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DATE: February 9, 2021

TO: Senator Sanborn, Representative Tepler and Members of the Joint Standing Committee on Health Coverage, Insurance and Financial Services

CC: Senator Vitelli
Colleen McCarthy Reid, OPLA Analyst
Bethany Beausang, Senior Policy Advisor, Office of Governor Janet T. Mills
Neil Korsen, MD, Chair MHDO Board of Directors
Commissioner Head, Vice-Chair, MHDO Board of Directors

FROM: Karynlee Harrington, Executive Director, Maine Health Data Organization

RE: Prescription Drug Transparency Report

Public Law, Chapter 470, *An Act to Further Expand Drug Price Transparency,* requires the Maine Health Data Organization to submit an annual report on prescription drug pricing to the Joint Standing Committee on Health Coverage, Insurance and Financial Services. Attached are the findings of our first annual report.

Please don't hesitate to contact me directly with any questions.

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Executive Summary

Public Law, Chapter 470, *An Act to Further Expand Drug Price Transparency* ("Public Law, Chapter 470") requires the Maine Health Data Organization (MHDO) to submit an annual report on prescription drug pricing to the Joint Standing Committee on Health Coverage, Insurance and Financial Services. The content of this report is presented in aggregate to satisfy requirements in the law that prohibit the disclosure of information attributable to a specific entity. Findings were developed using drug pricing component data MHDO received from pharmaceutical manufacturers, wholesale drug distributors and pharmacy benefits managers (PBMs) for calendar year 2019. For this first report, data requested from manufacturers was limited to drugs that met specified thresholds in the law between September 19, 2019 and December 31, 2019. This report also describes the entities in the pharmaceutical supply chain, their roles, and the complex financial transactions that occur within the supply chain using both MHDO prescription drug claims data and drug pricing component data.

Key Findings

- Generic drug prices rose at a higher percentage rate than brand drugs as an overall average; however, a majority of brand drugs are priced high enough that higher percentage increases for generic drugs do not result in an erosion in the discount afforded by generic drugs.
- Continued efforts to convert to generic drugs when available will provide additional cost savings to Mainers.
- The pharmaceutical supply chain is complex with steps that include physical product acquisition as well as transactional elements triggered by contract events between participants.
- The amount that a pharmacy is reimbursed by a commercial payer can vary greatly from one product to another depending on the amount that the Average Wholesale Price (AWP) – the typical contract price basis – is marked up from Wholesale Acquisition Cost (WAC).
- For NDCs reviewed by MHDO:
    - PBMs, on average, retained payments from payers in the form of spread[1] and/or administrative fees at a rate of approximately 11% over what PBMs reimbursed to pharmacies.
    - PBMs, on average, received rebates from manufacturers representing approximately 14% of the average WAC amount. Of this amount, approximately 79% was passed through to payers.
    - The average amount paid by commercial payers (including member cost share) after rebates for a given drug product was approximately 77% of WAC.
    - The consumer share of total costs after the application of rebates was approximately 27% for commercial claims.

[1] Spread occurs when a PBM charges a payer a contracted price for prescription drugs that is higher than the amount the PBM pays the pharmacy.

Introduction

In July 2019, Public Law, Chapter 470, *An Act to Further Expand Drug Price Transparency* ("Public Law, Chapter 470"), was enacted. This law enables Maine to better understand the factors that influence the cost of prescription drugs in the State. While several other states have enacted price transparency laws focused on data reported by manufacturers, Maine was the first to additionally require reporting from wholesale drug distributors and pharmacy benefits managers (collectively, "reporting entities"). This additional data evidences the costs to, and payments received by, reporting entities to make a prescription drug available to consumers and allows analysis of pharmaceutical pricing from manufacturer to pharmacy counter and beyond.

The Maine Health Data Organization (MHDO), recognizing that other states already capture and publicly report large volumes of records related to manufacturer price increases, opted to take a more focused approach to data collection. Pricing component data was requested for a subset of drugs that hit reporting triggers specified in statute or which were identified as high cost drugs having a significant impact on Mainers. For the 2019 reporting period, this subset was further constrained by the limited window of time for which trigger-based notifications were required based on a statutory effective date of September 19, 2019.

Public Law Chapter 470, An Act to Further Expand Drug Price Transparency Statutory Requirement

Public Law, Chapter 470 requires the MHDO to produce and post on its publicly accessible website an annual Drug Price Transparency Report. The content of the report is to include information developed from the notifications and disclosures submitted to MHDO from the reporting entities described above (manufacturers, wholesale drug distributors and pharmacy benefits managers). Specifically, the report will provide (if data is available), information 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 MHDO determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the State.

In addition to incorporating data submitted by reporting entities in this annual report, MHDO included pharmaceutical claims data submitted to the Maine All Payer Claims Database for calendar year 2019[2]. This supplemental data set enabled review of claim volume and costs during the same reporting period.

The MHDO annual report may not disclose information attributable to any manufacturer, wholesale drug distributor or pharmacy benefits manager and may not make public any information that is confidential pursuant to Title 22, Chapter 1683, Section 8733. MHDO shall submit this report to the joint standing committee of the Legislature having jurisdiction over health data reporting and prescription drug matters and the committee may report out legislation to the first regular or second regular session of the Legislature, depending on the year in which the report is submitted.

MHDO Rule Chapter 570, Uniform Reporting System for Prescription Drug Price Data Sets

MHDO's Board of Directors held a public hearing on November 21, 2019 regarding the MHDO's proposed rule, Chapter 570, *Uniform Reporting System for Prescription Drug Price Data Sets*. This rule

[2] APCD claims data is limited to single line, primary payer, paid claims to eliminate duplicate line claim counts and inflated payer amounts.

was created in accordance with the pharmacy reporting and data collection requirements defined in Public Law, Chapter 470. After responding to all public comments, the Board of Directors adopted MHDO Rule Chapter 570, in January 2020. See Attachment A-Copy of Rule Chapter 570.
The Registration and Submission Requirements defined in MHDO Rule Chapter 570 describe the requirements for the registration of reporting entities; conditions under which manufacturers must notify the MHDO of price increases and or new drugs; conditions under which the MDHO requires pricing component data from a reporting entity; the data elements contained in the various reports; proper coding, formatting and submission of data; and submission deadlines. See Attachment B-Copy of Pricing Component Data Templates.

Note: In October 2020, MHDO's board of directors provisionally adopted a set of proposed changes to Rule Chapter 570 for the purposes of clarification and uniformity in data submissions. After the development of the initial rule, Rule Chapter 570 is a major substantive rule which requires the review and approval of the Legislature and Governor.

Notifications by Manufacturers of Drug Price Increases and New Drugs

Rule Chapter 570 requires manufacturers to notify MHDO when the manufacturer has during the prior calendar year[3]:

1. Increased the wholesale acquisition cost of a brand-name drug by more than 20% per pricing unit;
2. Increased the wholesale acquisition cost of a generic drug that costs at least $10 per pricing unit by more than 20% per pricing unit; or
3. Introduced a new prescription drug for distribution in this State when the wholesale acquisition cost is greater than the amount that would cause the drug to be considered a specialty drug under the Medicare Part D program

Notifications by MHDO to Reporting Entities

MHDO is responsible for identifying specific drug products of interest and notifying reporting entities that they must report detailed pricing component data to MHDO for those drug products. Each drug product is identified by a National Drug Code (NDC), a code maintained by the federal Food and Drug Administration that is uniquely assigned by manufacturer, product and packaging. For the remainder of this report, NDC will be used to describe a manufacturer specific drug product.

Overview of Activity to Date

1. **Reporting Entity Registration**

   As of December 31, 2020, there were 337 manufacturers, 182 wholesale drug distributors and 32 pharmacy benefit managers registered with the MHDO.

2. **Manufacturer Notifications to MHDO**

   For the reporting first year (September 19, 2019 – December 31, 2019), MHDO received notifications from 65 manufacturers for 192 NDCs. Of these NDCs, 13 fell into the category for

[3] For the first year, only those price increases taken on or after September 19, 2019 count toward the thresholds defined above.

brand name drug price increases; 56 for generic drug price increases and 123 for newly introduced drugs.

MHDO Notification to Reporting Entities requesting Pricing Component Data

Manufacturers

Based on language in Rule Chapter 570, MHDO agreed to limit manufacturer price component data reporting to NDCs that met one of the triggers for manufacturer notification to MHDO as outlined above. MHDO notified 14 manufacturers, requesting data for a total of 35 NDCs. Of these NDCs, 0 fell into the category for brand name drug price increases; 6 for generic drug price increases and 29 for newly introduced drugs.

Wholesale Drug Distributors and Pharmacy Benefit Managers

MHDO requested pricing component data for 218 NDCs from wholesale drug distributors (wholesalers) and pharmacy benefits managers (PBMs). The NDCs included the 35 NDCs for which data was requested from manufacturers as well as:

a. NDCs that appeared on at least two of the lists of the MHDO's top 25 Drug Reports as required in Title 22, Chapter 1683, §8712 (5) for the most costly, most utilized and/or having the highest year-over-year cost increases for Mainers during the July 1, 2018 to June 30, 2019 comparison period – 13 NDCs

b. NDCs included in the same drug product family[4] as the NDCs above – 170 NDCs

The analysis performed in developing this report pertains solely to the NDCs for which pricing component data was requested except where explicitly stated otherwise.

3. Data Consolidation and Analysis

Pricing component data files were submitted by reporting entities to the MHDO Prescription Drug Price Data Portal. Data values not meeting expected data formats were isolated for analyst review. Pricing component data was next provisioned to a data mart for analysis and combined with descriptive drug product and historical pricing information compiled from Analy$ource[5], and pharmaceutical claims data submitted to the MHDO APCD by payers.

Trends in the Cost of Prescription Drugs

Wholesale Acquisition Cost Change

MHDO analyzed the average wholesale acquisition cost (WAC) percent change for NDCs requiring manufacturer notification to MHDO or appearing on two top 25 prescription drug lists during calendar year 2019 against the average WAC percent change of related NDCs within the same product family. MHDO found that generic drug prices rose at a higher percentage rate than brand drugs as an overall average for both groups. See Table 1 below.

[4] A drug product family is a group of drug products that share the same generic name and dosage form.

[5] Selected from FDB MedKnowledge (formerly known as NDDF Plus) data included with permission and copyrighted by First Databank, Inc.

Interest Category	NDCs Requiring Manufacturer Notification / Appearing on two Top 25 Drug Lists				NDCs In Related Drug Families			
		Average WAC Change %				Average WAC Change %		
	Total NDCs	Brand	Generic	Brand & Generic Combined	Total NDCs	Brand	Generic	Brand & Generic Combined
WAC Increase								
WAC < $200	4	No NDCs	153.32%	153.32%	5	37.98%	0.00%	22.79%
WAC $200 - $1,200	4	34.71%	135.96%	85.34%	17	0.00%	24.56%	20.23%
WAC > $1,200	1	No NDCs	100.00%	100.00%	0	No NDCs	No NDCs	No NDCs
All NDCs	**9**	**34.71%**	**140.74%**	**117.18%**	**22**	**18.99%**	**21.49%**	**20.81%**
New Drug								
WAC < $200	0	No NDCs	No NDCs	No NDCs	14	No NDCs	40.19%	40.19%
WAC $200 - $1,200	5	0.00%	No NDCs	0.00%	17	5.08%	25.22%	21.66%
WAC > $1,200	24	0.69%	0.00%	0.32%	29	2.63%	0.00%	1.54%
All NDCs	**29**	**0.48%**	**0.00%**	**0.26%**	**66**	**2.99%**	**22.89%**	**16.26%**
Top 25								
WAC < $200	5	2.44%	No NDCs	2.44%	34	3.16%	0.00%	2.04%
WAC $200 - $1,200	5	5.55%	No NDCs	5.55%	20	5.69%	0.00%	3.41%
WAC > $1,200	3	4.36%	No NDCs	4.36%	4	6.37%	No NDCs	6.37%
All NDCs	**13**	**4.08%**	**No NDCs**	**4.08%**	**82**	**4.29%**	**0.00%**	**2.81%**
All NDCs								
WAC < $200	9	2.44%	153.32%	69.49%	53	7.34%	20.09%	14.08%
WAC $200 - $1,200	14	8.10%	135.96%	26.37%	54	4.64%	19.36%	14.45%
WAC > $1,200	28	1.48%	7.14%	4.31%	63	3.34%	0.00%	2.12%
All NDCs	**51**	**4.20%**	**49.26%**	**21.87%**	**170**	**5.27%**	**16.57%**	**11.40%**

Table 1 – WAC Change Percent by Interest Category

MHDO examined the frequency of WAC changes during the three-year period ending December 31, 2019.

Key Findings:

- Of 221 NDCs reviewed, 81 NDCs had at least one WAC change – these NDCs represented approximately 14.5% of total pharmacy costs in Maine in 2019.
- On average, manufacturers applied WAC changes 2.33 times for the NDCs with an average incremental change percent of 28.54%.

Impact of WAC Increases on Pricing for Multisource Drug Products

MHDO evaluated the difference in price between brand and generic NDCs for products where brand and generic equivalents are available (multisource drug products). Pricing differences were reviewed both before and after application of WAC increases taken during the 2019 reporting period to evaluate the impact of generic drug prices increasing at a higher percentage rate than brand drugs.

The analysis revealed:

- Of 19 multisource drug products reviewed, 18 had generic NDCs priced lower on average than brand equivalent NDCs before WAC increases were applied; with generic NDCs priced 23.94% lower than brand equivalents overall.

- After application of 2019 WAC increases, the generic NDCs for all 18 products continued to be priced lower than brand equivalents with the overall average generic discount from brand price increasing by 1.61%, to 25.56%.
- One drug product had generic NDCs that were priced higher on average than the brand equivalent by 175.28% before the 2019 WAC increases were applied. After application of the 2019 WAC increases to the generic NDCs (representing a WAC increase percent of 271.92%), and with no price increase taken for the brand equivalent, the generic NDCs ended 2019 priced 476.63% above the brand equivalent.

Summary:
The majority of multisource drug products that MHDO reviewed had a difference in brand to generic price basis (i.e. starting price) large enough that higher percentage WAC increases applied to generic NDCs did not result in an erosion in the discount provided between brand and generic NDCs. When generic products are available the cost to the consumer is generally lower than the cost of the brand name product.

Brand to Generic Drug Utilization in Maine

MHDO reviewed the rate of utilization of generic drugs found in claims data submitted by payers to the APCD in CY 2019. The analysis determined that Mainers were provided brand drug products for 6.11% of claims where generic drugs were alternatively available. Expenditures for brand claims made up 36.42% of total claim payment amounts from payers and consumers for multisource drug products[6]. Continued efforts to convert to generic drugs when available will provide additional cost savings to Mainers.

Major Components of Prescription Drug Pricing along the Supply Chain

MHDO used pricing component data collected from reporting entities combined with pharmaceutical claims data submitted to the MHDO APCD by commercial payers for the same period to analyze key factors contributing to the cost of prescription drugs along the supply chain[7]. Medicaid and Medicare claims were excluded from this analysis because rebate amounts for government programs are not available.

Pharmaceutical Supply Chain
Primary entities in the pharmaceutical supply chain include:

- Manufacturers – entities that produce and/or repackage drug products for which they set the WAC value.

- Wholesale Drug Distributors – entities that distribute products, of which they are not the manufacturer, to non-consumer entities. Wholesalers acquire the products they distribute from manufacturers and later sell the products to pharmacies at market prices.

[6] Claim payments do not reflect the effect of drug rebates. 25.92% of the brand claims represented were prescribed as Dispense As Written, indicating the medical provider determined that the branded NDC was more appropriate for the patient and should not be filled as a generic.
[7] MHDO reviewed 74 unique NDCs for which pricing component data was submitted from reporting entities and APCD commercial claims were paid during 2019.

- Pharmacies – entities that fill patient prescriptions using drug products acquired from wholesalers[8].

- Pharmacy Benefit Managers (PBM) – third party administrators of prescription drug programs for payers with major duties including development and management of payer drug formularies, negotiation of contract pricing between payers and pharmacies, and negotiation of rebates from manufacturers for products administered on behalf of payers.

- Commercial Payers – Providers of health plans and insurance coverage for enrolled members. Payers establish contracted rates with pharmacies and cost sharing terms for the plans they administer.

The pharmaceutical supply chain is complex with steps that include physical product acquisition as well as transactional elements triggered by contract events between participants. A summary of major supply chain components and related findings are described below:

Wholesaler Acquisition - First step in the Supply Chain

A wholesaler's acquisition of drug products from manufactures is the first step in the supply chain. Typically, wholesalers purchase drug products at WAC and store them in distribution centers until the products are later purchased by pharmacies. Contracts between manufacturers and wholesalers may provide for accrual of rebates[9] to be paid to the wholesaler when the wholesaler later sells the product to a pharmacy. MHDO pricing component data provides that wholesalers received average rebate amounts of 10.29% for brand NDCs and 45.16% for generic NDCs (25.84% overall) when applied against acquisition cost on a per unit basis.

Acquisition of drug products by wholesalers is typically the last point in the supply chain where WAC is used as the price point of a transaction. From this point forward, WAC is instead used as a basis from which price values are derived through the application of mark ups and/or discounts from the value of WAC at the time of transaction.

Pharmacy Acquisition of Drug Products

The next step in the supply chain is a pharmacy's purchase of drug products from the wholesaler. Typically, wholesalers sell drug products to pharmacies at or below then current WAC values. Analysis of MHDO's pricing component data shows that annual revenues generated by wholesalers from sales to pharmacies were less than amounts spent by wholesalers to acquire the products from manufacturers by 15.45% for brand NDCs and 37.44% for generic NDCs (25.26% overall). Pharmacy costs were further reduced through rebates received from wholesalers by an average of 1.86% for brand NDCs and 15.82% for generic NDCs (8.09% overall).

Cost erosion between wholesaler acquisition from manufacturers, and pharmacy acquisition from wholesalers, develops through several factors. One element is that rebates receivable by wholesalers from manufacturers are largely passed through to pharmacies as price reductions. Another component

[8] Pharmacies may also contract directly with manufacturers to procure drug products. In these cases, MHDO assumes pharmacy acquisition costs are more favorable than what is otherwise available from wholesalers, increasing pharmacy profitability. All other supply chain components remain the same.

[9] Rebate means a discount, chargeback, or other price concession that affects the price of a prescription drug product.

results when wholesalers purchase large quantities of products that remain in inventory long enough that they gain value through subsequent WAC increases by manufacturers. This method of inflation-based compensation allows wholesalers to sell products to pharmacies at a price point that is above what was initially paid to acquire the product but below a then increased WAC price. Finally, revenue values reported to MHDO by wholesalers do not include distribution fees, rebates not attributable to specific NDCs (e.g. manufacturer volume rebates), and other miscellaneous fees (e.g. stocking allowances, service level considerations) paid to wholesalers by manufacturers**.** These additional income components enable wholesalers to offer product pricing to pharmacies below WAC while generating positive margin overall.

Purchasing a Prescription Drug Under a Commercial Insurance Plan – Consumers, Payers and PBMs
The final components of the supply chain are initiated when a patient submits a prescription at a pharmacy.

Consumer Payment
When a prescription is submitted by a consumer with health insurance coverage, the pharmacy submits a claim for reimbursement to the PBM contracted with the commercial payer of which the consumer is a member. The PBM then adjudicates the claim to determine the amount of reimbursement to which the pharmacy is entitled based on its contracted rate with the payer. In addition, the PBM notifies the pharmacy of the share of reimbursement that should be collected from the consumer at the time the prescription is filled.

Analysis of MHDO's commercial claims data for CY 2019 shows that on average, consumers paid 17.48% of consumer / plan payments before rebates for brand NDCs, 30.95% for generic NDCs and 23.49% overall.

Payer Payment
Commercial payers engage PBMs to negotiate contracted rates with pharmacies for the drugs the pharmacies dispense. As prescriptions are filled, PBMs charge payers their contracted rate less the consumer payment amount and facilitate payment to the pharmacy.

Rates negotiated between pharmacies and payers are typically derived as a percentage-based discount from Average Wholesale Price (AWP) plus a fixed price dispensing fee. Manufacturers may provide publishers of AWP with a recommended AWP value or specify a markup value to be applied to WAC. Where manufacturers do not provide AWP guidance, the value is typically set as a 20% markup over WAC[10]. The amount that a pharmacy is reimbursed by a payer (including consumer cost share) above the cost the pharmacy paid to procure the drug product can vary greatly from one NDC to another depending on the amount that AWP is marked up from WAC.

Another variable in prescription drug pricing is the method by which PBMs are paid for the services they provide. In some instances, the PBM charges the payer a contracted price for prescription drugs, and the contracted price for the prescription drugs differs from the amount the PBM pays the pharmacy - this arrangement is referred to as spread pricing. Payers, manufacturers and pharmacies may also pay PBMs administrative fees for their services.

[10] Thomson Reuters MicroMedex. Website. AWP Policy. Accessed Dec. 28, 2020 at https://www.micromedexsolutions.com/micromedex2/4.31.0/WebHelp/RED_BOOK/AWP_Policy/AWP_Policy.htm

Analysis of MHDO's pricing component data provided by PBMs shows that, on average, PBMs retained payments from payers in the form of spread and/or administrative fees at a rate of 4.02% above what PBMs reimbursed to pharmacies for brand NDCs and 19.81% for generic NDCs (11.06% overall).

As reported in the MHDO's commercial claims data, after consideration for spread pricing and/or administrative fees paid to PBMs, amounts paid by payers and consumers to pharmacies were higher than amounts paid by pharmacies to wholesalers by an average margin of 17.13% for brand NDCs and 28.18% for generic NDCs (22.06% overall).

Manufacturer Rebate Payment to PBMs

In addition to negotiating pharmacy reimbursement rates, PBMs develop and maintain product formularies used by payers to determine the level of cost sharing between a payer and its members. Drug products on a formulary are divided into tiers with different cost share ratios. Products on less preferable tiers result in higher out of pocket costs for members. To achieve placement on preferred formulary tiers, manufacturers negotiate rebates, based on a percentage of WAC, that are payable to PBMs as drug products are dispensed. PBMs then pass through some or all of the rebates to payers, reducing the net amount paid by the payer for the specific drug product. The difference between the rebate amount received and the rebate amount passed through is retained by the PBM as revenue.

Pricing component data reported by PBMs shows that, on average, PBMs received rebates from manufacturers representing 25.80% of the average WAC amount[11] for brand NDCs and 0.02% for generic NDCs (14.18% overall). Of the overall amount of rebates approximately 79% was passed through to commercial payers.

Income and expense throughout the supply chain

A breakdown of income and expense amounts and sources required to procure and dispense a single NDC for each entity in the supply chain using average percentages derived above is illustrated in Table 2 below.

[11] Average WAC is calculated by summing the mathematical product(s) of the number of days during the year a drug product is priced at a unique WAC value multiplied by the unique WAC value, and dividing the sum of all mathematical products by the number of days in the year. ((($a x 31 days) + ($b x 150 days) + ($c x 184 days)) / 365 days)

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Average Brand WAC	$ 3,297.63

Supply Chain Entity	Income by Payor							Expense by Payee							Net Income / Expense
	Manufacturer	Wholesaler	Pharmacy	PBM	Payer	Patient	Total	Manufacturer	Wholesaler	Pharmacy	PBM	Payer	Patient	Total	
Manufacturer		$ 3,297.33					$ 3,297.33		$ (339.73)		$ (850.72)			$ (1,190.45)	$ 2,106.88
Wholesaler	$ 339.73		$ 2,787.44				$ 3,127.17	$ (3,297.33)		$ (52.13)				$ (3,349.46)	$ (222.29)
Pharmacy		$ 52.13		$ 2,697.09		$ 595.34	$ 3,344.56		$ (2,787.44)					$ (2,787.44)	$ 557.12
PBM	$ 850.72				$ 2,809.97		$ 3,660.69			$ (2,697.09)		$ (711.26)		$ (3,408.35)	$ 252.34
Payer				$ 711.26			$ 711.26				$ (2,809.97)			$ (2,809.97)	$ (2,098.71)
Patient							$ -			$ (595.34)				$ (595.34)	$ (595.34)
Total	$ 1,190.45	$ 3,349.46	$ 2,787.44	$ 3,408.35	$ 2,809.97	$ 595.34	$ 14,141.01	$ (3,297.33)	$ (3,127.17)	$ (3,344.56)	$ (3,660.69)	$ (711.26)	$ -	$ (14,141.01)	$ -

Average Generic WAC	$ 323.03

Supply Chain Entity	Income by Payor							Expense by Payee							Net Income / Expense
	Manufacturer	Wholesaler	Pharmacy	PBM	Payer	Patient	Total	Manufacturer	Wholesaler	Pharmacy	PBM	Payer	Patient	Total	
Manufacturer		$ 326.84					$ 326.84		$ (147.63)		$ (0.07)			$ (147.70)	$ 179.14
Wholesaler	$ 147.63		$ 204.44				$ 352.07	$ (326.84)		$ (32.37)				$ (359.21)	$ (7.14)
Pharmacy		$ 32.37		$ 149.04		$ 83.29	$ 264.70		$ (204.44)					$ (204.44)	$ 60.26
PBM	$ 0.07				$ 185.85		$ 185.92			$ (149.04)		$ -		$ (149.04)	$ 36.88
Payer				$ -			$ -				$ (185.85)			$ (185.85)	$ (185.85)
Patient							$ -			$ (83.29)				$ (83.29)	$ (83.29)
Total Payment	$ 147.70	$ 359.21	$ 204.44	$ 149.04	$ 185.85	$ 83.29	$ 1,129.53	$ (326.84)	$ (352.07)	$ (264.70)	$ (185.92)	$ -	$ -	$ (1,129.53)	$ -

Average Overall WAC	$ 1,971.12

Supply Chain Entity	Income by Payor							Expense by Payee							Net Income / Expense
	Manufacturer	Wholesaler	Pharmacy	PBM	Payer	Patient	Total	Manufacturer	Wholesaler	Pharmacy	PBM	Payer	Patient	Total	
Manufacturer		$ 1,972.66					$ 1,972.66		$ (509.95)		$ (279.50)			$ (789.45)	$ 1,183.21
Wholesaler	$ 509.95		$ 1,474.19				$ 1,984.14	$ (1,972.66)		$ (119.37)				$ (2,092.03)	$ (107.89)
Pharmacy		$ 119.37		$ 1,279.05		$ 441.44	$ 1,839.86		$ (1,474.19)					$ (1,474.19)	$ 365.67
PBM	$ 279.50				$ 1,438.08		$ 1,717.58			$ (1,279.05)		$ (220.78)		$ (1,499.83)	$ 217.75
Payer				$ 220.78			$ 220.78				$ (1,438.08)			$ (1,438.08)	$ (1,217.30)
Patient							$ -			$ (441.44)				$ (441.44)	$ (441.44)
Total Payment	$ 789.45	$ 2,092.03	$ 1,474.19	$ 1,499.83	$ 1,438.08	$ 441.44	$ 7,735.02	$ (1,972.66)	$ (1,984.14)	$ (1,839.86)	$ (1,717.58)	$ (220.78)	$ -	$ (7,735.02)	$ -

Acquisition Cost | Rebate | Plan Payment | Patient Payment | PBM Reimbursement

Table 2 - Supply Chain Entity Net Income / Expense by Product Type

Revenue values reported to MHDO by wholesalers do not include distribution fees, rebates not attributable to specific NDCs (e.g. manufacturer volume rebates), and other miscellaneous fees (e.g. stocking allowances, service level considerations) paid to wholesalers by manufacturers.

Impacts on Insurance Premiums and Cost Sharing

After manufacturer rebates to PBMs are passed through to commercial payers (referred to as payers), the amount that was initially paid to pharmacies by payers was offset by 25.31% for brand NDCs with no reduction for generic NDCs, a 15.35% cost reduction overall. Because this cost reduction is only realized by payers, the overall consumer cost share percentage increased from 23.49% to 26.79% after rebates were applied. If rebate amounts were instead distributed between payers and consumers according to the rate of initial cost sharing, consumers would have realized out of pocket cost savings of 20.89% for brand NDCs, an 11.75% cost reduction overall.

Overall, for the subset of 74 NDCs reviewed by MHDO (see footnote 7), the average amount paid by payers (including member cost share) after rebates for a given NDC was 76.19% of the average WAC amount for brand NDCs and 78.04% for generic NDCs (77.01% overall).

In July 2019, Maine enacted Public Law Chapter 469, *An Act to Protect Consumers from Unfair Practices Related to Pharmacy Benefits Management*. Section 4350-A requires that beginning January 1, 2020 any compensation received by PBMs from manufacturers must be "remitted directly to the covered person at the point of sale to reduce the out-of-pocket cost to the covered person associated with a particular prescription drug; or remitted to, and retained by, the carrier. Compensation remitted to the carrier must be applied by the carrier in its plan design and in future plan years to offset the premium for covered persons."

Further, Section 4350-D specifies that for purposes of calculating a carrier's anticipated loss ratio, any PBM compensation from a carrier "[c]onstitutes an administrative cost incurred by the carrier in connection with a health plan; and [m]ay not constitute a benefit provided under a health plan." Specifically, "[a] carrier may claim only the amounts paid by the PBM to a pharmacy or pharmacist as an incurred claim."

Analysis of MHDO claims data submitted for 2020 and after should incorporate the new requirements described in Public Law Chapter 469.

Other Factors Contributing to the Cost of Prescription Drugs

MHDO requested and received a very limited data set from manufacturers for the 2019 reporting period. It is expected that future years' data submissions will allow for increased analysis in this area. Other states with similar price transparency legislation have examined these factors in more detail. A review of WAC increase data submitted by manufacturers to the California Office of Statewide Health Planning and Development for calendar year 2019 showed the most common manufacturer cost increase rationale included:

- Changes in market dynamics / conditions
- Clinical value of the product
- Costs of improvements to manufacturing
- Increased operating costs
- Ongoing research and development
- Costs of increased rebates in the supply chain to ensure product availability

Conclusion

Drug pricing along the pharmaceutical supply chain is highly complex. The information presented in this report is limited because of the amount of data MHDO was able to require in the first year and the restrictions in the law regarding confidentiality. Data received by MHDO for the first year of the program shows that there is high variability in pricing and rebate practices across reporting entities and drug products. It is our hope that the information we have focused on provides a baseline to understanding pharmaceutical pricing along the supply chain.

While reviewing trends in the cost of prescription drugs MHDO considered similar laws enacted across the country and reviewed information that has been made publicly available. Several states have previously reported WAC increases for generic drugs rising at a higher percentage rate overall than brand products where the products reviewed hit various price increase triggers. MHDO built on these findings by expanding its analysis to include equivalent drug products within the same drug family. The inclusion of these related drug products confirmed previous findings regarding generic increase percentages; however, it also demonstrated that the difference in price between brand and generic NDCs is significant enough that, despite generic costs increasing at a much higher rate than brand, the brand drug is increasingly more expensive than the equivalent generic.

MHDO plans to perform additional analysis of changes in pricing and rebate dynamics for multisource drug products over time given the focus on individual drugs and manufacturers to date. In addition, routine analysis of pharmaceutical claims data collected through all payer claims data and drug pricing data available for purchase publicly may allow more timely application of cost saving measures and/or identify additional areas for cost savings beyond what is available through government mandated retrospective reporting. As an example, Mainers may realize earlier cost savings available from earlier identification and adoption of new to market generic products as patent protection for brand drugs expires. Additionally, Mainers may benefit from notification of significant price increases to the Prescription Drug Affordability Review Board throughout the year. Such notice would enable timely inquiries to manufacturers regarding price increases and may allow prompt adjustments to formularies, specifically for public payers.

MHDO is pleased to present this initial analysis towards increasing consumer awareness of the factors contributing to the cost of prescription drugs. As state and federal agencies introduce and expand laws and regulations that aim to inform the public about the drivers and rationale for increasing costs in medications in the United States, researchers will benefit from additional publication and sharing of industry data, trends, and insights.

90-590 MAINE HEALTH DATA ORGANIZATION

Chapter 570: UNIFORM REPORTING SYSTEM FOR PRESCRIPTION DRUG PRICE DATA SETS

SUMMARY: This Chapter contains the provisions for filing pharmaceutical pricing data sets from prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers.

The provisions include:

Identification of the organizations required to register and report;

Establishment of requirements for the content, format, method, and time frame for filing prescription drug price data;

Establishment of standards for the data reported; and

Compliance provisions.

1. Definitions

Unless the context indicates otherwise, the following words and phrases shall have the following meanings:

A. **Acquisition date.** "Acquisition date" means the date that the manufacturer registered with the FDA as the labeler for the drug product.

B. **Brand-name drug.** "Brand-name drug" means a prescription drug, having a unique NDC, marketed under a proprietary name or registered trademark name, including a biological product, and approved under a New Drug Application or Biologics License Application.

C. **Generic drug.** "Generic drug" means a prescription drug, having a unique NDC, whether identified by its chemical, proprietary or nonproprietary name, that is not a brand-name drug, is therapeutically equivalent to a brand-name drug in dosage, strength, method of consumption, performance and intended use, and approved under an Abbreviated New Drug Application. "Generic drug" includes a biosimilar product.

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

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

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

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

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

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

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

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

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

   i. is intended for human use;

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

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

M. **Pricing component data.** "Pricing component data" means data unique to each reporting entity subject to this rule that evidences the cost to each reporting entity to make a prescription drug product available to consumers and the payments received by each reporting entity to make a prescription drug product available to consumers, taking into account any price concessions, and that is measured uniformly among and between the entities, as detailed by this rule adopted by the organization pursuant to 22 M.R.S., Chapter 1683, Section 8737.

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

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

P. **Rebate.** "Rebate" means a discount, chargeback, or other price concession that affects the price of a prescription drug product, regardless of whether conferred through regular

aggregate payments, on a claim-by-claim basis at the point-of-sale, as part of retrospective financial reconciliations (including reconciliations that also reflect other contractual arrangements), or by any other method. "Rebate" does not mean a "bona fide service fee", as such term is defined in Section 447.502 of Title 42 of the Code of Federal Regulations, published October 1, 2019.

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

R. **Specialty Drug Under Medicare Part D Program. "**Specialty Drug Under Medicare Part D Program" means a prescription drug product having a wholesale acquisition cost that exceeds the threshold set for a specialty drug by the Centers for Medicare and Medicaid Services under the Medicare Part D.

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

T. **Wholesale acquisition cost (WAC).** "Wholesale acquisition cost (WAC)" means a manufacturer's published list price for sale of a prescription drug product with a unique NDC to any wholesale drug distributor or other entity that purchases a prescription drug directly from the manufacturer, not including any price concessions.

U. **Wholesale drug distributor.** "Wholesale drug distributor" means an entity licensed by the State to engage in the sale of prescription drugs, of which it is not the manufacturer, to persons and/or entities other than a consumer or patient.

2. Registration and Submission Requirements

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

A. **Registration.** Each entity required to report shall complete an online registration form, or update an existing one, via the MHDO Prescription Drug Price Data Portal web interface (https://mhdo.maine.gov/pharma_portal/) by January 30th of each year. It is the responsibility of the reporting entity to complete, as needed, all company and contact information.

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

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

1) Increased the wholesale acquisition cost of a brand-name drug by more than 20% per pricing unit;

2) Increased the wholesale acquisition cost of a generic drug that costs at least $10 per pricing unit by more than 20% per pricing unit; or

3) Introduced a new prescription drug for distribution in this State when the wholesale acquisition cost is greater than the amount that would cause the drug to be considered a specialty drug under the Medicare Part D program (hereinafter "new drug").

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

1) **Manufacturers**: On or before April 10th, 2020, and February 15th of each year thereafter, the MHDO will notify, via e-mail, prescription drug manufacturers that are required to report new drug or price increase pricing component data as detailed in sections 2(J)(1) or 2(J)(2), respectively.

2) **Wholesale drug distributors**: On or before April 10th, 2020, and February 15th of each year thereafter, the MHDO will notify, via e-mail, wholesale drug distributors that are required to report pricing component data as detailed in section 2(J)(3).

3) **Pharmacy Benefits Managers**: On or before April 10th, 2020, and February 15th of each year thereafter, the MHDO will notify, via e-mail, pharmacy benefits managers that are required to report pricing component data as detailed in section 2(J)(4).

D. **Submission Method.** Data files must be submitted via the MHDO Prescription Drug Price Data Portal web interface (https://mhdo.maine.gov/pharma_portal/). E-mail attachments shall not be accepted.

E. **File Format.** The file format will be an MHDO-provided Excel template for each dataset submitted via a secure web upload interface. Submitters must use the current version of the appropriate template. The file format will contain the data elements found in the Reporting Specifications described in subsection 2(J). File naming conventions will be specified in the instructions included with each template.

F. **Codes.** Unless otherwise specified, only the code sources listed and described in the templated reports are to be utilized. Specific or unique coding systems shall not be permitted.

G. **Submission Deadline.** Prescription drug manufacturers, wholesale drug distributors and pharmacy benefits managers shall report no later than 60 days after notification from the MHDO, as described in section 2(C).

H. **Rejection of Submissions**. Failure to conform to the requirements of subsections D, E or F of this Section shall result in the rejection of the data file(s). All rejected files must be corrected and resubmitted to the MHDO or its designee within 30 days.

I. **Replacement of Data Files.** A manufacturer may replace data submitted to the MHDO with updated data within 90 days of the updated information becoming available. Any replacements after this period must be approved by the MHDO.

J. **Reporting Specifications.** For each drug product NDC indicated in the MHDO notice, the reporting entity must report the following data.

1) Manufacturer Report for New Drugs

Data Element Name	Description/Codes/Sources
NDC	The national drug code maintained by the FDA for the drug product that includes the labeler code, product code, and package code. A drug's NDC is typically expressed using 11 digits in a 5-4-2 format (xxxxx-yyyy-zz). The first five digits identify the manufacturer, the second four digits identify the product and strength, and the last two digits identify the package size and type. Do not leave blank.
Drug Indicator	1 = Brand Name; 2 = Generic
Introduced to Market Date	The date that the drug product was introduced to market.
WAC at Market Introduction	Wholesale acquisition cost of the drug product at market introduction.
Estimated Number of Patients	Estimated patient volume in the United States for this drug product
Acquisition Date	If the drug product was acquired by the manufacturer within the previous five years, the date of that acquisition.
Acquisition Price	If the drug product was acquired by the manufacturer within the previous five years, the purchase price of acquisition.
Acquisition Comments	Additional information related to the acquisition information provided, if applicable.
General Comments	Additional information related to the data submitted for this drug product, if applicable.

2) Manufacturer Report for Price Increase

Data Element Name	Description/Codes/Sources
NDC	The national drug code maintained by the FDA for the drug product that includes the labeler code, product code, and package code. A drug's NDC is typically expressed using 11 digits in a 5-4-2 format (xxxxx-yyyy-zz). The first five digits identify the manufacturer, the second four digits identify the product and strength, and the last two digits identify the package size and type. Do not leave blank.
Drug Indicator	1 = Brand Name; 2 = Generic
WAC Effective Date	The effective date of the wholesale acquisition cost increase for the drug product.
WAC Increase Amount	The amount of wholesale acquisition cost increase for the drug product.
WAC After Increase	The wholesale acquisition cost resulting from the reported cost increase for the drug product.
Baseline WAC Amount	The wholesale acquisition cost of the drug product on the later of the last day of the calendar year prior to the cost increase, the introduced to market date, or the acquisition date.
Unit Sales Volume in US	The number of units of the drug product sold in the United States during the calendar year of the cost increase.
Revenue in US	Revenue from sales in the United States for this drug product during the calendar year of the cost increase.
Total Rebate Payable Amount	Total rebate payable amount accrued for the drug product during the prior calendar year.
Cost Increase Factors	Reasons for WAC increase. 1 – Administrative expenses 2 – Scheduled price increase 3 – Changes in ingredient costs 4 – Changes in manufacturing 5 – Increased marketing & advertising costs 6 – Financial assistance 7 – R&D costs 8 – Rebates to PBMs/wholesalers 9 – Other rebates 10 – Supply shortage 11 – Sales costs 12 – State and Federal taxes 13 – Increase in profit targets 14 - Other/Specify

Data Element Name	Description/Codes/Sources
Acquisition Date	If the drug product was acquired by the manufacturer within the previous five years, the date of acquisition.
Company Acquired From Name	If the drug product was acquired by the manufacturer within the previous five years, the name of the company from which the drug was acquired.
Company Acquired From Tax ID Number	If the drug product was acquired by the manufacturer within the previous five years, the TIN of the company from which the drug was acquired.
Acquisition Price	If the drug product was acquired by the manufacturer within the previous five years, the purchase price of acquisition.
WAC at Acquisition	If the drug product was acquired by the manufacturer within the previous five years, and the acquisition date falls after the introduced to market date, the wholesale acquisition cost of the drug product at the time of acquisition.
WAC One Year Prior to Acquisition	If the drug product was acquired by the manufacturer within the previous five years, and the acquisition date falls more than 365 days after the introduced to market date, the wholesale acquisition cost of the drug product one year prior to the date of acquisition.
Introduced to Market Date	If the drug product was acquired by the manufacturer within the previous five years, the date the drug product was introduced to market.
WAC at Introduction to Market	If the drug product was acquired by the manufacturer within the previous five years, the wholesale acquisition cost of the drug product when it was introduced to market.
Acquisition Comments	Additional information related to the acquisition information provided, if applicable.
General Comments	Additional information related to the data submitted for this drug product, if applicable.

3) Wholesale Drug Distributor Report

Data Element Name	Description/Codes/Sources
NDC	The national drug code maintained by the FDA for the drug product that includes the labeler code, product code, and package code. A drug's NDC is typically expressed using 11 digits in a 5-4-2 format (xxxxx-yyyy-zz). The first five digits identify the manufacturer, the second four digits identify the product and strength, and the last two digits identify the package size and type. Do not leave blank.
Unit Acquisition Volume in US	The number of units of the drug product acquired in the United States by the wholesale drug distributor during the prior calendar year.
Total Acquisition Amount	Total spent before rebates by the wholesale drug distributor to acquire the drug product in the United States during the prior calendar year.
Total Rebate Receivable Amount	Total rebate receivable amount accrued by the wholesale drug distributor for the drug product during the prior calendar year.
Unit Sales Volume in US	Number of units of the drug product sold by the wholesale drug distributor in the United States during the prior calendar year.
Revenue in US	Revenue from sales in the United States generated by the wholesale drug distributor for this drug product during the prior calendar year.
Total Rebate Payable Amount	Total rebate payable amount accrued by the wholesale drug distributor for the drug product during the prior calendar year.
General Comments	Additional information related to the data submitted for this drug product, if applicable.

4) Pharmacy Benefits Manager Report

Data Element Name	Description/Codes/Sources
NDC	The national drug code maintained by the FDA for the drug product that includes the labeler code, product code, and package code. A drug's NDC is typically expressed using 11 digits in a 5-4-2 format (xxxxx-yyyy-zz). The first five digits identify the manufacturer, the second four digits identify the product and strength, and the last two digits identify the package size and type. Do not leave blank.
Pricing Units Administered	The number of pricing units of the drug product filled for which the PBM administered claims during the prior calendar year.
Total Pharmacy Reimbursement	Total reimbursement amount accrued and payable to pharmacies for pricing units of the drug product filled for which the PBM administered claims during the prior calendar year.
Total Payment Received	Total reimbursement and/or administrative fee amount accrued and receivable from payers for pricing units of the drug product filled for which the PBM administered claims during the prior calendar year.
Total Rebate Receivable Amount	Total rebate receivable amount accrued by the PBM for the drug product during the prior calendar year.
Total Rebate Payable Amount	Total rebate payable amount accrued by the PBM for the drug product during the prior calendar year.
General Comments	Additional information related to the data submitted for this drug product, if applicable.

3. **Evaluation; Notification; Response**

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

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

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

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

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

4. Compliance

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

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

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

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

5. Extensions to Data Submission Requirements

If a reporting entity, due to circumstances beyond its control, is temporarily unable to meet the terms and conditions of this Chapter, a written request must be made to the Compliance Officer of the MHDO as soon as it is practicable after the reporting entity has determined that an extension is required. The written extension request shall include the same elements as the corrective action plan in Section 4(C).

6. Confidentiality

Information provided to the MHDO as required by this chapter by a manufacturer, wholesale drug distributor or pharmacy benefits manager is confidential and not a public record under Title 1, chapter 13, except that the MHDO may share information:

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

B. **Aggregate.** In the aggregate, as long as it is not released in a manner that allows the identification of an individual drug or manufacturer, wholesale drug distributor or pharmacy benefits manager.

STATUTORY AUTHORITY: 22 M.R.S. §§ 8703(1), 8704(1), 8705-A and 8705-A(3), 8731, 8732, 8733, 8734, 8735 and 8737.

EFFECTIVE DATE: February 4, 2020