



JANET T. MILLS
GOVERNOR

MHDO Maine Health
Data Organization
Information | Insight | Improvement

151 CAPITOL STREET
102 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0102

JOEL ALLUMBAUGH
CHAIR
COMMISSIONER ANNE HEAD
VICE-CHAIR
KARYNLEE HARRINGTON
EXECUTIVE DIRECTOR

DATE: December 14, 2022

TO: 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
Joel Allumbaugh, 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 2019, 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 third annual report.

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

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Executive Summary

Public Law 2019, Chapter 470, *An Act to Further Expand Drug Price Transparency* (“Public Law 2019, 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 findings of this report were developed using drug pricing component data MHDO received per the requirements of 90-590 CMR Chapter 570, Uniform Reporting System for Prescription Drug Price Data Sets, from pharmaceutical manufacturers, wholesale drug distributors and pharmacy benefits managers (PBMs) for calendar year 2021; pharmacy claims data submitted by payers per the requirements of 90-590 CMR Chapter 243, Uniform Reporting System for Health Care Claims Data Sets; and drug pricing data procured from Wolters Kluwer.

This third annual report continues to build on previous analysis of data elements collected for drugs that meet requirements for reporting under Public Law 2019, Chapter 470 and expands further to explore the impact of both price increases and decreases on actual amounts paid by payers during the reporting period. Where practical, MHDO compares analytical findings from one year to the next to show changes for a given measure. These comparisons must be considered broadly given that the specific drugs analyzed differ from one year to the next. Additionally, the Covid-19 pandemic is a factor that impacted access to medical care beginning in 2020 and may have been an influencer of drug pricing behavior during the 2021 reporting period.

Pricing details related to drug products with price increases of significance as well as overall price change statistics by therapeutic class are provided in Appendices B and C.

Key Findings

- During the previous five years, the percentage of drugs that incur wholesale acquisition cost (WAC) increases has decreased from 14.41% in 2017 to 9.67% in 2021.
- The average percent of increase of 9.90% across brand and generic drugs that had WAC increases in 2021 remains above the consumer price index (CPI-U) for 2021 of 7.0%.
- Less than 1% of all drugs in the market (15 drugs total) had WAC increases in 2021 that hit one of the triggers requiring Public Notice of Substantial Drug Price Change as described in Title 22, §8732, (1-A)(A-C)
- Pricing and rebate practices vary greatly between brand and generic drugs before and after generic drugs enter the marketplace. As a result, changes in wholesale acquisition cost (WAC) by manufacturers are more directly correlated to amounts paid by payers for brand drugs than for generic drugs.
 - The amount that a retail pharmacy is reimbursed by a payer can vary greatly from one product to another depending on the amount that the Average Wholesale Price (AWP) – the typical negotiated price basis – is marked up from WAC.
 - AWP for brand drugs is generally a markup of 20% above WAC and changes as WAC is changed over time.
 - AWP for generic drugs often reflects a discount from the WAC or AWP value of the equivalent brand drug at the time the first generic product is introduced to market and does not change as the value of generic WAC changes over time. While WAC prices differ between generic manufacturers, AWP prices show very little variation and are often the same value.
 - Pharmacies are incentivized to reduce costs by acquiring generic products from manufacturers with the lowest WAC. However, payers do not receive a corollary benefit from lower WAC

prices when AWP, the basis for pharmacy reimbursement, remains static across generic manufacturers. Instead, the reductions the manufacturers make in WAC result in a higher margin to the pharmacy – in some instances a pharmacy receives greater income for a product than the product’s manufacturer.

- MHDO identified 77 NDCs with average costs of over \$100 per fill and payer paid amounts of greater than 10x the WAC amount – See Appendix B
- MHDO reviewed 430 unique NDCs for which pricing component data was submitted from reporting entities and APCD commercial claims were paid during 2021. Data was requested for NDCs included on [MHDO’s List of Trigger NDCs for CY2021](#), falling on at least two of the lists of the [MHDO’s top 25 Drug Reports](#), or having average claim paid amounts of more than 10 times WAC – See Appendix D. For these 430 NDCs:
 - The average amount paid by commercial payers (including member cost share) after rebates represented 71.21% of WAC for brand drugs – a decrease of 11% from the net paid amount reflected for 2020 (82.71%).
 - The generic drug WAC prices in our sample remained static or decreased for all but one drug; however, the average amount paid by commercial payers (including member cost share) as a percentage of WAC after rebates for generic drugs rose to 163.65%. This represents a 20% increase in average markup from the same measure in 2020 (143.47%) and a continued impact of manufacturer WAC decreases without concurrent decreases to AWP.
 - PBMs received rebates from manufacturers representing 26.68% of the average WAC amount for brand NDCs and 0.17% for generic NDCs.
 - PBMs, on average, retained payments from payers in the form of spread¹ and/or administrative fees at a rate of approximately 13.97% over what PBMs reimbursed to pharmacies, an increase from the rate of 2.14% reported for 2020.
 - The consumer share of total payment after the application of rebates was approximately 14.75% for commercial claims, a similar rate to drugs reviewed for 2020.

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.

Below is a key to commonly used abbreviations and terms used in the report:

Abbreviations

APCD – All Payer Claims Database

AWP – Average Wholesale Price

FDA – The federal Food and Drug Administration

NDC – National Drug Code

PBM – Pharmacy Benefits Manager

WAC – Wholesale Acquisition Cost

Definitions

Average Wholesale Price – a prescription drug term originally intended to convey the average price for medications offered at the wholesale level. Manufacturers may provide publishers of AWP with a suggested 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 WAC².

Brand Drug – 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.

Drug Product Family – a group of one or more prescription drugs that share a unique generic drug description (non-trade name) and drug form.

Fill – The dispensing of a prescription drug by a pharmacist whether as the initial dispensing of a prescription or as a subsequent refill.

Generic Drug – a prescription drug, having a unique NDC, whether identified by its chemical, proprietary or nonproprietary name, that is not a brand drug, is therapeutically equivalent to a brand 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.

Market Price – the price set by a wholesaler for sale of a drug product to a pharmacy. This price may vary from one pharmacy to another and change independent of manufacturer price changes.

Multisource Drug – a brand drug or generic drug that is available from more than one manufacturer.

Negotiated Price – the price established between payers and pharmacies to be paid to pharmacies for drug products as they are dispensed.

National Drug Code – a code maintained by the federal Food and Drug Administration that is uniquely assigned by manufacturer, product, and packaging.

Rebate – a discount, chargeback, or other price concession that affects the price of a prescription drug product.

Single Source Drug – a brand drug or generic drug that is only available from one manufacturer.

Therapeutic Class – a group of drugs used for the treatment, remediation, or cure of a specific disorder or disease.

Wholesale Acquisition Cost – a manufacturer's published list price for sale of a prescription drug product with a unique NDC to a wholesale drug distributor or other entity that purchases a prescription drug directly from the manufacturer, not including any price concessions.

² WoltersKluwer Website. AWP Policy. Accessed September 7, 2022 at <https://www.wolterskluwer.com/-/media/project/wolterskluwer/oneweb/www/health/ce/files/clinical/wkh-awp-policy.pdf>

Introduction

Public Law 2019, Chapter 470, was enacted to enable Maine to better understand the factors that influence the cost of prescription drugs in the State. The law requires reporting per the requirements of 90-590 CMR Chapter 570, Uniform Reporting System for Prescription Drug Price Data Sets, from pharmaceutical manufacturers, wholesale drug distributors and PBMs (collectively, “reporting entities”). Data collected provides details regarding the costs to, and payments received by, reporting entities to make a prescription drug available to consumers and allows analysis of pharmaceutical pricing and rebates at milestones throughout the supply chain. A summary of 90-590 CMR Chapter 570 and related processes is included as Appendix D.

MHDO published its first annual report on prescription drug pricing in February 2020 with a focus on the relationships between entities in the pharmaceutical supply chain and the role they each play in affecting costs to consumers. The second annual report was published in January 2021 and explored the impacts of manufacturer price changes on the costs realized by payers and consumers over time.

This third annual report updates several metrics provided in the previous reports; and provides a broader scope of analysis related to drugs with high costs and significant markups between manufacturer list prices and amounts paid by payers and consumers at the point of sale.

Under contract with MHDO, Ten2Eleven Business Solutions provided MHDO technical support in the preparation of this report.

Title 22, §8736. Public report

Title 22, §8736, 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 disclosures submitted to MHDO from manufacturers, wholesale drug distributors and pharmacy benefits managers, referred to as reporting entities. 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.

Overview of Prescription Drug Spending in Maine

In 2021, prescription drug spending by and on behalf of Mainers was \$2.4B as reported to the MHDO APCD for all NDCs per the requirements in 90-590 Rule Chapter 243, *Uniform Reporting System for Health Care Claims Data Sets*. This represents approximately 25% of the total health care spending in the state as reported in the MHDO's APCD. A breakdown of pharmacy claims by payer type is provided in Table 2 below.

Payer Type	Total Pharmacy Claims	Total Paid Amount
Commercial	3,697,520	\$702,812,274
MaineCare	2,677,990	\$452,671,698
Medicare	7,343,753	\$1,243,561,873
Total	13,719,263	\$2,399,045,845

Table 2 – Pharmacy Claims by Payer Type

The top 10 most costly drug families based on MHDO data in 2021 are shown in Table 3 below.

Drug Family	Therapeutic Class	Total Claims	Total Paid
Adalimumab Pen-injector Kit	Analgesics - Anti-Inflammatory	18,226	\$134,678,730
Apixaban Tablet	Hematological Agents - Anticoagulants	114,162	\$96,455,494
Ustekinumab Solution Prefilled Syringe	Dermatologicals	3,288	\$72,082,653
Dulaglutide Solution Pen-injector	Endocrine and Metabolic Agents - Antidiabetics	47,946	\$58,646,653
Lenalidomide Capsule	Miscellaneous Therapeutic Classes (Oncology Agent)	2,960	\$49,351,662
Insulin Glargine Solution Pen-injector	Endocrine and Metabolic Agents - Antidiabetics	68,817	\$43,545,590
Empagliflozin Tablet	Endocrine and Metabolic Agents - Antidiabetics	40,639	\$39,563,412
Buprenorphine HCl-Naloxone HCl Dihydrate Film	Analgesics – Opioid (Use Disorder)	207,035	\$36,497,691
Elexacaftor-Tezacaftor-Ivacaftor Tablet Therapy Pack	Antihistamines/Nasal Agents/Cough & Cold/Respiratory/Misc (Cystic Fibrosis Agent)	1,415	\$34,077,277
Rivaroxaban Tablet	Hematological Agents - Anticoagulants	37,081	\$33,609,375

Table 3 – 2021 Top 10 Most Costly Drug Families

The top 10 most utilized drug families based on MHDO data in 2021 are shown in Table 4 below.

Drug Family	Therapeutic Class	Total Claims	Total Paid
Atorvastatin Calcium Tablet	Cardiovascular Agents - Antihyperlipidemics	446,779	\$9,338,196
Levothyroxine Sodium Tablet	Endocrine and Metabolic Agents - Thyroid Agents	391,186	\$9,723,112
Lisinopril Tablet	Cardiovascular Agents - Antihypertensives	370,288	\$3,219,317
Albuterol Sulfate Aerosol Solution	Antihistamines/Nasal Agents/Cough & Cold/Respiratory/Misc - Antiasthmatic And Bronchodilator Agents	262,967	\$14,420,385
Sertraline HCl Tablet	Central Nervous System Agents - Antidepressants	256,183	\$3,975,792
Omeprazole Capsule Delayed Release	Gastrointestinal Agents - Ulcer Drugs/Antispasmodics/Anticholinergics	253,785	\$4,324,082
COVID-19 (SARS-CoV-2) mRNA Virus Vaccine Suspension	Vaccines	248,850	\$8,439,158
Amlodipine Besylate Tablet	Cardiovascular Agents - Calcium Channel Blockers (Antihypertensive)	242,669	\$2,156,994
Gabapentin Capsule	Neuromuscular Agents - Anticonvulsants	210,609	\$4,300,339
Buprenorphine HCl-Naloxone HCl Dihydrate Film	Analgesics – Opioid (Use Disorder)	207,035	\$36,497,691

Table 4 – 2021 Top 10 Most Costly Drug Families

The top 10 drug families with the highest year over year increase in 2021 based on MHDO data are shown in Table 5 below.

Drug Family	Therapeutic Class	Additional Claims Over Claims Count in 2020	Additional Paid Amounts Over Paid Amounts in 2020
Adalimumab Pen-injector Kit	Analgesics - Anti-Inflammatory	1,715	\$21,717,625
Apixaban Tablet	Hematological Agents - Anticoagulants	14,811	\$21,201,907
Dulaglutide Solution Pen-injector	Endocrine and Metabolic Agents - Antidiabetics	14,986	\$20,274,772
Ustekinumab Solution Prefilled Syringe	Dermatologicals	581	\$15,809,543
Empagliflozin Tablet	Endocrine and Metabolic Agents - Antidiabetics	13,079	\$14,267,303
COVID-19 (SARS-CoV-2) mRNA Virus Vaccine Suspension	Vaccines	248,030	\$8,425,562
Palbociclib Tablet	Antineoplastics And Adjunctive Therapies	583	\$8,186,504
Dupilumab Solution Pen-injector	Dermatologicals	2,280	\$7,716,955
Fluticasone-Umeclidinium-Vilanterol Aerosol Powder Breath Activated	Antihistamines/Nasal Agents/Cough & Cold/Respiratory/Misc - Antiasthmatic And Bronchodilator Agents	7,017	\$7,363,659
Semaglutide Solution Pen-injector	Endocrine and Metabolic Agents - Antidiabetics	4,897	\$6,841,138

Table 5 – 2021 Top 10 Highest Year over Year Cost Increase Drug Families

Trends in the Cost of Prescription Drugs

Changes in Wholesale Acquisition Costs

MHDO analyzed the average change in WAC pricing for both brand and generic name drugs during calendar year 2021 for NDCs for which pricing component data was submitted. NDCs included on MHDO's List of Trigger NDCs for CY2021, appearing on at least two of the lists of the MHDO's top 25 Drug Reports, or having average claim paid amounts over 10x WAC were compared to related NDCs within the same product family.

In 2021 the data shows that the WAC set by manufactures for generic drugs decreased in all but one category, while the WAC set by manufacturers for existing brand drugs rose in most categories at similar rates to what was observed in the MHDO's previous annual reports. See Table 6 below.

2021 Inclusion Criteria	Target NDCs				NDCs In Related Drug Product Families			
	Total NDCs	Average WAC Percent Change			Total NDCs	Average WAC Percent Change		
		Brand	Generic	Brand & Generic Combined		Brand	Generic	Brand & Generic Combined
High Cost / High Margin								
WAC < \$100	16	No NDCs	-21.10%	-21.10%	229	4.97%	-11.38%	-11.24%
WAC \$100 - \$500	15	No NDCs	-20.27%	-20.27%	204	-18.03%	-8.35%	-8.87%
WAC > \$500	0	No NDCs	No NDCs	No NDCs	136	0.97%	-2.72%	-1.77%
All NDCs	31	No NDCs	-20.70%	-20.70%	569	-3.22%	-8.58%	-8.13%
Multiple Top 25 Lists								
WAC < \$100	0	No NDCs	No NDCs	No NDCs	27	0.56%	0.00%	0.19%
WAC \$100 - \$500	14	2.37%	0.00%	1.36%	44	2.47%	0.00%	0.90%
WAC > \$500	8	4.87%	No NDCs	4.87%	20	3.26%	0.00%	3.10%
All NDCs	22	3.62%	0.00%	2.63%	91	2.42%	0.00%	1.17%
New Drug Trigger								
WAC < \$100	0	No NDCs	No NDCs	No NDCs	111	3.54%	-11.26%	-10.46%
WAC \$100 - \$500	3	No NDCs	-82.43%	-82.43%	172	3.81%	-10.03%	-7.38%
WAC > \$500	45	0.24%	-12.40%	-7.06%	200	3.95%	-2.40%	1.15%
All NDCs	48	0.24%	-19.64%	-11.77%	483	3.90%	-8.40%	-4.56%
WAC Increase Trigger								
WAC < \$100	0	No NDCs	No NDCs	No NDCs	1	No NDCs	0.00%	0.00%
WAC \$100 - \$500	1	No NDCs	21.15%	21.15%	12	4.99%	0.00%	0.83%
WAC > \$500	0	No NDCs	No NDCs	No NDCs	1	5.00%	No NDCs	5.00%
All NDCs	1	No NDCs	21.15%	21.15%	14	4.99%	0.00%	1.07%
All NDCs								
WAC < \$100	16	No NDCs	-21.10%	-21.10%	368	2.13%	-10.73%	-10.13%
WAC \$100 - \$500	33	2.37%	-21.21%	-15.49%	432	-0.37%	-8.12%	-7.01%
WAC > \$500	53	1.61%	-12.40%	-5.26%	357	3.25%	-2.56%	0.16%
All NDCs	102	1.78%	-17.76%	-11.06%	1,157	2.26%	-7.97%	-5.79%

Table 6 – WAC Percent Change by Interest Category

Manufacturer Price Trends Over Time

MHDO used publicly available pricing data to analyze WAC pricing trends over the previous five years for all drug products with at least one incurred claim in the Maine APCD during 2021. The analysis shows that during the five-year period the percentage of drugs that incur price increases has decreased overall from 14.14% of active NDCs in 2017 to 9.67% in 2021; however, the data shows a slight increase (0.86%) over 2020. The average percent of increase for price increases has also decreased over time; however, the 2021 average percent of increase of 9.90% remains above the consumer price index (CPI-U) for 2021 of 7.0%.

While the percentage of brand and generic drugs with WAC decreases has varied over time the average percent of decrease has remained between -49.31% and -49.83% during the last three years with a value of -49.40% in 2021. See Table 7 and Chart 1 below.

NDC Group / Year	Active NDCs ³	All Changes			WAC Increases			WAC Decreases		
		WAC Change NDCs	Percent Active NDCs w/ WAC Change	Average WAC Percent Change	WAC Increase NDCs	Percent Active NDCs w/ WAC Increase	Average WAC Percent Increase	WAC Decrease NDCs	Percent Active NDCs w/ WAC Decrease	Average WAC Percent Decrease
2017	18,113	3,884	21.44%	-1.28%	2,610	14.14%	19.43%	1,274	7.03%	-43.69%
2018	20,598	3,710	18.01%	1.65%	2,688	13.05%	20.16%	1,022	4.96%	-47.05%
2019	23,579	3,659	15.52%	4.19%	2,598	11.02%	26.04%	1,061	4.50%	-49.31%
2020	26,877	4,030	14.99%	-12.02%	2,367	8.81%	14.54%	1,663	6.19%	-49.83%
2021	30,639	4,755	15.52%	-12.43%	2,964	9.67%	9.90%	1,791	5.84%	-49.40%

Table 7 – Prescription Drug WAC Change Statistics by Year

WAC Change Statistics by Year

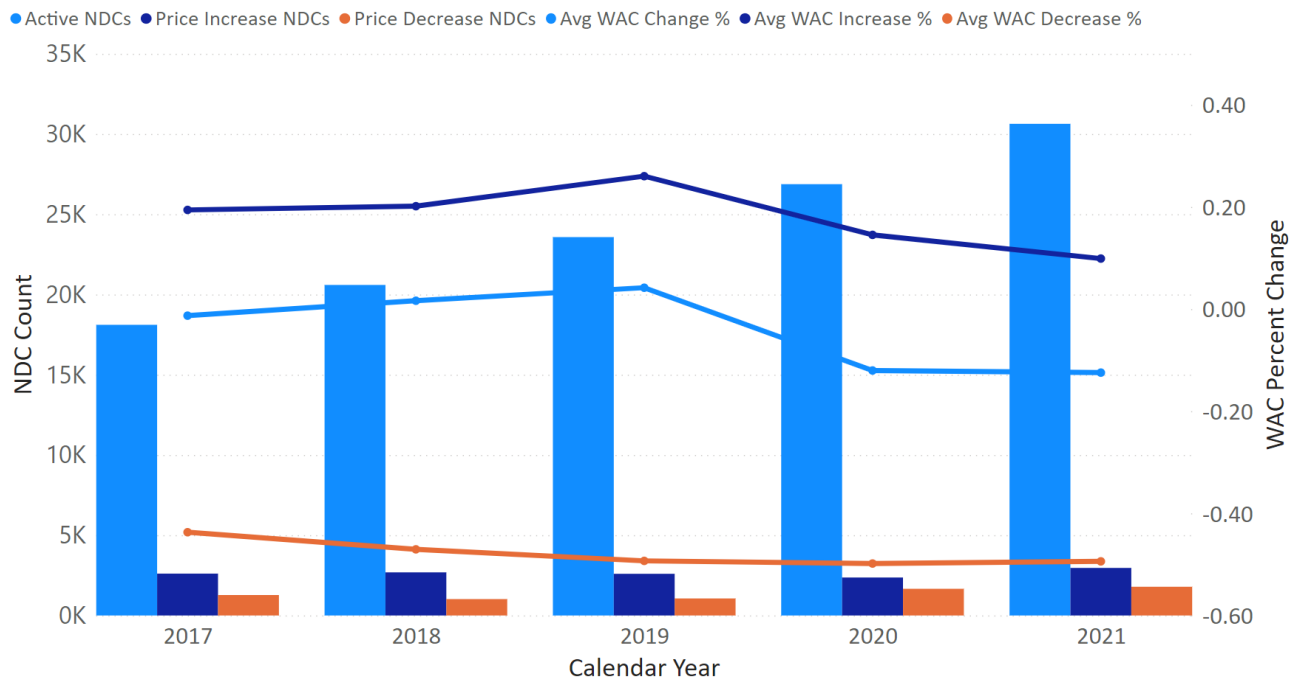


Chart 1 – WAC Change Statistics by Year

³ Active NDCs are those NDCs that are currently available in the market.

There were 30,639 active brand and generic prescription drugs for which Mainers filled prescriptions in 2021. Less than 1% of these drugs (15 drugs total – 10 brand drugs and 5 generic drugs) had WAC increases in 2021 that hit triggers requiring Public Notice of Substantial Drug Price Change.

Impact of WAC Changes on Pricing for Multisource Drug Products

MHDO used pricing component data submitted by reporting entities to evaluate the difference in price between brand and generic NDCs for products where brand and generic equivalents were available during the year (multisource drug products). Of 84 multisource drug products reviewed, 81 had generic NDCs priced lower than brand equivalent NDCs before and after application of WAC changes, with an average year end generic discount from brand WAC of 62.26%. The brand manufacturer for 3 of these drug products decreased the brand WAC of each item by 77.46%, resulting in a price that was 3.28% less than the average generic WAC for the same products.

MHDO next applied average net costs per unit⁴ for each drug product to evaluate the difference in amounts actually paid by payers for brand and generic drugs. When generic products were dispensed, the cost to payers was significantly lower than what was paid when equivalent brand name products were used, with an average net cost reduction of 50.93%.

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 MHDO APCD in CY 2021. The analysis determined that Mainers were provided brand drug products for 5.76% of claims where generic drugs were alternatively available, which is slightly lower than 2020. Payments for brand name drugs made up 45.20% of total payment amounts from payers and consumers for multisource drug products⁵. . A comparison of year-over-year brand to generic drug utilization statistics is provided in Table 7 below.

Description	MHDO Report Year		
	2019	2020	2021
Brand Drug Utilization	6.11%	5.92%	5.76%
Brand Cost Percentage	36.42%	38.84%	45.20%
Percent Brand Claims Indicated Dispensed as Written	25.92%	26.77%	21.61%

Table 7 – Year-Over-Year Brand to Generic Drug Utilization Statistics

⁴ Average net costs were determined by decreasing the total paid amount reported by payers by the average rebate amount reported by reporting entities for the same NDCs on a per unit basis.

⁵ Claim payments do not reflect the effect of drug rebates. 21.61% 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.

Analysis of Manufacturer Pricing and Drug Costs to Payers

MHDO analyzed pharmaceutical claims data to evaluate the impact of both price increases and decreases on actual amounts paid by payers during the reporting period. Analysis was limited to 3,159 NDCs that incurred WAC changes during 2021 and for which claims were incurred both before and after the WAC changes. This sample includes the following drug products that were listed on MHDO's report of Top 25 Most Frequently Prescribed Drugs for 2021:

Therapeutic Class	Drug Name
ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexians	Lisdexamfetamine Dimesylate
Antihistamines/Nasal Agents/Cough & Cold/Respiratory/Misc - Antiasthmatic And Bronchodilator Agents	Albuterol Sulfate
	Budesonide-Formoterol Fumarate Dihydrate
	Fluticasone Furoate-Vilanterol
	Fluticasone Propionate HFA
	Tiotropium Bromide Monohydrate
	Umeclidinium Bromide
	Umeclidinium-Vilanterol
Endocrine and Metabolic Agents - Antidiabetics	Dulaglutide
Gastrointestinal Agents - Ulcer Drugs/Antispasmodics/Anticholinergics	Pantoprazole Sodium
Genitourinary Agents - Miscellaneous	Tamsulosin HCl
Hematological Agents - Anticoagulants	Apixaban
Neuromuscular Agents - Anticonvulsants	Gabapentin
Vaccines	Zoster Vaccine Recombinant Adjuvanted

Wholesale Acquisition Cost (WAC) Relationship to Payer Paid Amounts

The WAC change analysis showed a relative correlation between average WAC increase amounts (7.34%) and increases to average amounts paid by payers (8.34%) after WAC increases took place. However, where WAC prices decreased, the relative percent of decrease in amounts paid by payers was significantly lower, with WAC prices decreasing 49.75% and average amounts paid only decreasing 10.09%. See table 8 below.

2021 WAC Increases			2021 WAC Decreases		
NDC Count	Average WAC Percent Change	Average Payer Paid Percent Change	NDC Count	Average WAC Percent Change	Average Payer Paid Percent Change
1,931	7.34%	8.34%	1,228	-49.75%	-10.09%

Table 8 – WAC Change Impact on Payer Paid Amounts

Average Wholesale Price (AWP) Relationship to Payer Paid Amounts

Negotiated prices between pharmacies and payers are typically derived as a percentage-based discount from AWP plus a fixed price dispensing fee. Manufacturers may provide publishers of AWP with a suggested 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.

MHDO organized the NDCs analyzed above into brand and generic items and categorized them by source type (single source vs. multisource) to evaluate differences in pricing behaviors and methods across categories. AWP values were also incorporated for comparison to WAC and claims paid values. Statistical outcomes of the analysis are provided in Appendix A.

Key findings based on MHDO's sample of prescription drugs:

- Brand drugs
 - Most drug products with WAC increases in 2021 were brand drugs (88.85% of NDCs in the sample).
 - Amounts paid by payers after the application of WAC increases rose at a slightly higher rate than the rate of WAC increase
 - AWP for brand drugs increased at nearly the same rate as WAC increased.
 - AWP for brand drugs had an average markup from WAC between 19.98% and 20.10% after price increases.
 - PBMs receive rebates for brand drugs that further offset costs to payers and may result in net costs below WAC. Data submitted to MHDO by PBMs for a subset of 132 brand NDCs dispensed in Maine during 2021 indicated average rebate amounts of approximately 27%.
- Generic drugs
 - Multisource generic drugs made up 96.75% of all NDCs with WAC decreases and had an average percent decrease of 49.70%.
 - The average amount paid by payers for multisource generic drugs after WAC decreases fell by only 9.37%.
 - When represented as a percentage of WAC, payer paid amounts for multisource generic drugs with WAC decreases increased by 122.70% with average payer paid amounts reflecting 251.31% of WAC after WAC decreases.
 - AWP for multisource generic drugs with WAC decreases did not fall at the same rate as WAC and remained within 5.96% of pre-WAC change AWP.
 - **AWP for multisource generic drugs had an average markup from WAC of 1,823.67% after WAC decreases.**
 - Unlike brand drugs, PBMs generally do not receive rebates from generic manufacturers. Data submitted to MHDO by PBMs for a subset of 297 generic NDCs dispensed in Maine during 2021 indicated average rebate amounts of less than 1%.

AWP and Generic Drugs

MHDO reviewed AWP price history for the generic drugs reviewed and found that AWP values were often set by manufacturers as a discount from the WAC or AWP value of the equivalent brand drug as it existed at the time the first generic product was introduced to market. For generic drugs, AWP often does not change as the value of WAC changes over time. As a result, while WAC prices differ between generic manufacturers, AWP prices show very little variation and are often the same across manufacturers.

Pharmacies are incentivized to reduce costs by acquiring generic products from manufacturers with the lowest WAC. However, payers do not receive a corollary benefit from lower WAC prices when AWP, the basis for pharmacy reimbursement, remains static across generic manufacturers. Instead, the reductions the manufacturers make in WAC result in a higher margin to the pharmacy – in some instances a pharmacy receives greater income for a product than the product’s manufacturer. To illustrate the impact of this phenomenon, MHDO identified 77 NDCs with average payer paid amounts of over \$100 per fill and average cost mark ups of more than 10x WAC – see Appendix B.

Case Study – Zytiga (Abiraterone Acetate) 250 Mg 120 Count Tablets

MHDO reviewed brand and generic WAC and AWP pricing to amounts paid by payers between 2019 and 2021 for multisource drug product Zytiga (Abiraterone Acetate) 250 Mg 120 Count Tablets. Zytiga is used to treat men with prostate cancer that has spread to other parts of the body. Pharmacy claims totaling \$18.7M were paid for the drug product in Maine during the three-year period. The brand product was introduced to market in 2011 by Janssen Biotech with a WAC value of \$5,000.00 and an AWP value of \$6,000.00. The drug then launched generically in November 2018 with first generic products having WAC prices for a 30-day course of therapy that ranged between \$3,499.40 and \$8,840.58.

AWP values for the first generic products were specified at either \$11,050.73 or \$11,664.66, exactly 90% and 95% respectively of Janssen’s AWP value for the brand name drug at the time (\$12,278.59). Additional generic manufactures have since joined the market with the same or similar AWP values. In all instances, AWP values initially set by generic manufacturers did not change after product introduction to market. See Table 9 below.

	Manufacturer	NDC	Price Period		WAC	AWP	Average Payer Paid Amount
			Effective Date	End Date			
Brand	JANSSEN BIOTECH	57894015012	5/2/2011	12/27/2011	\$5,000.00	\$6,000.00	Not Reviewed
			12/28/2011	6/4/2012	\$5,495.00	\$6,594.00	
			6/5/2012	3/4/2013	\$5,819.21	\$6,983.05	
			3/5/2013	10/14/2013	\$6,395.31	\$7,674.37	
			10/15/2013	8/5/2014	\$6,836.59	\$8,203.91	
			8/6/2014	5/5/2015	\$7,376.68	\$8,852.02	
			5/6/2015	3/2/2016	\$7,996.32	\$9,595.58	
			3/3/2016	2/8/2017	\$8,628.03	\$10,353.64	
			2/9/2017	1/2/2018	\$9,395.88	\$11,275.06	
			1/3/2018	1/9/2019	\$10,232.16	\$12,278.59	\$9,145.35
		1/10/2019	12/31/2021	\$10,887.02	\$13,064.42	\$10,803.78	
Generic	AMNEAL PHARMACEUTICALS	69238116507	1/8/2019	12/8/2019	\$3,499.40	\$11,664.66	\$5,833.16
			12/9/2019	7/16/2020	\$800.00		\$4,832.55
			7/17/2020	12/31/2021	\$475.00		\$3,904.82
	APOTEX	60505432701	11/23/2018	11/26/2019	\$4,972.77	\$11,050.61	\$6,413.09
			11/27/2019	2/11/2020	\$2,625.00		\$4,749.77
			2/12/2020	12/31/2021	\$2,000.00		\$3,776.06
	AVKARE	42291002412	12/7/2019	12/31/2021	\$431.30	\$11,664.66	\$6,550.79
	CELLTRION USA	72606056601	2/7/2020	12/31/2021	\$425.00	\$510.00	\$371.27
	DR.REDDY'S LABORATORIES, INC.	43598035804	6/11/2020	12/31/2021	\$425.00	\$11,664.70	\$6,892.82
	MYLAN	00378692078	11/21/2018	1/2/2020	\$4,665.86	\$11,664.66	\$6,795.06
			1/3/2020	12/31/2021	\$1,700.00		\$5,521.89
	NORTHSTAR RX	16714096301	9/7/2020	12/31/2021	\$336.92	\$11,223.27	\$1,167.08
	NOVADOZ PHARMACEUTICALS	72205003092	8/7/2019	2/16/2020	\$1,505.00	\$11,649.00	\$3,621.09
			2/17/2020	6/9/2020	\$600.00		\$3,878.20
			6/10/2020	12/31/2021	\$225.00		\$3,614.04
	PATRIOT PHARMACEUTICALS LLC	57894015512	11/26/2018	12/31/2021	\$9,188.48	\$11,026.18	\$5,748.35
	RISING PHARMACEUTICALS	64980041812	11/1/2019	3/23/2021	\$600.00	\$11,664.66	\$3,859.69
3/24/2021			12/31/2021	\$260.00	\$3,971.67		
WOCKHARDT USA	64679002101	4/9/2019	7/26/2021	\$1,500.00	\$11,664.66	\$4,891.54	
		7/27/2021	12/31/2021	\$225.00		\$4,385.42	

Table 9 – Zytiga (Abiraterone Acetate) 250 Mg 120 Count Tablet – WAC, AWP and Average Payer Paid Amount by Price Period

During the three-year period for which MHDO prescription claims were reviewed (2019-2021), the average WAC for generic Zytiga products fell from \$5,165.18 to \$1,432.71. In contrast, average generic AWP prices fell from \$11,291.37 to \$10,594.21.

The average amount paid by payers for the brand Zytiga product before rebates was \$10,802.17 and was closely correlated to the brand WAC amount during the period which was \$10,887.02.

The average amount paid by payers for generic Zytiga products was \$4,619.38, a markup above average WAC of 163.92% during this period. See Chart 2 below. When calculated on an average markup per claim basis, the average amount paid as a percentage of WAC on the day the prescription was filled was 741.84%.

Zytiga 250 Mg 120 Count Tablet - WAC & AWP Correlation to Payer Paid Amounts

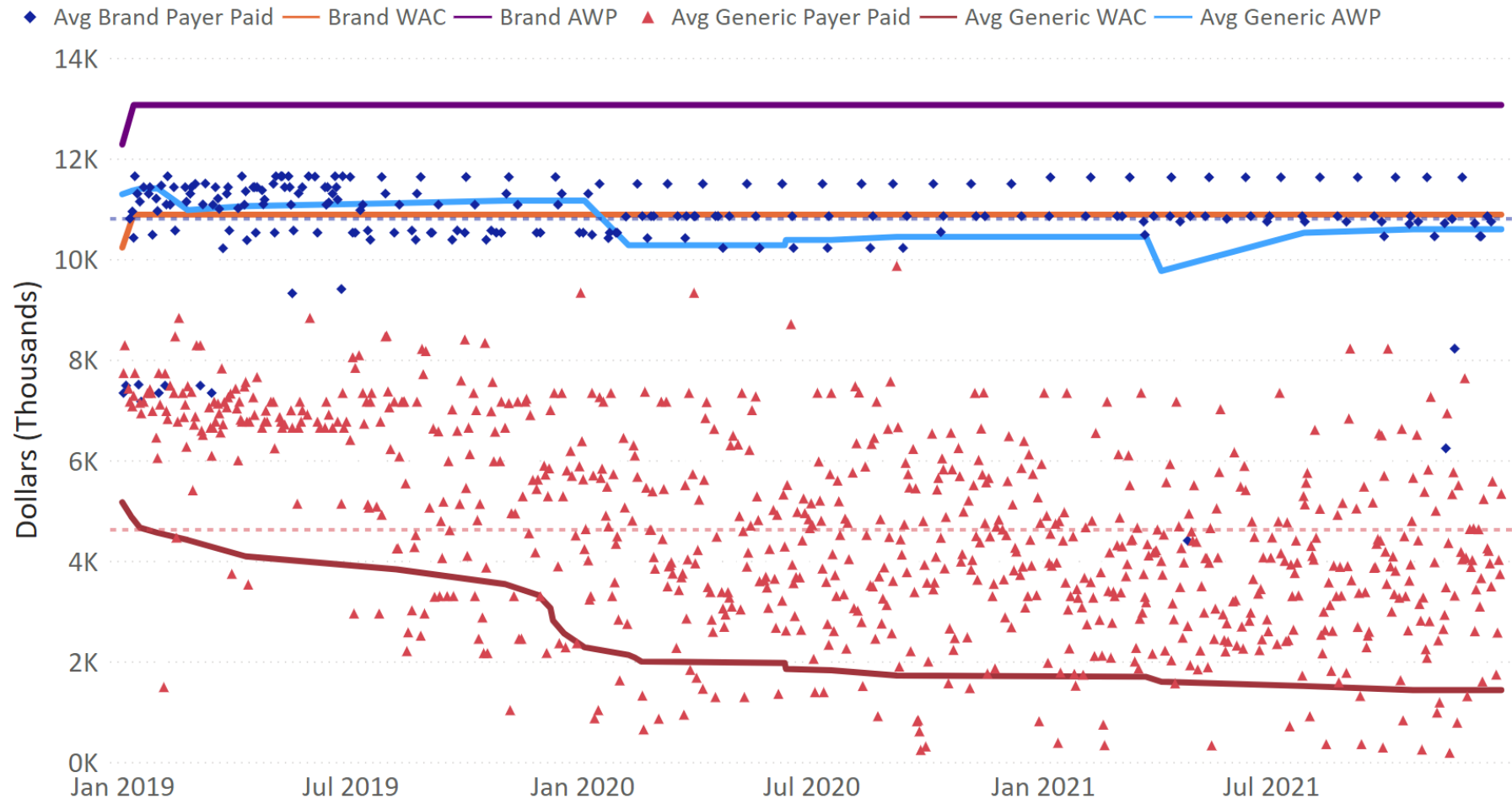


Chart 2 – Zytiga (Abiraterone Acetate) 250 Mg 120 Count Tablet – WAC & AWP Correlation to Payer Paid Amounts

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 chain⁶. Medicaid and Medicare claims were excluded from this analysis because rebate amounts for government programs are not available.

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.
- Pharmacies – entities that fill patient prescriptions using drug products acquired from wholesalers⁷.
- 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 contractual arrangements. While manufacturers set the WAC prices of the drugs they sell, manufacture rebates play a major role in lowering the acquisition costs realized by wholesalers and pharmacies, and the final amounts paid by payers.

Rebates accrue as drug products are exchanged between supply chain entities over time and may represent a fixed amount per unit or a percentage of an agreed upon price point such as WAC. A summary of average manufacturer rebates reported by reporting entities during 2021 is provided in Table 10 below. Rebate values are calculated at an NDC level for each reporting entity as the total rebate receivable amount divided by the average WAC amount⁸ for the NDC.

⁶ MHDO reviewed 430 unique NDCs for which pricing component data was submitted from reporting entities and APCD commercial claims were paid during 2021.

⁷ 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.

⁸ 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. $((\$a \times 31 \text{ days}) + (\$b \times 150 \text{ days}) + (\$c \times 184 \text{ days})) / 365 \text{ days}$

Source Group	Brand / Generic	NDC Count	Average Manufacturer Rebates (Percent of WAC)		
			Wholesale Rebate	PBM Rebate	Total Rebate
Single Source	Brand	58	6.73%	27.61%	34.35%
	Generic	2	13.40%	0.00%	13.40%
Multisource	Brand	74	11.50%	26.59%	37.94%
	Generic	295	32.89%	0.17%	32.83%

Table 10 – Average Manufacturer Rebates by Source Group and Drug Type

While rebates play a role in amounts ultimately paid by payers, amounts paid by payers and consumers to pharmacies are determined by contract pricing established and managed by PBMs. Commercial payers engage PBMs to negotiate payment rates with pharmacies for the drugs the pharmacies dispense. As prescriptions are filled, PBMs charge payers their negotiated price less the consumer payment amount and facilitate payment to the pharmacy. Analysis of pricing component data provided by PBMs shows that negotiated prices paid by payers and consumers to pharmacies were higher than market prices paid by pharmacies to wholesalers (the amount paid to acquire the drug dispensed) by an average margin of 1.56% for brand NDCs and 360.09% for generic NDCs.

Analysis of MHDO’s CY 2021 commercial claims data for the 430 NDCs reviewed shows that on average, consumers paid 10.95% of consumer / plan payments before rebates for brand NDCs (average consumer share of \$314.20 on \$2,868.95 claim paid amount) and 15.64% for generic NDCs (average consumer share of \$134.25 on \$858.35 claim paid amount).

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 16.75% for brand NDCs with no reduction for generic NDCs. If rebate amounts were distributed between payers and consumers at the point of sale (when the consumer is at the pharmacy), consumers would have realized out-of-pocket cost savings of approximately 14.91% for brand name NDCs.

A comparison of out-of-pocket amounts paid per person between 2019 and 2021 as reported to MHDO for all NDCs per the requirements in 90-590 Rule Chapter 243, Uniform Reporting System for Health Care Claims Data Sets, is provided in table 11 below.

Claim Incurred Year	Total Patient Population	Patient Total Out of Pocket Amount									
		\$0		\$0.01 - \$250.00		\$250.01 - \$500.00		\$500.01 - \$1,000.00		Over \$1,000.00	
		Patient Count	Population Percent	Patient Count	Population Percent	Patient Count	Population Percent	Patient Count	Population Percent	Patient Count	Population Percent
2019	788,895	113,687	14.41%	515,627	65.36%	76,709	9.72%	48,908	6.20%	33,965	4.31%
2020	774,337	147,100	19.00%	476,053	61.48%	72,141	9.32%	45,647	5.89%	33,396	4.31%
2021	803,530	271,534	33.79%	392,541	48.85%	64,260	8.00%	41,962	5.22%	33,233	4.14%

Table 11 – Year over year comparison of out-of-pocket paid amounts per person

Overall, for the subset of 430 NDCs reviewed by MHDO (see footnote 6), the average amount paid by payers (including member cost share) after rebates for a given NDC was 71.21% of the average WAC amount for brand NDCs and 163.65% for generic NDCs. On average, consumers paid 14.75% of the total paid amount after rebates overall.

Public Law 2019, Chapter 469, Section 4350-A

Public Law 2019, Chapter 469, *An Act to Protect Consumers from Unfair Practices Related to Pharmacy Benefits Management*, Section 4350-A requires 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.”

The sample of pricing component data (430 NDCs in the sample) reported to MHDO by PBMs shows that of the overall value of rebates received in 2021 only 48.45% was passed through to commercial payers, a significant decrease from the of 90.96% reported passed through in 2020.

90-590, CMR Chapter 570, *Uniform Reporting System for Prescription Drug Price Data Sets*, specifies that rebate data submitted by PBMs should represent receivable and payable amounts accrued during the year. One PBM provided a statement that the rebate values provided represented payment amounts for prior year accruals. While this data was not incorporated into MHDO’s analysis, incorrect reporting of rebates paid for prior period accruals by PBMs is a potential influencer in the decrease in passthrough percentage represented above. Further, to validate the requirements in PL 2019, Chapter 469, in a comprehensive way, MHDO would need to collect rebate data for all NDCs.

Public Law 2019, Chapter 469, Section 4350-D

Public Law Chapter 469, 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."

As requested, MHDO analyzed the paid amounts reported by payers in the MHDO APCD for prescription drugs against the sample of pricing component data provided by PBMs to evaluate compliance with Section 4350-D. The analysis found that the average pharmacy reimbursement amount reported by PBMs represented 90.92% of the average APCD paid amount across NDCs. This is a decrease of 6.94% from the same measure in 2020 (97.86%).

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 2.62% above what PBMs reimbursed to pharmacies for brand NDCs and 18.99% for generic NDCs (13.97% overall).

Conclusion

In this third annual report, MHDO leveraged changes enacted by Public Law 2021, Chapter 305 to request pricing component data from reporting entities for a broader range of NDCs for calendar year 2021. This additional data provided a greater sample size from which MHDO was able to evaluate rebate values for high cost and highly utilized drug products. Additionally, MHDO expanded its analysis of the correlation of WAC and AWP values to amounts actually paid by consumers and payers with particular focus on drugs with high costs and significant markups between manufacturer list prices and amounts paid.

A commonality across reports is the fact that drug pricing along the pharmaceutical supply chain is highly complex. The increased sample of data received by MHDO for the third year continues to show that there is variability in pricing and rebate practices across reporting entities and drug products and that no single entity in the pharmaceutical supply chain is responsible for the increases in prescription drug costs in Maine. Instead, the relationship between prices set by manufacturers to contractual markups and rebate incentives throughout the supply chain benefit each entity in different ways depending on whether a drug is a brand drug or a generic drug, and the number of manufacturers from which a given drug product is available.

The volume and rate of WAC increases appear to show signs of improvement when viewed against the previous five years; however, WAC increases continue to occur at rates that exceed the annual consumer price index and with greater frequency for brand drugs than observed for generic drugs. While generic drugs showed a general decrease in WAC during the year, AWP values remained largely static resulting in only marginal decreases in amounts paid by payers and consumers for generic products when compared to the reduction in cost realized by pharmacies.

Additional research regarding drug procurement costs to pharmacies, rebates received and paid by PBMs, and net paid amounts realized by payers across all drugs dispensed in the State is recommended to examine the efficacy of Public Law 2019, Chapter 469 and identify areas of potential cost savings. To provide this analysis, MHDO should consider adding new requirements to 90-590 CMR Chapter 243, Uniform Reporting System for Health Care Claims Data Sets, for payers to provide rebate and administrative cost data by NDC.

MHDO is pleased to present this analysis towards increasing awareness of the various factors contributing to the cost of prescription drugs.

Appendix A – Correlation between WAC Changes and AWP Pricing

NDCs with Claims Incurred Before and After 2021 WAC Changes⁹

Change Type / Source Type	Brand / Generic	NDC Count	Average WAC Change Percent	Average AWP Change Percent	Average AWP Percent of WAC After Change	Average AWP Percent of WAC Change Percent	Average APCD Paid Change Percent	Average APCD Paid Percent of WAC After Change	Average APCD Paid Percent of WAC Change Percent	Average APCD Paid Percent of AWP After Change	Average APCD Paid Percent of AWP Change Percent
Price Increases											
Single Source	Brand	978	5.30%	5.29%	119.98%	0.00%	8.45%	97.59%	-3.06%	81.33%	-2.54%
	Generic	43	23.70%	16.73%	126.50%	-13.97%	3.86%	90.70%	-23.22%	72.08%	-8.36%
Multisource	Brand	736	5.51%	5.23%	120.09%	-0.05%	9.48%	110.09%	4.60%	91.80%	3.89%
	Generic	174	22.46%	14.14%	182.74%	-65.88%	4.00%	92.24%	-20.19%	67.71%	-6.58%
Price Decreases											
Single Source	Brand	1	-77.46%	-77.46%	120.00%	0.01%	-80.83%	92.20%	-16.19%	76.83%	-13.50%
	Generic	12	-44.46%	-9.01%	949.55%	-465.39%	-3.35%	387.02%	176.70%	146.75%	100.88%
Multisource	Brand	27	-51.70%	-43.12%	188.56%	55.62%	-41.85%	105.78%	20.61%	73.92%	7.20%
	Generic	1,188	-49.74%	-5.98%	1826.22%	935.06%	-9.38%	251.46%	122.83%	37.13%	4.86%

⁹ Analysis of NDCs that incurred WAC changes during 2021 and for which claims were submitted to the MHDO APCD that were incurred both before and after the WAC changes.

Appendix B – NDCs with Average Fill Cost in Maine Over \$100 / Average Markup > 10x WAC¹⁰

NDC	Item Description	Manufacturer	Average APCD Paid Per Fill	Average APCD Paid Per Unit Dispensed	Average WAC Per Unit Dispensed	Average APCD Paid Per Fill Percent of WAC
43598035804	Abiraterone Acetate 250 MG Tablet 120.000 EA	DR.REDDY'S LABORATORIES, INC.	\$7,342.94	\$61.19	\$3.54	1727.73%
72205003092	Abiraterone Acetate 250 MG Tablet 120.000 EA	NOVADOZ PHARMACEUTICALS	\$3,203.55	\$28.59	\$1.88	1558.05%
64980041812	Abiraterone Acetate 250 MG Tablet 120.000 EA	RISING PHARMACEUTICALS	\$3,624.60	\$33.21	\$2.93	1321.51%
64679002101	Abiraterone Acetate 250 MG Tablet 120.000 EA	WOCKHARDT USA	\$2,532.12	\$36.01	\$7.83	1018.72%
65162089903	Aripiprazole 15 MG Tablet 30.000 EA	AMNEAL PHARMACEUTICALS	\$109.16	\$3.38	\$0.31	1551.36%
60505267503	Aripiprazole 15 MG Tablet 30.000 EA	APOTEX	\$363.74	\$24.25	\$1.49	1631.08%
67877043303	Aripiprazole 15 MG Tablet 30.000 EA	ASCEND LABORATORIES	\$101.94	\$2.78	\$0.24	1213.77%
31722082830	Aripiprazole 15 MG Tablet 30.000 EA	CAMBER PHARMACEUTICALS	\$131.60	\$4.51	\$0.81	1017.29%
43598096830	Aripiprazole 15 MG Tablet 30.000 EA	DR.REDDY'S LABORATORIES, INC.	\$286.37	\$10.89	\$0.90	1261.33%
16729028210	Aripiprazole 20 MG Tablet 30.000 EA	ACCORD HEALTHCARE	\$151.37	\$5.78	\$0.41	1292.46%
67877043403	Aripiprazole 20 MG Tablet 30.000 EA	ASCEND LABORATORIES	\$122.91	\$2.95	\$0.28	1083.97%
31722082930	Aripiprazole 20 MG Tablet 30.000 EA	CAMBER PHARMACEUTICALS	\$190.79	\$5.23	\$0.74	1246.75%
43598096630	Aripiprazole 5 MG Tablet 30.000 EA	DR.REDDY'S LABORATORIES, INC.	\$137.78	\$4.97	\$0.84	1207.52%
16714087402	Atorvastatin Calcium 10 MG Tablet 500.000 EA	NORTHSTAR RX	\$162.63	\$2.08	\$0.13	1447.51%
00904647561	Baclofen 10 MG Tablet 100.000 EA UD	MAJOR PHARMACEUTICALS	\$1,061.90	\$22.59	\$0.42	5355.21%
16729007329	Capecitabine 500 MG Tablet 120.000 EA	ACCORD HEALTHCARE	\$873.13	\$10.83	\$1.02	1137.82%
72485020512	Capecitabine 500 MG Tablet 120.000 EA	ARMAS PHARMACEUTICALS	\$1,073.51	\$12.36	\$1.00	1306.73%
72205000792	Capecitabine 500 MG Tablet 120.000 EA	NOVADOZ PHARMACEUTICALS	\$610.30	\$7.17	\$0.50	1519.26%
69097041002	Cinacalcet HCl 30 MG Tablet 30.000 EA	CIPLA USA	\$656.93	\$18.51	\$1.97	1817.02%
16729044015	Cinacalcet HCl 30 MG Tablet 90.000 EA	ACCORD HEALTHCARE	\$333.70	\$19.53	\$0.82	2449.58%
16729044110	Cinacalcet HCl 60 MG Tablet 30.000 EA	ACCORD HEALTHCARE	\$697.82	\$23.94	\$2.75	1295.21%
69097041102	Cinacalcet HCl 60 MG Tablet 30.000 EA	CIPLA USA	\$855.69	\$21.91	\$2.43	1720.25%

¹⁰ Average WAC Per Unit Dispensed values represent WAC per unit of measure (tablet, caplet, etc.) as of the date of fill provided in Wolters Kluwer's Medi-Span MedFile v2 data file database. Average APCD Paid Amounts are based on pharmacy claims data submitted by payers for claims incurred in by Mainers during calendar year 2022. Average APCD Paid Per Unit dispensed represents the total amount paid by payers and consumers for a drug during the year divided by the total number of units (tablets, caplets, etc.) dispensed.

NDC	Item Description	Manufacturer	Average APCD Paid Per Fill	Average APCD Paid Per Unit Dispensed	Average WAC Per Unit Dispensed	Average APCD Paid Per Fill Percent of WAC
16729044210	Cinacalcet HCl 90 MG Tablet 30.000 EA	ACCORD HEALTHCARE	\$935.18	\$21.33	\$5.07	1071.75%
71093015401	Cinacalcet HCl 90 MG Tablet 30.000 EA	ACI HEALTHCARE USA	\$2,185.96	\$60.72	\$5.00	1215.79%
69097041202	Cinacalcet HCl 90 MG Tablet 30.000 EA	CIPLA USA	\$2,760.12	\$61.34	\$2.07	3690.26%
43598036930	Cinacalcet HCl 90 MG Tablet 30.000 EA	DR.REDDY'S LABORATORIES, INC.	\$6,104.09	\$67.82	\$4.39	1545.76%
42291007760	Clobetasol Propionate 0.05 % Ointment 60.000 GM UU	AVKARE	\$257.50	\$4.50	\$0.14	3182.87%
27241021030	Clomipramine HCl 25 MG Capsule 30.000 EA	AJANTA PHARMA LIMITED	\$480.92	\$5.55	\$0.50	1075.60%
16571068309	Clomipramine HCl 25 MG Capsule 90.000 EA	RISING PHARMACEUTICALS	\$306.28	\$3.40	\$0.33	1021.04%
16571068409	Clomipramine HCl 50 MG Capsule 90.000 EA	RISING PHARMACEUTICALS	\$1,149.19	\$6.38	\$0.40	1596.10%
60505353205	Clopidogrel Bisulfate 300 MG Tablet 500.000 EA	APOTEX	\$193.83	\$96.92	\$7.42	1306.92%
71839010701	Daptomycin 500 MG Solution Reconstituted 1.000 EA UD	BE PHARMACEUTICALS	\$884.22	\$392.98	\$35.00	1111.32%
70700027030	Deferasirox 180 MG Tablet 30.000 EA	XIROMED	\$8,528.08	\$71.07	\$1.00	7106.73%
70710127603	Deferasirox 180 MG Tablet 30.000 EA	ZYDUS PHARMACEUTICALS (USA)	\$2,112.05	\$70.40	\$5.47	1287.82%
70700027130	Deferasirox 360 MG Tablet 30.000 EA	XIROMED	\$4,478.36	\$49.76	\$2.00	2531.31%
68462049630	Deferasirox 500 MG Tablet Soluble 30.000 EA	GLENMARK PHARMACEUTICALS	\$4,400.67	\$73.34	\$6.66	1101.27%
60687036911	Dicyclomine HCl 10 MG Capsule 1.000 EA UD	AMERICAN HEALTH PACKAGING	\$366.64	\$28.20	\$0.55	5127.83%
69238209503	Emtricitabine-Tenofovir Disoproxil Fumarate 200-300 MG Tablet 30.000 EA	AMNEAL PHARMACEUTICALS	\$789.84	\$18.45	\$1.33	1472.39%
65862035430	Emtricitabine-Tenofovir Disoproxil Fumarate 200-300 MG Tablet 30.000 EA	AUROBINDO PHARMA	\$748.49	\$19.28	\$2.55	1078.44%
42385095330	Emtricitabine-Tenofovir Disoproxil Fumarate 200-300 MG Tablet 30.000 EA	LAURUS LABS PRIVATE LIMITED	\$755.00	\$15.80	\$0.83	2258.12%
68180028706	Emtricitabine-Tenofovir Disoproxil Fumarate 200-300 MG Tablet 30.000 EA	LUPIN PHARMACEUTICALS	\$472.55	\$15.75	\$1.00	1575.15%
33342010607	Emtricitabine-Tenofovir Disoproxil Fumarate 200-300 MG Tablet 30.000 EA	MACLEODS PHARMACEUTICALS	\$1,130.57	\$20.07	\$1.00	1573.43%
64380071904	Emtricitabine-Tenofovir Disoproxil Fumarate 200-300 MG Tablet 30.000 EA	STRIDES PHARMA	\$1,254.43	\$29.77	\$2.50	1300.34%
70710136703	Emtricitabine-Tenofovir Disoproxil Fumarate 200-300 MG Tablet 30.000 EA	ZYDUS PHARMACEUTICALS (USA)	\$707.37	\$16.96	\$2.13	1284.52%
00093770456	Emtricitabine-Tenofovir Disoproxil Fumarate 200-300 MG Tablet 30.000 EA UU	TEVA PHARMACEUTICALS USA	\$1,191.93	\$23.56	\$11.24	1603.35%
31722083430	Entecavir 1 MG Tablet 30.000 EA	CAMBER PHARMACEUTICALS	\$901.53	\$32.20	\$2.22	1755.04%
51991089133	Erlotinib HCl 100 MG Tablet 30.000 EA	BRECKENRIDGE	\$6,050.14	\$201.67	\$13.33	1512.54%
51660020030	Ezetimibe 10 MG Tablet 30.000 EA	OHM LABS	\$495.66	\$6.47	\$0.45	1388.09%
00904644261	Hydralazine HCl 50 MG Tablet 100.000 EA UD	MAJOR PHARMACEUTICALS	\$227.40	\$18.95	\$0.14	13761.80%

NDC	Item Description	Manufacturer	Average APCD Paid Per Fill	Average APCD Paid Per Unit Dispensed	Average WAC Per Unit Dispensed	Average APCD Paid Per Fill Percent of WAC
72485020290	Imatinib Mesylate 100 MG Tablet 90.000 EA	ARMAS PHARMACEUTICALS	\$1,438.04	\$19.97	\$1.22	1687.47%
51991037690	Imatinib Mesylate 100 MG Tablet 90.000 EA	BRECKENRIDGE	\$6,826.74	\$75.85	\$1.20	6332.67%
00093762998	Imatinib Mesylate 100 MG Tablet 90.000 EA	TEVA PHARMACEUTICALS USA	\$1,455.21	\$15.37	\$1.49	1102.44%
72485020330	Imatinib Mesylate 400 MG Tablet 30.000 EA	ARMAS PHARMACEUTICALS	\$4,958.88	\$175.63	\$4.33	4210.31%
59651024130	Imatinib Mesylate 400 MG Tablet 30.000 EA	AUROBINDO PHARMA	\$4,108.36	\$107.30	\$4.33	3152.49%
51991037733	Imatinib Mesylate 400 MG Tablet 30.000 EA	BRECKENRIDGE	\$1,327.63	\$38.48	\$4.25	1039.23%
47335047583	Imatinib Mesylate 400 MG Tablet 30.000 EA	SUN PHARMACEUTICALS	\$2,336.81	\$75.89	\$6.93	1181.64%
00093763056	Imatinib Mesylate 400 MG Tablet 30.000 EA	TEVA PHARMACEUTICALS USA	\$4,081.70	\$133.70	\$5.61	3055.42%
13107019799	Losartan Potassium 100 MG Tablet 1000.000 EA	AUROBINDO PHARMA USA	\$238.80	\$2.65	\$0.07	3817.75%
51079025501	Metoprolol Tartrate 25 MG Tablet 1.000 EA UD	MYLAN INSTITUTIONAL	\$151.90	\$10.85	\$0.10	10850.00%
72888002301	Metoprolol Tartrate 75 MG Tablet 100.000 EA	ADVAGEN PHARMA	\$351.22	\$1.95	\$0.18	1087.03%
67877042712	Mycophenolate Sodium 360 MG Tablet Delayed Release 120.000 EA	ASCEND LABORATORIES	\$1,362.01	\$4.86	\$0.37	1217.77%
31722061290	Pregabalin 75 MG Capsule 90.000 EA	CAMBER PHARMACEUTICALS	\$125.05	\$1.10	\$0.13	1516.44%
50742063660	Quetiapine Fumarate 150 MG Tablet Extended Release 24 Hour 60.000 EA	INGENUS PHARMACEUTICALS	\$1,074.88	\$11.94	\$0.28	4342.95%
65862068890	Sildenafil Citrate (Pulmonary Hypertension) 20 MG Tablet 90.000 EA	AUROBINDO PHARMA	\$195.96	\$1.59	\$0.22	1288.94%
59762003301	Sildenafil Citrate (Pulmonary Hypertension) 20 MG Tablet 90.000 EA	GREENSTONE	\$129.81	\$6.18	\$0.52	1197.49%
65862088060	Tadalafil (Pulmonary Hypertension) 20 MG Tablet 60.000 EA	AUROBINDO PHARMA	\$421.19	\$8.08	\$0.83	1522.59%
69097052603	Tadalafil (Pulmonary Hypertension) 20 MG Tablet 60.000 EA	CIPLA USA	\$1,377.24	\$24.47	\$0.83	2795.81%
00093333406	Tadalafil (Pulmonary Hypertension) 20 MG Tablet 60.000 EA	TEVA PHARMACEUTICALS USA	\$1,646.68	\$28.46	\$1.41	2121.96%
27241011303	Tadalafil 10 MG Tablet 30.000 EA	AJANTA PHARMA LIMITED	\$459.14	\$16.33	\$0.67	2302.68%
33342026707	Tadalafil 10 MG Tablet 30.000 EA	MACLEODS PHARMACEUTICALS	\$100.35	\$12.54	\$0.48	2640.79%
27241011105	Tadalafil 2.5 MG Tablet 500.000 EA	AJANTA PHARMA LIMITED	\$281.19	\$9.37	\$0.33	2812.18%
27241011403	Tadalafil 20 MG Tablet 30.000 EA	AJANTA PHARMA LIMITED	\$580.54	\$29.36	\$0.67	4563.03%
27241011203	Tadalafil 5 MG Tablet 30.000 EA	AJANTA PHARMA LIMITED	\$189.33	\$3.10	\$0.33	1026.65%
42291078730	Tadalafil 5 MG Tablet 30.000 EA UU	AVKARE	\$170.00	\$5.67	\$0.33	1727.59%
31722082211	Tetrabenazine 25 MG Tablet 112.000 EA	CAMBER PHARMACEUTICALS	\$23,505.26	\$65.29	\$5.36	1218.80%
70436010209	Tetrabenazine 25 MG Tablet 112.000 EA	SLATE RUN PHARMACEUTICALS	\$5,242.85	\$50.39	\$4.24	1261.21%
69097096453	Vigabatrin 500 MG Packet 50.000 EA UD	CIPLA USA	\$8,678.04	\$90.20	\$9.57	1270.57%

Appendix C – Average WAC and Payer Paid Change Percent by Therapeutic Class

All Active Prescription Drugs

Therapeutic Class	Active NDCs	Average WAC Change Percent	Average APCD Paid Change Percent
ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiant	882	-5.73%	-4.12%
Allergenic Extracts/Biologicals Misc	4	4.49%	-3.26%
Analgesics - Anti-Inflammatory	882	3.36%	0.39%
Analgesics - Nonnarcotic	87	-0.88%	0.24%
Analgesics - Opioid	989	-0.06%	0.08%
Anorectal And Related Products	87	0.59%	1.14%
Anti-Infective Agents - Amebicides	1	0.00%	0.00%
Anti-Infective Agents - Aminoglycosides	78	-2.89%	0.34%
Anti-Infective Agents - Anthelmintics	19	0.49%	-3.40%
Anti-Infective Agents - Antifungals	238	-2.91%	4.27%
Anti-Infective Agents - Antimalarials	68	-3.54%	-1.73%
Anti-Infective Agents - Antimycobacterial Agents	49	0.11%	0.23%
Anti-Infective Agents - Antivirals	450	-3.64%	-1.03%
Anti-Infective Agents - Cephalosporins	395	-2.96%	0.19%
Anti-Infective Agents - Fluoroquinolones	138	-0.42%	0.10%
Anti-Infective Agents - Macrolides	212	-2.74%	-1.60%
Anti-Infective Agents - Misc	555	-2.01%	-1.09%
Anti-Infective Agents - Penicillins	418	-2.70%	1.00%
Anti-Infective Agents - Tetracyclines	239	-2.23%	-0.84%
Antidotes And Specific Antagonists	104	-0.31%	0.75%
Antihistamines/Nasal Agents/Cough & Cold/Respiratory/Misc - Antiasthmatic And Bronchodilator Agents	526	-1.98%	0.24%
Antihistamines/Nasal Agents/Cough & Cold/Respiratory/Misc - Antihistamines	166	0.30%	-1.95%
Antihistamines/Nasal Agents/Cough & Cold/Respiratory/Misc - Cough/Cold/Allergy	155	0.70%	1.33%
Antihistamines/Nasal Agents/Cough & Cold/Respiratory/Misc - Misc	21	1.19%	1.46%
Antihistamines/Nasal Agents/Cough & Cold/Respiratory/Misc - Nasal Agents - Systemic And Topical	47	-7.49%	-1.48%
Antineoplastics And Adjunctive Therapies	794	-1.78%	0.35%
Cardiovascular Agents - Antianginal Agents	166	1.76%	0.99%
Cardiovascular Agents - Antiarrhythmics	197	-2.06%	-0.53%
Cardiovascular Agents - Antihyperlipidemics	1,140	-1.99%	-0.08%
Cardiovascular Agents - Antihypertensives	1,819	-1.34%	0.09%
Cardiovascular Agents - Beta Blockers	875	-1.75%	0.05%
Cardiovascular Agents - Calcium Channel Blockers	593	0.24%	-0.16%
Cardiovascular Agents - Cardiotonics	43	-3.46%	-2.49%
Cardiovascular Agents - Diuretics	497	-1.39%	-0.25%
Cardiovascular Agents - Misc	370	-2.32%	-0.27%
Cardiovascular Agents - Vasopressors	126	-3.37%	-3.69%
Central Nervous System Agents - Antianxiety Agents	502	-0.35%	-1.14%
Central Nervous System Agents - Antidepressants	1,727	-1.70%	0.31%
Central Nervous System Agents - Antipsychotics/Antimanic Agents	1,415	-4.04%	-1.08%
Central Nervous System Agents - Hypnotics/Sedatives/Sleep Disorder Agents	391	-5.01%	-0.33%
Dermatologicals	2,080	-2.79%	-1.15%

Therapeutic Class	Active NDCs	Average WAC Change Percent	Average APCD Paid Change Percent
Endocrine and Metabolic Agents - Androgens-Anabolic	121	-0.78%	1.77%
Endocrine and Metabolic Agents - Antidiabetics	936	-0.05%	1.03%
Endocrine and Metabolic Agents - Contraceptives	469	-3.55%	-1.75%
Endocrine and Metabolic Agents - Corticosteroids	397	0.69%	6.81%
Endocrine and Metabolic Agents - Estrogens	179	1.46%	1.07%
Endocrine and Metabolic Agents - Misc	445	-4.19%	-0.17%
Endocrine and Metabolic Agents - Oxytocics	10	0.00%	0.00%
Endocrine and Metabolic Agents - Progestins	61	-5.24%	-3.05%
Endocrine and Metabolic Agents - Thyroid Agents	385	-12.81%	-1.27%
Gastrointestinal Agents - Antidiarrheal/Probiotic Agents	40	-2.67%	0.00%
Gastrointestinal Agents - Antiemetics	194	-3.26%	-1.13%
Gastrointestinal Agents - Digestive Aids	34	3.37%	2.62%
Gastrointestinal Agents - Laxatives	51	0.99%	0.14%
Gastrointestinal Agents - Misc	256	-1.65%	-0.24%
Gastrointestinal Agents - Ulcer Drugs/Antispasmodics/Anticholinergics	645	-2.74%	0.19%
General Anesthetics	3	0.00%	0.00%
Genitourinary Agents - Miscellaneous	245	-4.87%	2.20%
Gout Agents	132	-4.60%	-2.30%
Hematological Agents - Anticoagulants	514	-6.01%	0.16%
Hematological Agents - Hematopoietic Agents	196	0.44%	0.80%
Hematological Agents - Hemostatics	63	-4.95%	2.27%
Hematological Agents - Misc	151	2.50%	0.06%
Local Anesthetics-Parenteral	68	0.70%	-8.40%
Medical Devices And Supplies	1	0.00%	0.00%
Migraine Products	273	-1.15%	18.10%
Miscellaneous Therapeutic Classes	278	-1.05%	0.26%
Mouth/Throat/Dental Agents	137	0.61%	0.63%
Neuromuscular Agents - Anticonvulsants	1,538	-1.47%	1.08%
Neuromuscular Agents - Antimyasthenic/Cholinergic Agents	21	0.58%	-0.52%
Neuromuscular Agents - Antiparkinson And Related Therapy Agents	471	-1.17%	0.30%
Neuromuscular Agents - Musculoskeletal Therapy Agents	432	-3.44%	1.12%
Neuromuscular Agents - Neuromuscular Agents	19	0.95%	0.82%
Nutritional Products - Dietary Products/Dietary Management Products	96	0.91%	-0.27%
Nutritional Products - Minerals & Electrolytes	388	-0.60%	2.48%
Nutritional Products - Multivitamins	87	0.85%	-1.59%
Nutritional Products - Nutrients	46	3.40%	-1.31%
Nutritional Products - Vitamins	37	-0.30%	-2.32%
Ophthalmic Agents	427	-0.58%	0.80%
Otic Agents	38	-2.21%	-0.93%
Passive Immunizing And Treatment Agents	119	4.30%	2.03%
Pharmaceutical Adjuvants	79	0.89%	29.38%
Psychotherapeutic and Neurological Agents - Miscellaneous - Misc	549	-2.93%	0.15%
Toxoids	26	3.59%	34.15%
Urinary Antispasmodics	312	-2.08%	-1.55%
Vaccines	86	3.56%	23.64%
Vaginal And Related Products	58	1.00%	1.03%

Appendix D – Summary of Rule Chapter 570 and Related Processes

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

90-590, CMR Chapter 570, *Uniform Reporting System for Prescription Drug Price Data Sets*, defines the requirements for the registration of reporting entities; conditions under which MHDO must provide notice of substantial drug price changes or introductions; conditions under which the MHDO 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.

As of June 22, 2021, 518 manufacturers, 199 wholesale drug distributors and 33 pharmacy benefit managers have registered with the MHDO.

Public Notice of Substantial Drug Price Change or Introduction

Beginning January 30, 2022, MHDO is required to compile and publicly post on its website a list of all prescription drugs for which a manufacturer has during the prior calendar year:

1. Increased the WAC of a brand drug by more than 20% per pricing unit;
2. Increased the WAC 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 WAC 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

Beginning February 15, 2022, and annually thereafter, MHDO must produce and post on its publicly accessible website a list of drug product families for which it intends to require reporting of pricing component data by reporting entities. In determining this list, MHDO considers the relevance of specific drug products in providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the state. MHDO included 50 drug product families in [the list for calendar year 2021](#), each of which met at least two of the following criteria:

- Average claim paid amount per prescription \geq \$100
- Aggregate paid amount of $>$ \$1M
- One or more NDCs:
 - included on [MHDO's List of Trigger NDCs for CY2021](#); or
 - included 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, 2020 to June 30, 2021 comparison period; or
 - having average claim paid amount \geq 10x WAC

MHDO Notification to Reporting Entities requesting Pricing Component Data

MHDO is responsible for identifying specific drug products of interest and notifying reporting entities that they must report detailed pricing component data to MHDO as defined in 90-590 CMR Chapter 570, Uniform Reporting System for Prescription Drug Price Data Sets, for those drug products. Each drug product is identified by its NDC. For the remainder of this report, NDC will be used to describe a manufacturer specific drug product.

MHDO requested pricing component data from reporting entities for 1,259 NDCs (which represents less than 1% of all NDCs) based on inclusion criteria described in Table 1 below:

2021 Target Inclusion Criteria	Distinct Manufacturers	Target NDCs	Related NDCs	Brand NDCs	Generic NDCs	Total NDCs
High Cost / High Margin	75	31	569	48	552	600
Multiple Top 25 Lists	24	22	91	60	53	113
New Drug Trigger	61	48	483	170	361	531
WAC Increase Trigger	6	1	14	3	12	15
Total	115	102	1,157	281	978	1,259

Table 1 – 2021 Target Inclusion Criteria

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. The subset of NDCs for which MHDO received pricing component data is used to highlight pricing, rebate, and brand to generic drug utilization statistics for drugs identified as having high impact to prescription drug costs in Maine.

In addition to incorporating data submitted by reporting entities in this annual report, MHDO included descriptive drug product and historical pricing information compiled from Wolters Kluwer’s Medi-Span MedFile v2 data file, and pharmaceutical claims data submitted to the MHDO APCD as required by 90-590 Rule Chapter 243, Uniform Reporting System for Health Care Claims Data Sets. These supplemental data sets enabled review of claim volume and costs before and during the 2021 reporting period. Additionally, portions of the report use supplemental data to expand beyond NDCs reported by reporting entities to show more general trends in the overall prescription drug marketplace.