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Date: February 2, 2024

To: Senator Bailey, Representative Perry and Members of the Joint Standing Committee on Health Coverage, Insurance and Financial Service

CC: Colleen McCarthy Reid, Principal Analyst, Office of Policy, and Legal Analysis
Bethany Beausang, Senior Policy Advisor, Office of Governor Janet T. Mills
Senator Vitelli, Senate Majority Leader
Joel Allumbaugh, Chair MHDO Board of Directors
Commissioner Head, Vice-Chair, MHDO Board of Directors
Meg Garratt-Reed, Executive Director, Maine Office of Affordable Health Care
Maine Prescription Drug Affordability Board

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 fourth annual report. This report has been posted to MHDO's website which can be found here: <https://mhdo.maine.gov/RxDrugPricingTransparency.htm>.

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

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Prescription Drug Price Transparency 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 per the requirements of 90-590 Chapter 570, Uniform Reporting System for Prescription Drug Price Data Sets, from manufacturers, wholesale drug distributors and pharmacy benefits managers, referred to as reporting entities. Specifically, the report provides 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.

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

This is MHDO's fourth annual report.

Highlights of MHDO's Prescription Drug Transparency Report

Highlights and conclusions of MHDO's fourth annual report include:

- Factors in the prescription drug market impact brand and generic pricing such that lower prices that exist for entities in the pharmaceutical supply chain are not always realized by payers and consumers.
- Variation in pricing and rebate practices exists amongst different manufacturers, wholesale distributors, and PBMs (referred to in this report as reporting entities) and depends on the type of drug (e.g., brand vs. generic, single source vs. multiple source). No single reporting entity in the pharmaceutical supply chain is responsible for prescription drug costs in Maine.
 - Manufacturers specify the wholesale acquisition cost (WAC) for the drugs they produce.
 - Wholesalers typically pay manufacturers the WAC price to acquire the drugs and later sell the drugs to pharmacies at market prices (often less than WAC).
 - Manufacturers may provide publishers of prescription drug pricing with a suggested average wholesale price (AWP) value. Where manufacturers do not provide AWP guidance, the value is typically set as WAC + 20% by data publishers¹.
 - Manufacturers do not receive revenue based on the AWP; instead AWP values represent the price that the manufacturer suggests that wholesalers charge when selling the manufacturer's drug to the wholesaler's customers. In practice, wholesalers sell most drugs to pharmacies at or below the value of WAC.
 - PBMs negotiate contracted rates between pharmacies and payers for the drugs the pharmacies dispense. Contracted rates are typically derived as a percentage-based discount from AWP plus a fixed price dispensing fee. As a result, when AWP values are set at substantially higher values than WAC, payers may pay significantly more to the pharmacy than the cost from the manufacturer.

¹ 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>

- Increases in wholesale acquisition costs (WAC) continue to occur at rates that exceed the annual consumer price index and with greater frequency for brand drugs than observed for generic drugs.
- The value of average wholesale price (AWP) is more directly related to the cost of generic drugs than is the cost to pharmacies to purchase the drugs. While generic drugs showed a general decrease in WAC during the year, the 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 for these drugs realized by pharmacies.
- The top 10 most costly drug families (groups of drugs that share a unique generic drug description (non-trade name) and drug form) reported in Maine for 2022 remain the same as reported in 2021. These drugs are commonly prescribed for indications including rheumatoid arthritis, Crohn disease, blood clots, diabetes, multiple myeloma, cystic fibrosis, and opioid use disorder.
- Eight of the top 10 drug families that were most utilized and having the highest year over year cost increase remain the same as reported in 2021. These drugs are commonly prescribed for indications including high cholesterol, hypothyroidism, high blood pressure, asthma, depression, heartburn, and epilepsy.
- For the subset of 474 drugs (referred to as NDCs) reviewed by MHDO:
 - The average amount paid by payers (including member cost share) after rebates for a given NDC was 84.32% of the average WAC amount for brand NDCs and 335.36% for generic NDCs.
 - On average, PBMs received rebates from manufacturers representing 13.27% of the average WAC amount for brand NDCs and 0.64% for generic NDCs (3.03% overall). Of the overall amount of rebates reported in the sample, approximately 51.43% was passed through to commercial payers while 48.57% was retained by the PBM.
 - On average, wholesalers received rebate amounts of 10.47% for brand drugs and 32.54% for generic drugs (28.36% overall) when applied against acquisition cost on a per unit basis. Rebates received by wholesalers from manufacturers are largely passed through to pharmacies as price reductions, allowing wholesalers to sell drugs to pharmacies at a cost that is less than WAC.

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 WAC.

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.

Pharmaceutical Supply Chain Entities

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 drug 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 consumer prescriptions using drug products acquired from wholesalers².
- 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.

² 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.

- 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.

Overview of Prescription Drug Spending in Maine

In 2022, prescription drug payments reported to the MHDO for all NDCs per the requirements in 90-590 Rule Chapter 243, *Uniform Reporting System for Health Care Claims Data Sets*, was approximately \$2.6B, representing approximately 24% of all payments reported to MHDO. A breakdown of pharmacy claims by payer type is provided in the table below.

Payer Type	Total Pharmacy Claims	Total Paid Amount
Commercial	3,672,016	\$779,816,606
MaineCare	2,782,301	\$505,364,014
Medicare	7,268,751	\$1,350,440,811
Total	13,723,068	\$2,635,621,431

The top 10 most costly drug families based on MHDO data in 2022 are shown in the table below. Drug families are groups of drugs that share a unique generic drug description (non-trade name) and drug form.

Drug Family	Therapeutic Class	Total Claims	Total Paid
Adalimumab Pen-injector Kit	Analgesics - Anti-Inflammatory	19,109	\$152,006,928
Apixaban Tablet	Hematological Agents - Anticoagulants	123,986	\$115,198,002
Ustekinumab Solution Prefilled Syringe	Dermatologicals	4,16	\$96,754,311
Dulaglutide Solution Pen-injector	Endocrine and Metabolic Agents - Antidiabetics	61,446	\$80,994,981
Empagliflozin Tablet	Endocrine and Metabolic Agents - Antidiabetics	54,716	\$56,277,991
Lenalidomide Capsule	Miscellaneous Therapeutic Classes (Oncology Agent)	2,940	\$50,530,291
Insulin Glargine Solution Pen-injector	Endocrine and Metabolic Agents - Antidiabetics	63,576	\$42,185,862
Elexacaftor-Tezacaftor-Ivacaftor Tablet Therapy Pack	Antihistamines/Nasal Agents/Cough & Cold/Respiratory/Misc (Cystic Fibrosis Agent)	1,500	\$38,352,137
Rivaroxaban Tablet	Hematological Agents - Anticoagulants	37,472	\$36,547,892
Buprenorphine HCl-Naloxone HCl Dihydrate Film	Analgesics - Opioid (Use Disorder)	187,050	\$36,217,770

The top 10 most utilized drug families based on MHDO data in 2022 are shown in the table below.

Drug Family	Therapeutic Class	Total Claims	Total Paid
Atorvastatin Calcium Tablet	Cardiovascular Agents - Antihyperlipidemics	456,597	\$9,582,547
Levothyroxine Sodium Tablet	Endocrine and Metabolic Agents - Thyroid Agents	381,583	\$9,045,233
Lisinopril Tablet	Cardiovascular Agents - Antihypertensives	364,502	\$3,078,651
Albuterol Sulfate Aerosol Solution	Antihistamines/Nasal Agents/Cough & Cold/Respiratory/Misc - Antiasthmatic And Bronchodilator Agents	285,109	\$14,526,349
Sertraline HCl Tablet	Central Nervous System Agents - Antidepressants	260,123	\$4,004,337
Omeprazole Capsule Delayed Release	Gastrointestinal Agents - Ulcer Drugs/Antispasmodics/Anticholinergics	249,437	\$4,189,045
Amlodipine Besylate Tablet	Cardiovascular Agents - Calcium Channel Blockers (Anihypertensive)	246,859	\$2,273,413
Gabapentin Capsule	Neuromuscular Agents - Anticonvulsants	206,459	\$4,850,872
Losartan Potassium Tablet	Cardiovascular Agents - Antihypertensives	205,266	\$3,032,377
Metoprolol Succinate Tablet Extended Release 24 Hour	Cardiovascular Agents - Beta Blockers	196,022	\$4,931,526

The top 10 drug families with the highest year over year paid amount increase in 2022 based on MHDO data are shown in the table below.

Drug Family	Therapeutic Class	Total Claims	Total Paid
Ustekinumab Solution Prefilled Syringe	Dermatologicals	863	\$24,484,954
Dulaglutide Solution Pen-injector	Endocrine and Metabolic Agents - Antidiabetics	13,164	\$21,935,106
Apixaban Tablet	Hematological Agents - Anticoagulants	9,562	\$18,530,753
Empagliflozin Tablet	Endocrine and Metabolic Agents - Antidiabetics	13,824	\$16,422,431
Adalimumab Pen-injector Kit	Analgesics - Anti-Inflammatory	733	\$16,206,727
Semaglutide Solution Pen-injector	Endocrine and Metabolic Agents - Antidiabetics	10,759	\$14,419,535
Risankizumab-rzaa Solution Auto-injector	Dermatologicals	769	\$13,920,739
Dupilumab Solution Pen-injector	Dermatologicals	2,585	\$9,617,568
Fluticasone-Umeclidinium-Vilanterol Aerosol Powder Breath Activated	Antihistamines/Nasal Agents/Cough & Cold/Respiratory/Misc - Antiasthmatic And Bronchodilator Agents	5,262	\$6,296,175
Dapagliflozin Propanediol Tablet	Endocrine and Metabolic Agents - Antidiabetics	4,608	\$5,174,941

Trends in the Cost of Prescription Drugs

MHDO used publicly available prescription drug pricing data to analyze changes in the wholesale acquisition costs of drug products set by pharmaceutical manufacturers over the previous five years for all drug products with at least one claim reported in the MHDO's data during 2022³.

The analysis shows that during the five-year period:

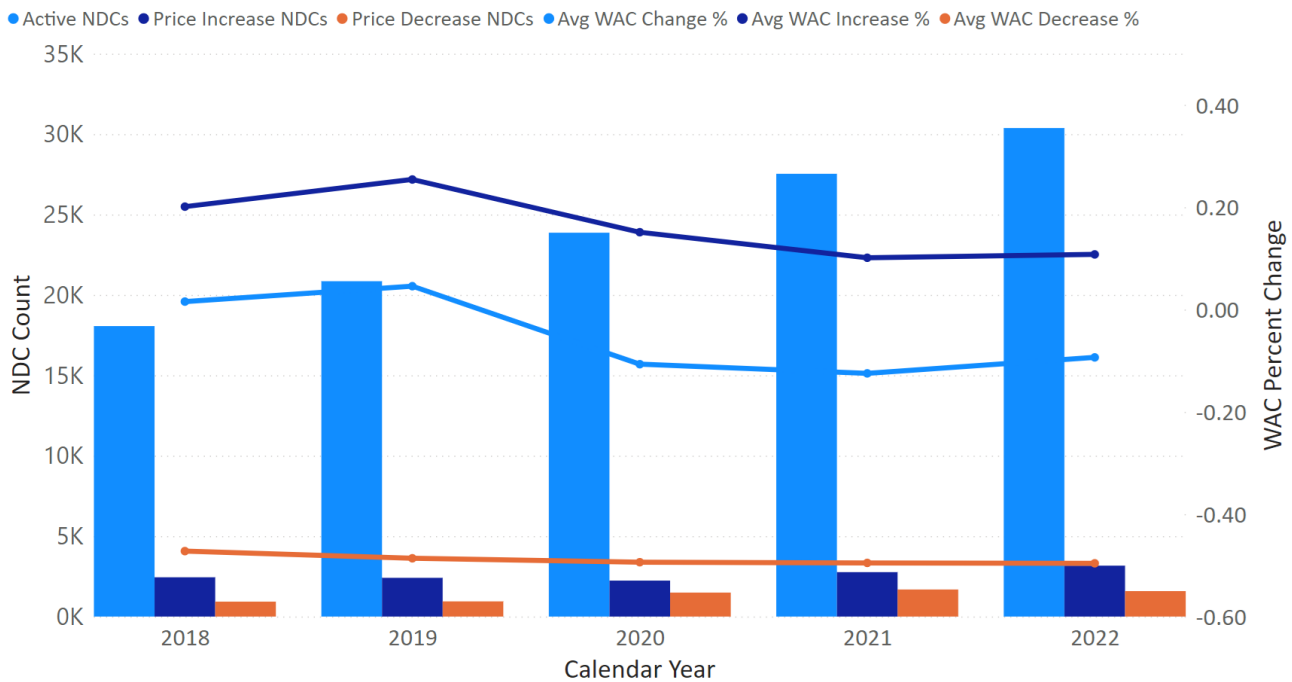
- A majority of drugs do not have changes in wholesale acquisition cost (WAC). In 2022, 84.35% of active NDCs had no change in WAC.
- The percentage of drugs that incur price increases has decreased overall from 13.52% of active NDCs in 2018 to 10.44% in 2022; however, the number of drugs with price increases gradually increased over the previous two years.
- The average percent of increase for price increases has also decreased over time.
- The 2022 average percent of increase of 10.79% remains above the consumer price index (CPI-U) for 2022 of 6.5% and is slightly higher (0.68%) than the 2021 average rate of increase.
- Of 3,176 drugs with price increases in 2022, 46.55% were single source brand products, 31.63% were multi-source brand products, and 21.82% were generic products.
- The percentage of brand and generic drugs with WAC decreases has varied over time the average percent of decrease has gradually grown during the five-year period with a value of -49.60% in 2022.
- Of 1,585 drugs with price decreases in 2022, 1.27% were single source brand products, 4.26% were multi-source brand products, and 94.47% were generic products.

See the table and chart below.

Time Frame	Number of Active Drugs (NDCs)	All Changes			WAC Increases			WAC Decreases		
		Number of Drugs with Changes in WAC	Percent of Drugs with Changes in WAC	Average WAC Percent Change	Number of Drugs with Increases in WAC	Percent of Drugs with Increases in WAC	Average WAC Percent Increase	Number of Drugs with Decreases in WAC	Percent of Drugs with Decreases in WAC	Average WAC Percent Decrease
2018	18,099	3,377	18.66%	1.57%	2,447	13.52%	20.11%	930	5.14%	-47.21%
2019	20,894	3,357	16.07%	4.58%	2,412	11.54%	25.41%	945	4.52%	-48.61%
2020	23,912	3,731	15.60%	-10.67%	2,238	9.36%	15.12%	1,493	6.24%	-49.35%
2021	27,581	4,456	16.16%	-12.47%	2,769	10.04%	10.11%	1,687	6.12%	-49.52%
2022	30,430	4,761	15.65%	-9.31%	3,176	10.44%	10.79%	1,585	5.21%	-49.60%

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

WAC Change Statistics by Year



Of 42,496 active brand and generic prescription NDCs in the pharmaceutical market, Mainers filled prescriptions for 30,430 drugs in 2022. Less than 1% of these drugs (70 drugs total – 64 brand drugs and 6 generic drugs) had increases in the wholesale acquisition costs in 2022 of more than 20%.

Impact of Changes in the Wholesale Acquisition Costs on Pricing for Multisource Drug Products

MHDO used pricing component data submitted by manufacturers, wholesale distributors and pharmacy benefit managers (referred to as reporting entities) per the reporting requirements in 90-590 Chapter 570, *Uniform Reporting System for Prescription Drug Price Data Sets*, to evaluate the difference in the Wholesale acquisition cost between brand and generic drugs for products where brand and generic equivalents were available during the year (multisource drug products). Of 37 multisource drugs reviewed, each had generic versions priced lower than their brand equivalents before and after application of changes in the wholesale acquisition costs. On average the generic drugs in this sample were 68.85% less than the brand name drugs. After incorporating rebate information, when generic drugs 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 61.13%⁴.

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.

Brand to Generic Drug Utilization in Maine

In CY 2022 the MHDO claims data shows that consumers in Maine were provided brand drug products for 4.71% of claims where generic drugs were alternatively available, which is slightly lower than 2021. Payments for brand name drugs reported in the MHDO claims data made up 36.49% 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 the table below.

Description	Time Frame			
	2019	2020	2021	2022
Brand Drug Utilization as Percent of Total Claims	5.32%	5.78%	5.14%	4.71%
Brand Cost Percentage	31.41%	33.62%	33.29%	36.49%
Percent Brand Claims Indicated Dispensed as Written	26.30%	26.94%	23.97%	23.08%

⁵ Claim payments do not reflect the effect of drug rebates. 23.08% of the brand claims represented for 2022 were prescribed as Dispense As Written, indicating the medical provider determined that the branded NDC was more appropriate for the consumer and should not be filled as a generic.

Analysis of Manufacturer Pricing, Contract Negotiations, and Drug Costs to Payers

Consistent with previous reports, MHDO analyzed the pharmaceutical claims data submitted to MHDO per the requirements of 90-590 Chapter 243, *Uniform Reporting System for Health Care Claims Data Sets*, to evaluate the impact of both increases and decreases in the wholesale acquisition costs on actual amounts paid by payers during the reporting period. This Analysis was limited to 3,144 drugs (specifically NDCs) that incurred a change in the WAC during 2022 and for which claims were incurred both before and after the changes in the WAC.

Wholesale Acquisition Cost (WAC) & the Relationship to Payer Paid Amounts

- The analysis showed a relative correlation between average WAC increase amounts (7.72%) and increases to average amounts paid by payers (9.37%) after WAC increases took place.
- Where WAC prices decreased, the relative percent of decrease in amounts paid by payers was significantly lower, with WAC prices decreasing 49.76% and average amounts paid only decreasing 4.10%. See table below.

Total Drugs Reviewed (NDCs)	2022 WAC Increases			2022 WAC Decreases		
	NDC Count	Average WAC Percent Change	Average Payer Paid Percent Change	NDC Count	Average WAC Percent Change	Average Payer Paid Percent Change
3,131	2,046	7.72%	9.37%	1,098	-49.76%	-4.10%

WAC Change Impact on Payer Paid Amounts

Average Wholesale Price (AWP) & the Relationship to Payer Paid Amounts

Commercial payers (insurance companies) engage a pharmacy benefits manager (PBM) to negotiate payment rates between the commercial payer and the pharmacies for the drugs that the pharmacies dispense.

Negotiated payment rates are typically derived as a percentage-based discount from the average wholesale price (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 the table below.

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	961	5.98%	6.00%	120.00%	0.01%	6.69%	98.71%	-0.56%	82.25%	-0.48%
	Generic	69	13.20%	12.91%	133.94%	-0.61%	49.68%	89.70%	-0.94%	69.54%	-0.53%
Multisource	Brand	781	5.68%	5.68%	119.97%	0.00%	9.49%	124.76%	8.82%	104.15%	7.44%
	Generic	235	20.02%	13.90%	250.74%	-32.00%	8.11%	89.27%	-11.29%	59.13%	-2.87%
Price Decreases											
Single Source	Brand	4	-56.95%	-56.96%	119.99%	0.00%	-55.08%	100.08%	5.36%	83.33%	4.47%
	Generic	8	-26.10%	0.00%	1,085.04%	335.07%	11.84%	137.79%	1.22%	15.52%	-5.65%
Multisource	Brand	54	-63.07%	-11.17%	357.04%	237.42%	-9.17%	125.29%	31.59%	46.84%	-31.41%
	Generic	1,032	-49.21%	-3.85%	1,901.86%	915.27%	-3.76%	284.41%	138.28%	31.83%	2.50%

NDCs with Claims Incurred Before and After 2022 WAC Changes

Key findings based on MHDO's sample of prescription drugs

- Brand drugs
 - Most drug products with WAC increases in 2022 were brand drugs (85.14% of NDCs in the sample).
 - Amounts paid by payers after the application of WAC increases for brand drugs 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 19.97% and 20.00% 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 91 brand NDCs dispensed in Maine during 2022 indicated average rebate amounts of 13.27%.
- Generic drugs
 - Multisource generic drugs made up 93.99% of all NDCs with WAC decreases and had an average percent decrease of 49.21%.
 - The average amount paid by payers for multisource generic drugs after WAC decreases fell by only 3.76%.
 - When represented as a percentage of WAC, payer paid amounts for multisource generic drugs with WAC decreases increased by 138.28% with average payer paid amounts reflecting 284.41% 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 3.85% of pre-WAC change AWP.
 - **AWP for multisource generic drugs had an average markup from WAC of 1,901.86% 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 386 generic NDCs dispensed in Maine during 2022 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. This pricing practice differs from brand drug pricing where manufacturers typically do not provide AWP guidance resulting in a default AWP value of 120% of WAC.

Pharmacies are able to reduce the cost of drug inventory 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.

Analysis of pricing component data provided to MHDO by PBMs via 90-590 Chapter 570, *Uniform Reporting System for Prescription Drug Price Data Sets*, shows that negotiated payments made by payers and consumers to pharmacies were higher than what pharmacies paid to Wholesaler Distributors to acquire the drug dispensed by an average margin of 11.75% for brand NDCs and 630.44% for generic NDCs.

Manufacturer Prescription Drug Rebates

Prescription drug rebates accrue as drug products are purchased and dispensed between manufacturers, wholesale distributors, pharmacy benefits managers and payers over time and may represent a fixed amount per unit or a percentage of an agreed upon price point such as WAC. MHDO reviewed 477 unique brand and generic drugs (specifically NDCs) for which pricing component data was submitted to MHDO per the requirements of 90-590 Chapter 570, *Uniform Reporting System for Prescription Drug Price Data Sets*, and MHDO's commercial claims data was submitted by payers per the requirements of 90-590 Chapter 243, *Uniform Reporting System for Health Care Claims Data Sets*, for the time period 2022.

A summary of the average manufacturer rebates reported to MHDO for 2022 is provided in the table below. Rebate percentage values are calculated at the drug (NDC) level for each reporting entity as the total rebate receivable amount divided by the total number of whole NDC units sold by wholesalers or administered by PBMs (i.e., the total rebate receivable per NDC unit) divided by the average WAC amount⁶ for the NDC.

Source Group	Brand / Generic	NDC Count	Average Manufacturer Rebates (Percent of WAC)		
			Wholesale Rebate	PBM Rebate	Total Rebate
Single Source	Brand	29	7.69%	14.11%	21.80%
	Generic	1	6.04%	0.00%	6.04%
Multisource	Brand	62	11.59%	13.30%	24.89%
	Generic	385	33.00%	0.63%	33.63%

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 10.17% for brand NDCs and 0.05% 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 9.20% for brand name NDCs.

Overall, for the subset of 477 NDCs reviewed by MHDO, the average amount paid by payers (including member cost share) after rebates for a given NDC was 84.32% of the average WAC amount for brand NDCs and 335.36% for generic NDCs.

⁶ 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. $((\$a \times 31 \text{ days}) + (\$b \times 150 \text{ days}) + (\$c \times 184 \text{ days})) / 365 \text{ days}$

Major Components of Prescription Drug Pricing along the 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 drug 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 consumer prescriptions using drug products acquired from wholesalers
- 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 agreements between participants. A summary of the major supply chain components are described below:

Wholesaler Acquisition - First step in the Supply Chain

A wholesaler's acquisition of drug products from manufacturers is the first step in the supply chain. Typically, wholesalers purchase drug products at the 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 to be paid to the wholesaler when the wholesaler later sells the product to a pharmacy. MHDO used pricing component data provided by wholesalers for calendar year 2022 as defined in 90-590 Chapter 570, *Uniform Reporting System for Prescription Drug Price Data Sets*, to calculate the percent of acquisition costs that are rebated from manufacturers to wholesalers on a per unit basis. Rebate percentage values are calculated at the drug (NDC) level for each wholesaler as the total rebate receivable amount divided by the total number of units sold (the total rebate receivable per unit) divided by the wholesaler's average acquisition amount per unit for the NDC. On average wholesalers received rebate amounts of 10.47% for brand drugs and 32.54% for generic drugs (28.36% overall) when applied against acquisition cost on a per unit basis.

Acquisition of drug products by wholesalers is typically the last point in the pharmaceutical 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 (AWP, manufacturer rebates, etc.) are derived through the application of mark ups and/or discounts from the value of WAC.

Pharmacy Acquisition of Drug Products

The next step in the pharmaceutical supply chain is a pharmacy's purchase of drug products from a wholesale distributor (wholesalers). 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 16.93% for brand NDCs and 54.68% for generic NDCs (47.55% overall). Pharmacy costs

were further reduced through rebates received from wholesalers by an average of 0.63% for brand NDCs and 5.46% for generic NDCs (4.54% overall).

Wholesalers generally sell drugs to pharmacies for less than the amount they spend to purchase the drugs from manufacturers. This cost reduction develops through several factors:

- Rebates received by wholesalers from manufacturers are largely passed through to pharmacies as price reductions.
- 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.
- Wholesalers generate operational income that is not directly derived from specific drug products. Examples 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 (not reported to MHDO) 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 consumer submits a prescription at a pharmacy.

Consumer Payment

When an insured consumer submits a prescription, the pharmacy submits a claim for reimbursement to the Pharmacy Benefits Manager (PBM) contracted with the insured's commercial payer. 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 insured at the time the prescription is filled.

Payer Payment

Commercial payers engage PBMs to negotiate 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. Pharmaceutical 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. 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.

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 1.19% above what PBMs reimbursed to pharmacies for brand NDCs and 26.94% for generic NDCs (22.07% overall).

As reported in the MHDO's commercial claims data for the subset of 477 NDCs reviewed, and 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 11.93% for brand NDCs and 628.72% for generic NDCs (512.10% overall).

Manufacturer Rebate Payment to PBMs

In addition to negotiating pharmacy reimbursement rates, PBMs develop and maintain drug formularies used by payers to determine the level of cost sharing for specific drugs between a payer and its members. Drugs on a formulary are divided into tiers with different cost share ratios. Drugs 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 to MHDO by PBMs shows that, on average, PBMs received rebates from manufacturers representing 13.27% of the average WAC amount for brand NDCs and 0.64% for generic NDCs (3.03% overall). Of the overall amount of rebates in the sample approximately 51.43% was passed through to commercial payers.

Case Study - Impact of AWP Based Contract Pricing on Costs to Payers and Consumers

Zytiga (Abiraterone Acetate) 250 Mg 120 Count Tablets – a typical 30-day supply used for Prostate Cancer that has spread.

MHDO reviewed brand and generic WAC and AWP manufacturer pricing to amounts paid by payers and consumers between 2019 and 2022 for the 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 reported to MHDO for the drug totaled \$25.4M during the four-year period (2019-2022).

Background Information:

- Manufacturers specify the wholesale acquisition cost (WAC) for the drugs they produce.
- Wholesalers typically pay manufacturers the WAC price to acquire the drugs and later sell the drugs to pharmacies at market prices (often less than WAC).
- Manufacturers may provide publishers of prescription drug pricing with a suggested average wholesale price (AWP) value. Where manufacturers do not provide AWP guidance, the value is typically set as WAC + 20% by data publishers (see [footnote 1](#)).
- Manufacturers do not receive revenue based on the AWP; instead AWP values represent the price that the manufacturer suggests that wholesalers charge when selling the manufacturer's drug to the wholesaler's customers. In practice, wholesalers sell most drugs to pharmacies at or below the value of WAC.
- PBMs negotiate contracted rates between pharmacies and payers for the drugs the pharmacies dispense. Contracted rates are typically derived as a percentage-based discount from AWP plus a fixed price dispensing fee. As a result, when AWP values are set at substantially higher values than WAC, payers may pay significantly more to the pharmacy than the cost from the manufacturer.
- The brand Zytiga 250 Mg 120 count 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 for a 30-day supply.
- Abiraterone Acetate (generic for Zytiga) launched generically in November 2018 with WAC prices for a 30-day course of therapy that ranged between \$3,499.40 and \$8,840.58. By this time WAC for the brand product had increased to \$10,232.16.
- The AWP values for the first generic products were specified at either \$11,050.73 or \$11,664.66, exactly 90% and 95% respectively of the November 2018 AWP value for the brand product of \$12,278.59.
- Between January 2019 and June 2020, additional manufacturers introduced generic products to market with the same or similar AWP values.
- AWP values set by generic manufacturers on the day their products entered the market have not been reduced even as WAC values have decreased.

See the table below which details the values of WAC, AWP, and Average Payment Amounts for a 30-day course of therapy of Abiraterone Acetate 250 Mg tablets for each manufacturer price period.

	Manufacturer	NDC	Price Period		WAC	AWP	Average Payer / Consumer 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	12/31/2022	\$10,887.02	\$13,064.42	\$10,786.28
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	12/31/2022	\$475.00		\$3,172.48
	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	4/6/2022	\$2,000.00		\$3,786.59
			4/7/22	12/31/22	\$1,000.00		\$3,427.78
	AVKARE	42291002412	12/7/2019	12/31/2022	\$431.30	\$11,664.66	\$6,550.79
	CELLTRION USA	72606056601	2/7/2020	1/17/2022	\$425.00	\$510.00	\$371.27
			1/18/2022	12/31/2022		\$11,532.51	\$4,494.03
	DR.REDDY'S LABORATORIES, INC.	43598035804	6/11/2020	12/31/2022	\$425.00	\$11,664.70	\$5,404.08
	MYLAN	00378692078	11/21/2018	1/2/2020	\$4,665.86	\$11,664.66	\$6,795.06
			1/3/2020	12/31/2022	\$1,700.00		\$5,570.95
	NORTHSTAR RX	16714096301	9/7/2020	12/31/2022	\$336.92	\$11,223.27	\$1,603.49
	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	12/31/2022	\$225.00		\$3,944.51
	PATRIOT PHARMACEUTICALS LLC	57894015512	11/26/2018	12/31/2022	\$9,188.48	\$11,026.18	\$5,747.47
	RISING PHARMACEUTICALS	64980041812	11/1/2019	3/23/2021	\$600.00	\$11,664.66	\$3,859.69
			3/24/2021	12/31/2022	\$260.00		\$4,566.54
WOCKHARDT USA	64679002101	4/9/2019	7/26/2021	\$1,500.00	\$11,664.66	\$4,891.54	
		7/27/2021	12/31/2022	\$225.00		\$6,079.83	

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

Zytiga 250 Mg 120 Count Tablets – WAC & AWP Correlation to Payer Paid Amounts

During the four-year period for which MHDO prescription claims were reviewed (2019-2022):

- The average WAC for generic products fell from \$5,165.18 to \$1,106.59 resulting from new entrants to market with lower WAC values and manufacturer WAC price decreases over time.
- The average AWP for generic products decreased at a much lower rate of decrease from \$11,291.37 to \$10,774.73. This reduction was only attributed to new entrants to the market; no manufacturers applied price decreases for AWP.
- The average amount paid by payers for brand Zytiga before rebates was \$10,652.32 and was closely correlated to the brand WAC amount during the four-year period which was \$10,887.02. The average amount paid per claim as a percentage of WAC was 98.06%.
- The average amount paid by payers for generic Zytiga products was \$4,513.29. The average amount paid per claim as a percentage of WAC was 825.19%.

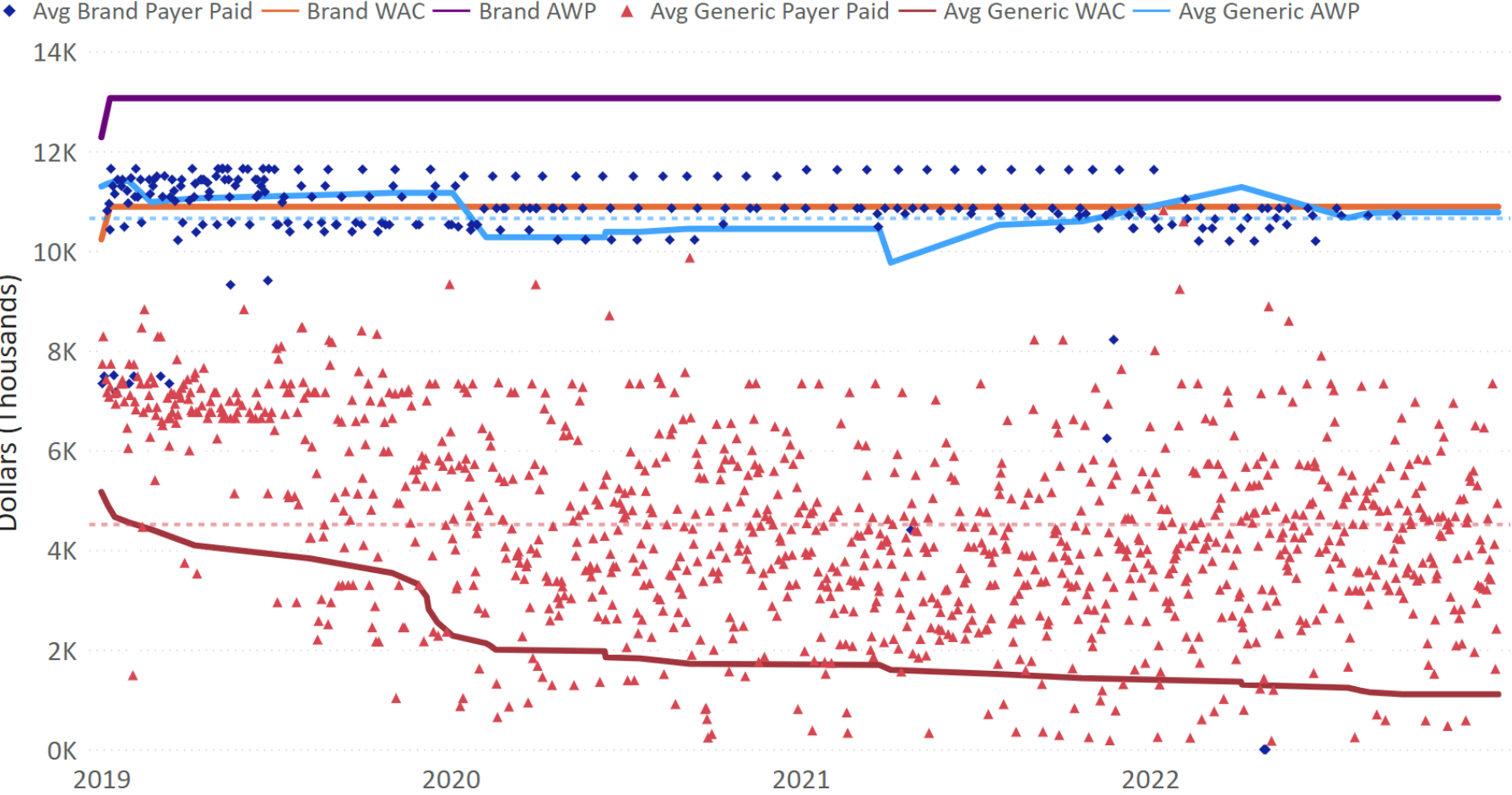
In February 2020, the manufacturer Celltrion introduced its generic Zytiga product to market with a WAC price of \$425.00 and did not specify an AWP price. As a result, data publishers established a default AWP of \$510.00 based on the value of WAC + 20%. AWP remained \$510.00 from February 2020 to January 2022. During this period, payers paid an average of \$371.27 for a 30-day course of therapy for the Celltrion product.

In January 2022, Celltrion increased the AWP of their generic Zytiga product from the default value of \$510.00 to a specified value of \$11,532.11. Celltrion did not increase the value of WAC which remained \$425.00. **After the AWP increase, the average amount paid by payers for the Celltrion product increased by 1,210.45% to \$4,494.03.** See highlighted values in the table above.

Although Celltrion specified a higher AWP for this drug, they did not receive additional payment from purchasers of their product as a result of the increase. However, after increasing the basis value for payment to pharmacies (AWP) without increasing the drug cost (WAC), Celltrion increased its market share in Maine from 0.69% of prescriptions filled between 2020 and 2021 to 14.4% of prescriptions filled in 2022.

A visual correlation of average claim paid amounts to WAC and AWP values for brand and generic products is provided in the chart below.

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



Data Sources and Methodology

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 October 24, 2023, 591 pharmaceutical manufacturers, 204 wholesale drug distributors and 34 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 74 drug product families in [the list for calendar year 2022](#), each having one or more NDCs that was:

- included on any one 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, 2021 to June 30, 2022 comparison period and filtered for commercial payers;
- a top 25 brand NDC with the highest total out of pocket cost for commercial payers (July 1, 2021 – June 30, 2022); or
- a top 25 generic NDC with the highest total out of pocket cost for commercial payers (July 1, 2021 – June 30, 2022)

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 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. Throughout the report, NDC is used to describe a manufacturer specific drug product.

MHDO requested pricing component data from reporting entities for 807 NDCs (which represents less than 1% of all NDCs) that are manufactured by 124 distinct manufacturers. Of these NDCs, 119 were brand drugs and 688 were generic drugs.

Data Consolidation and Analysis

Pricing component data files for CY 2022 were submitted by reporting entities to the MHDO Prescription Drug Price Data Portal in the summer of 2023. 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 2022 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.