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

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

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

**Comment 9: (Confidentiality, Section 6)**

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

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

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

1. **MHDO Staff submitted the following comments:**

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

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

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

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

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

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

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