

# Prescription Drug Price Transparency Program results and recommendations – 2023

(As required by ORS 646A.689)



#### **About DCBS:**

The Department of Consumer and Business Services (DCBS) is Oregon's largest consumer protection and business regulatory agency.

For more information, visit https://www.oregon.gov/dcbs.

### **About Oregon DFR:**

The Division of Financial Regulation (DFR) protects consumers and regulates insurance, depository institutions, trust companies, securities, and consumer financial products and services and is part of DCBS. Visit dfr.oregon.gov.

### **About the Drug Price Transparency Program:**

Oregon's Drug Price Transparency Program is part of DFR and provides accountability for prescription drug pricing through the notice and disclosure of specific drug costs and price information from pharmaceutical manufacturers, health insurers, and consumers. Visit <a href="https://dfr.oregon.gov/drugtransparency">https://dfr.oregon.gov/drugtransparency</a>. We encourage consumers to report price increases to us online at <a href="https://dfr.oregon.gov/rxdrugprices">https://dfr.oregon.gov/rxdrugprices</a> or contact the program at <a href="mailto:rx.prices@dcbs.oregon.gov">rx.prices@dcbs.oregon.gov</a> or leave a message at 503-947-7200 (or toll-free at 833-210-4560).

### Terms and acronyms used throughout this report:

National drug code (NDC): Drug products are identified using these unique numbers, which serve as universal product identifiers for drugs and can be found online in the U.S. Food and Drug Administration (FDA) NDC directory.

Pharmacy benefit manager (PBM): An organization that handles some or all the pharmacy benefits for a health plan and generally controls formulary decisions, pharmacy networks, and price negotiations with others in the supply chain. Some PBMs have corporate ownership or affiliation with insurers, pharmacy chains, and other health care entities.

Wholesale acquisition cost (WAC): The manufacturer's list price to wholesalers or other direct purchasers in the U.S. not including any price reductions, sometimes referred to as the "list price." This price is defined in federal law.

See additional pharmaceutical terms in the glossary on our website.

### **Additional report information:**

This report is based on all data submitted to the program from Sept. 1, 2022, through Aug. 31, 2023, and consumer survey responses received before the finalization of the report.

Throughout our report we also reference drug prices and therapeutic class information extracted from the Medi-Span drug database:

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# **Acknowledgments**

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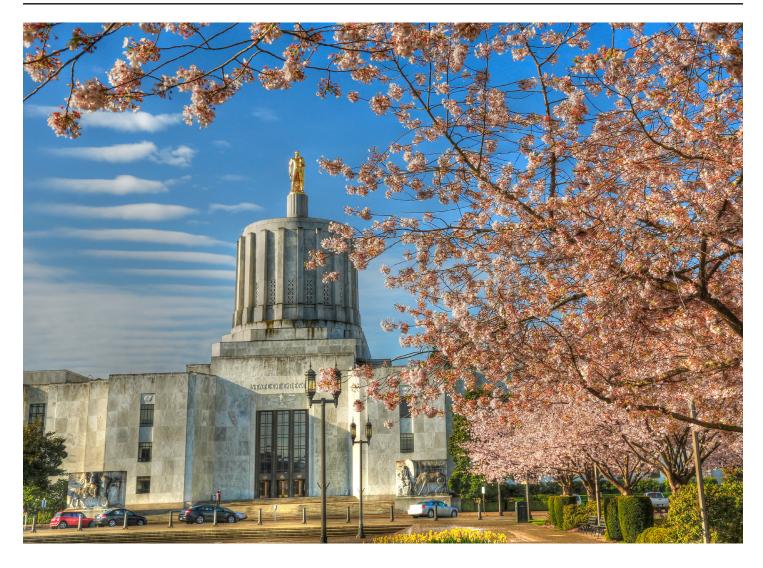
# **Table of contents**

Acknowledgments	3
Introduction	6
Executive summary	7
Background	7
Program overview	7
Results	7
Recommendations	8
Background	12
Overview of prescription drugs	13
Prescription drug spending in the U.S. and Oregon	16
Oregon prescription drug spending	17
Special topic: Cost and coverage of weight-loss medications	18
Oregon's Drug Price Transparency (DPT) Program	21
Consumer price increase notices	21
Stories from Oregonians	22
Prescription drug manufacturers	25
New specialty drug reports	26
Highest WAC prices in new specialty drug reports	28
Public funds in new specialty drug reports	30
Marketing description	30
Pricing methodology	32
Annual price increase reports	35
Recent trends and market dynamics	37
Price increase factors	40
Largest reported price increases	42
Profits and revenues in annual price increase reports	44
Direct costs in annual price increase reports	46
Public funds in annual price increase reports	47
Drug prices in other countries	47
Manufacturer compliance and enforcement efforts	48
Trade secret claims from manufacturer reports	49
Health insurance companies	50
Plan spending on prescription drugs	50
Consumer cost sharing	54
Rebates	56

# Table of contents, continued

Most prescribed drugs	58
Most costly drugs	60
Drugs with the greatest increases in health plan spending	62
Policy recommendations	63
Manufacturer reporting	63
Recommendation 1: Expanded reporting requirements for patient assi programs	
Health insurer and pharmacy benefit manager (PBM) reporting Recommendation 2: Require insurers and PBMs to report on their use of accumulator" programs	of "copay
Global recommendations	
Recommendation 3: Transparency across the pharmaceutical supply cl Recommendation 4: Consider an expansion of bulk purchasing and implementing state manufacturing of prescription drugs to ensure lev the state's purchasing power	erage of
Price increase notice reporting  Recommendation 5: Update reporting thresholds to align 60-day notice annual increase reporting	ce and
Drug policies in other states	
Conclusion	
Resources	
Health insurance issues and access	
For information on a specific drug	
For general information on prescription drugs	
Appendix A – Average annual price increase formula	
Appendix B – Types of plans for insurer reports received in 2023	/0

### Introduction



This fifth annual report to the Oregon Legislature describes information collected by the Oregon Drug Price Transparency Program with recommendations for legislative changes to contain the cost of prescription drugs and reduce the effects of price increases. This report provides information about prescription drug effects and trends based on data received from prescription drug manufacturers, health insurance companies, and consumers in the following sections:

- Background on prescription drugs and spending
- Special topic: Cost and coverage of weight loss medications

- Oregon's Drug Price Transparency Program and consumer reported information
- Prescription drug manufacturer information and data collected from reports
- Compliance and enforcement efforts
- Trade secret claims
- · Insurance company reporting data
- · Policy recommendations to the Legislature

These topics are covered briefly in the executive summary, followed by detailed information in the appropriate sections concluding with key findings.

## **Executive summary**

### **Background**

Throughout our country, people are having trouble affording necessary medications. Prescription drugs help many Oregonians to stay alive, live longer, and have an improved quality of life. Not being able to afford lifesaving, life-improving prescriptions causes harm to patients and their families and contributes to additional burdens on our health care system. Some can only afford prescriptions by doing without other needs, and there is a reduction in quality of life that can, and often does, affect overall health. Affordability and access remain of high concern to consumers and lawmakers alike.

To gather more information about these high prices, the Oregon Legislature created the Drug Price Transparency (DPT) Program by passing Oregon's Prescription Drug Price Transparency Act in 2018 (House Bill 4005). The program's purpose is to provide accountability by disclosing to the public specific pricing information reported by pharmaceutical manufacturers, health insurers, and consumers.

# **Program overview**

The program continues to engage manufacturers and collect information to inform the public hearing and legislative reports. In December 2023, the program will hold its fifth annual public hearing. Program staff will submit this report to the Legislature by Dec. 15 and post it to the program's website for public access.

Data from consumers, insurers, and pharmaceutical manufacturers is collected and analyzed by program staff throughout the year. This report summarizes the findings from data collected since the 2022 annual legislative report.

### Results

Oregon's DPT Program has been collecting and analyzing the information received from drug manufacturers, health insurers, and consumers for five years. The program is working to deepen the state's understanding of the factors that influence prescription drug prices and how drug prices affect Oregonians.

Based on the information collected, the program has made the following key findings in this report:

 Most health insurers reported receiving between 10 percent and 25 percent of total pharmaceutical spending in rebates.
 UnitedHealthcare reported the highest rebates received as a percentage of prescription spending at 24.8 percent. Samaritan and Kaiser reported the lowest rebates received, at 5.1 and 0.3 percent, respectively. The program does not have sufficient data to suggest whether there are any correlations between rebates and spending within the prescription drug data.



<sup>&</sup>lt;sup>1</sup> House Bill 4005 (2018), https://olis.oregonlegislature.gov/liz/2018R1/Measures/Overview/HB4005.

- Humira, manufactured by AbbVie Inc., continues to be the most costly drug contributing to more plan spending than any other drug for five years running. In 2022, health insurance companies in Oregon reported \$75.24 million in spending on Humira.
- Antineoplastics and adjunctive therapies, which are used to treat cancer, were the most frequent category of new specialty drugs reported to the program. The highest wholesale acquisition cost (WAC) for a brand name drug was \$3.5 million for Hemgenix, a treatment for hemophilia B.
- The largest price increases were for generic drugs. The median price increase reported for generic drugs was 20 percent, and the median price increase reported for brand name drugs was 14.9 percent. The largest price increase reported to the program in 2022 was a 25 percent increase from \$575 to \$718.75 for Aquasol A, a generic vitamin A solution manufactured by Casper Pharma.
- The program received drug reports from several manufacturers for the generic drug fingolimod (30 capsules, 0.5 mg). The new drug reports showed WAC prices ranging from \$1,000 to \$8,883.89. In looking at the current prices of these drugs from 10 different manufacturers, they have been reduced by most manufacturers and now have WAC prices ranging from \$220.21 to \$2,220.97. The WAC price for generic fingolimod was reduced by 84 percent to 97 percent from its starting price by most manufacturers, while a few are at the same price. Because price decreases are not reported to us, this may be evidence of how competition in the generics market can bring down the price of a drug.
- The quality of information submitted by manufacturers was extremely variable, ranging

- from refusals to provide any information to generalized descriptions to detailed information of a company's reasons for increasing the price of a drug. This continues to be an issue when attempting to determine the reasons why a drug is priced high when it comes to market or when price increases are reported to the program. For context, the program has received more than 1,900 reports with more than 10,500 data elements claimed as trade secrets since 2019. Of that total, 475 reports with 1,577 data elements claimed as trade secret have been received since last year's report.
- The program's compliance efforts have progressed to issuing noncompliance warning notices to manufacturers to address manufacturer behavior and the volume, variances, and complexities mentioned above. If the manufacturers do not come into compliance following our initial noncompliance notices, we will prepare a file to send to the division's enforcement unit.

Information collected from this year and previous years continues to be valuable to further understanding and contributing to ongoing efforts to address the effects of costly prescription drugs on Oregonians.

### Recommendations

This report is required by the Prescription Drug Price Transparency Act, which also requires proposed recommendations for legislative changes to contain the cost of prescription drugs and reduce the effects of price increases. Some of this year's recommendations propose improvements to the program that would provide more quality data to better inform policy decisions.



### **Manufacturer reporting**

# Recommendation 1: Expanded reporting requirements for patient assistance programs

The program currently receives information on patient assistance programs as part of our annual price increase reports. In 2023, we only received information on 18 patient assistance programs from eight manufacturers. While this limited information showed more than \$2.5 million in benefits for 2,302 Oregonians, it is only a small fraction of the estimated more than 200 patient assistance programs available and is not enough for meaningful analysis. Patient assistance programs include manufacturer "coupons" and other payments that reduce a patient's out-of-pocket cost to fill a prescription.

Patient assistance has been a source of controversy in recent legislative sessions. Drug manufacturers argue that patient assistance helps patients whose insurance does not fully cover the cost of a needed medication. Insurance companies argue that patient assistance undermines their efforts to control health care costs by incentivizing patients to use expensive brand name drugs even when a generic alternative is available. Patient advocates have also argued for a ban on "copay accumulators" (insurance plan designs that do not credit third-party payments, such as patient assistance, against an individual's deductible or out-of-pocket maximum).

However, as currently structured, the program's patient assistance program reporting is poorly matched to the market landscape. New drug reports do not require any patient assistance program reporting, and most price increase reports are for generic drugs, which would be extremely unlikely to maintain a patient assistance program.

As recommended in previous reports, the program recommends the Legislature consider removing the patient assistance program reporting requirement from our price increase reports, and instead requiring all manufacturers to report annually on all patient assistance programs they maintain or fund. This will both remove the reporting requirement in our price increase reports while also allowing us to develop comprehensive data on the use of patient assistance. This deeper and more informed analysis will help the program and the Legislature better understand the roles of patient assistance and copay accumulators in developing future policy.

# Health insurer and pharmacy benefit manager (PBM) reporting

# Recommendation 2: Require insurers and PBMs to report on their use of "copay accumulator" programs

Much of the recent discourse around manufacturerfunded patient assistance has been driven by the increased use of "copay accumulator" programs in Oregon. This term refers to a practice in which an insurer will not count third-party payments, such as manufacturer coupons, against a consumer's annual cost-sharing limits. In other words, a patient who uses patient assistance to access a highcost medication would still need to meet their deductible using personal funds after they would have otherwise met their deductible using patient assistance.

Insurers argue that copay accumulators are an effective strategy to lower overall prescription drug spending and reduce premiums for their members, in part because manufacturer assistance may drive patients to continue using high-cost medications even when equally effective generic or biosimilar

alternatives are available. Copay accumulators are a way that insurers try to counteract this incentive to lower overall costs and reduce premiums for the wider population of consumers. Patient advocates argue that this imposes steep financial burdens on patients – especially for patients who must meet their deductible before coverage kicks in – and may result in some patients going without needed medications. To provide an adequate analysis of the issue and its effect on drug pricing, additional transparency in this area is needed.

Accordingly, as a corollary to expanded reporting on patient assistance programs, the program recommends the Legislature require insurers and PBMs report data regarding their "copay accumulator" programs in Oregon. Data elements could include (1) which plans are subject to copay accumulator programs; (2) what drugs are subject to copay accumulators; (3) how much additional revenue is generated by copay accumulators; and (4) how revenue generated by copay accumulators is allocated by insurers and PBMs.

### **Global recommendations**

# Recommendation 3: Transparency across the pharmaceutical supply chain

The price of a prescription drug is influenced by numerous factors. This includes the interactions and financial negotiations between pharmaceutical supply chain entities. Oregon has enacted several policies that address prescription drug price transparency across parts of the supply chain; however, there are still gaps in transparency.

The program recommends the Legislature consider additional transparency measures across the pharmaceutical supply chain. These would include entities with no reporting or regulatory oversight, such as wholesalers and pharmacy services administrative organizations (PSAOs), to fully understand what influences and contributes to the price of the drug. New transparency measures would also include aspects of the pharmaceutical supply chain that may affect the cost to consumers such as coupons, discounts, fees, incentive

programs, assistance programs, list price, markups, and rebates. Understanding how these entities and cost factors influence the supply chain, and ultimately the costs consumers face, is necessary to developing policy recommendations to address these issues.

# Recommendation 4: Consider an expansion of bulk purchasing and implementing state manufacturing of prescription drugs to ensure leverage of the state's purchasing power

In 2020, the California Legislature authorized the creation of a state-operated generic drug manufacturer, CalRx. This new entity will contract with other generic manufacturers and act as a relabeler, with the long-term goal of establishing its own manufacturing capacity. CalRx would supply generic medications to the citizens of the state where the open market has failed to produce an adequate supply of fairly priced pharmaceuticals.

CalRx mirrors the structure of several other recent generic manufacturing initiatives. These include Civica Rx, a nonprofit generic manufacturer established by a coalition of philanthropies and health systems, and Cost Plus Drug Company, a generic manufacturer offering low-cost "cash only" pharmaceuticals directly to consumers. While all of these entities are commonly described as drug manufacturers, most of their activity is more in line with bulk purchasing and relabeling of drugs.

The first project for CalRx is to contract with Civica Rx to manufacture the three most commonly used long-acting and rapid-acting types of insulin (biosimilar insulin) at a lower cost to Californians. Test runs of the manufacturing are expected to begin soon, and Civica Rx is expected to file for U.S. Food and Drug Administration (FDA) approval in 2024.

The Oregon Prescription Drug Program (OPDP) is a statutorily defined program operated by the Oregon Health Authority (OHA). In cooperation with other states and through an interstate

agreement, OPDP participates in a regional drug purchasing consortium, recently rebranded as ArrayRx. OPDP does not have the authority to establish its own multistate purchasing entity. As in last year's report, the program continues to recommend the Legislature grant this authority and direct OPDP to further expand the program's ability to leverage purchasing power for prescription drugs purchased by public and commercial entities. Doing so would help open opportunities for adoption of a state contracted manufacturing or direct-bulk-purchasing model.

In making this recommendation, bulk purchasing must be understood as two separate functions. There is a purchaser – a wholesaler who must do the actual purchasing and acquisition to take possession of the drugs. The second is a payment and claims administration service for payers and is commonly provided by PBMs.

Additionally, the program recommends the Legislature explore a directive to the state Medicaid program to purchase drugs through OPDP for the fee-for-service and coordinated care organization (CCO) delivery systems to truly leverage bulk purchasing of prescription drugs and PBM services. This model would also realize other financial efficiencies, including state supplemental rebates for a uniform preferred drug list (PDL) and eliminate the need for the state's 16 CCOs to separately manage drug benefits.

Finally, the program recommends the establishment of a centralized office of pharmacy purchasing to provide coordination and oversight of all state purchasing, ensuring Oregon is completely leveraging the state's position in the marketplace.

### **Price increase notice reporting**

Recommendation 5: Update reporting thresholds to align 60-day notice and annual increase reporting

Reporting thresholds for the drug price transparency program vary depending on the type of report. To simplify how to calculate when a report is required, the program recommends changing the comparison date to two years prior for the 60-day price increase notices and the annual increase reports.

Instead of a daily weighted average price comparison for the annual increase report, a report would be required if the price on Dec. 31 of the year that just ended is more than 10 percent higher than the price on Dec. 31 two years earlier.

Instead of a 365-day review period for the 60-day price increase notice, a report would be required if the price on the date of the planned increase for a brand name drug will be more than 10 percent (or 25 percent for a generic drug) higher than the price two years earlier, similar to California's review period. The program also recommends removing the requirement that the generic drug price also be \$300 or more for a 60-day notice. These updates would make it easier to explain and calculate when a report is required.



# **Background**

Throughout our country, people are having trouble affording necessary medications. Prescription drugs help many Oregonians to stay alive, live longer, and have an improved quality of life. In a recent Kaiser Family Foundation (KFF) poll, 30 percent of respondents have cut prescription drug costs by skipping doses, cutting pills in half, or using overthe-counter alternatives. The KFF polling also found that all age groups and a large span of income levels are struggling to afford the medications prescribed by their physician or other health care professional.<sup>2</sup>

Not being able to afford lifesaving, life-improving prescriptions causes harm to patients and their families and contributes to additional burdens on our health care system. Some can only afford

prescriptions by doing without other needs, and there is a reduction in quality of life that can, and often does, affect overall health. Affordability and access remain of high concern to consumers and lawmakers alike.

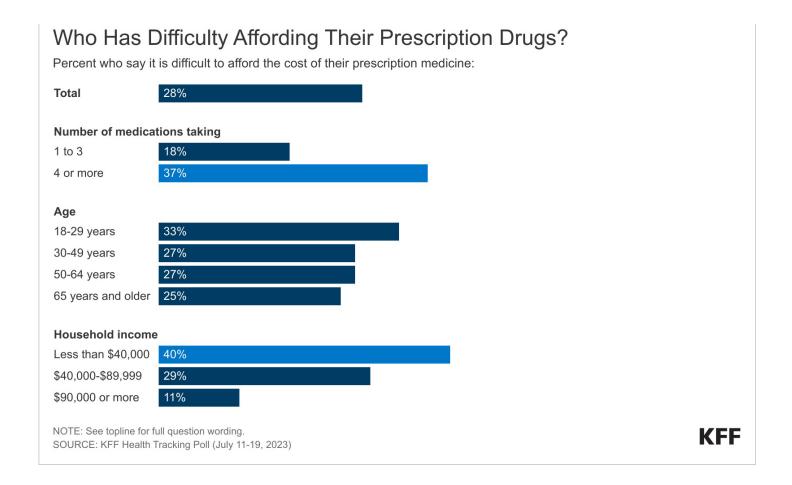
To gather more information about these high prices, the Oregon Legislature created the Drug Price Transparency (DPT) Program by passing Oregon's Prescription Drug Price Transparency Act in 2018 (House Bill 4005).<sup>3</sup> The program's purpose is to provide accountability by disclosing to the public specific pricing information reported by pharmaceutical manufacturers, health insurers, and consumers.



<sup>&</sup>lt;sup>2</sup> Kirzinger, Ashley et al. "Public Opinion on Prescription Drugs and Their Prices." KFF, Aug. 21, 2023. https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/. Accessed Oct. 27, 2023.

<sup>&</sup>lt;sup>3</sup> House Bill 4005 (2018), https://olis.oregonlegislature.gov/liz/2018R1/Measures/Overview/HB4005.

**Figure 1:** Percent, broken down by age and household income, of those who have difficulty affording their prescriptions<sup>4</sup>



### **Overview of prescription drugs**

A prescription drug is a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. It is prescribed by a health care practitioner to a person and is required to be purchased from a pharmacy when administered by the patient.<sup>5</sup> A prescription drug can be either a brand name drug or generic drug. Brand name prescription drugs are generally covered by a patent that provides

protections to the drug developer for a set period of time in which no one else can produce the same drug. A generic drug has the same active ingredients as a brand name drug and competes with the brand name drug once the patent has expired.<sup>6</sup> Generic drugs typically cost less than brand name drugs and are used more frequently due to their reduced cost.

<sup>&</sup>lt;sup>4</sup> Kirzinger, Ashley et al. "Public Opinion on Prescription Drugs and Their Prices." KFF, Aug. 21, 2023. https://www.kff.org/health-costs/poll-fin-ding/public-opinion-on-prescription-drugs-and-their-prices/. Accessed Oct. 27, 2023.

<sup>&</sup>lt;sup>5</sup> "Prescription Drugs and Over-the-Counter (OTC) Drugs: Questions and Answers." U.S. Food & Drug Administration, Nov. 13, 2017. https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers. Accessed Oct. 27, 2023.

<sup>&</sup>lt;sup>6</sup> "Generic Drugs: Questions & Answers." U.S. Food & Drug Administration, March 16, 2021. https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers. Accessed Nov. 30, 2023.

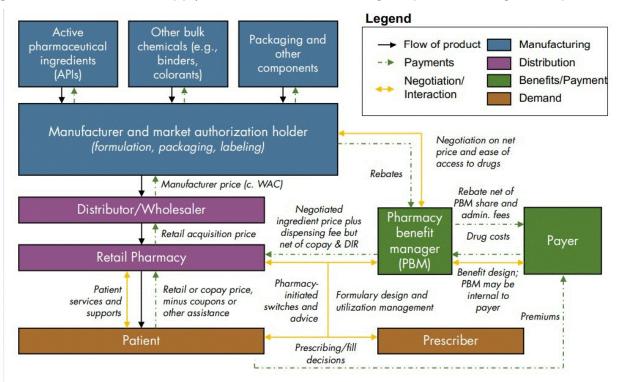
Drugs can also be distinguished between small molecule and biologic drugs. Small molecule drugs are generally manufactured through a controlled chemical reaction, while biologics are generally manufactured through the manipulation of living cells.<sup>7</sup>

Many high-cost prescription drugs and new innovative therapies – including technologies such as chimeric antigen receptor T-cells (CAR-T) and monoclonal antibodies – are considered biologics. However, even some well-established prescription compounds, such as insulin and human growth hormone, would technically be considered biologics under current law if they were developed today.8

Most prescription drugs are initially priced by the drug manufacturer with a wholesale acquisition cost (WAC), which is sometimes referred to as the list price. It is the starting point for the drug price and does not include any rebates or discounts. There are several other ways to measure the cost of prescription drugs, such as average wholesale price (AWP) and average manufacturer price (AMP), which are used as starting points for negotiating drug prices between pharmaceutical supply chain entities.

The cost to the consumer purchasing a drug at the pharmacy is determined through a complex set of factors throughout the pharmaceutical

Figure 2: Pharmaceutical supply chain for brand name drugs dispensed through retail pharmacies9



NOTES: c. = circa; DIR = direct and indirect remuneration; WAC = wholesale acquisition cost. Arrows denote relationships involving the flow of product (black arrows), information or negotiation (yellow arrows), and payments (green dashed arrows).

<sup>&</sup>lt;sup>7</sup> "Biological Product Definitions." U.S. Food & Drug Administration. https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf. Accessed Oct. 27, 2023.

<sup>&</sup>lt;sup>8</sup> Morrow, Thomas MD, and Hull Felcone, Linda. "Defining the Difference: What Makes Biologics Unique." Biotechnology Healthcare, vol. 1,4, 24-9, September 2004. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564302/. Accessed Oct. 27, 2023.

<sup>&</sup>lt;sup>9</sup> Mulcahy, Andrew W. and Kareddy, Vishnupriya. "Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships." RAND Corporation, 2021. https://pubmed.ncbi.nlm.nih.gov/35837523/. Accessed Oct. 27, 2023



supply chain. Manufacturers, wholesale distributors, pharmacies, pharmacy benefit managers (PBMs), health insurance companies, medical providers, and consumers make up the majority of the actors involved in the pharmaceutical supply chain.

The price a consumer pays at the pharmacy can be influenced by the industry practices and financial negotiations between pharmaceutical supply chain entities and the consumer's health insurance. Figure 2 shows a supply chain example for a brand name drug for a person insured through their employer. People who are uninsured typically pay the list price of the drug, which can be changed by the drug manufacturer. Both the insured and uninsured can also use a discount card program such as Oregon's ArrayRx to receive a lower cost.<sup>10</sup>

For people with health insurance, prescription drug costs are typically regulated through placement on a formulary tier determined by their insurance company that can change from year to year. Placement on a higher tier typically results in a higher cost to the consumer. Many health insurance companies will require a copay or coinsurance payment when the consumer pays for the prescription drug at the pharmacy. A copay is a flat fee, such as \$10 per prescription, and coinsurance is a percentage of the drug cost, such as 20 percent of the drug price. Additionally, the negotiated reimbursement rate between the pharmacy and a health insurance carrier can affect what the consumer pays for the drug. Some drugs have

zero copay and some drugs are not covered. Once a person reaches the maximum out-of-pocket amount for their health insurance plan, they no longer have a copay or coinsurance.

There are several ways prescription drugs can be categorized: based on the disease they treat (therapeutic class); what type of pharmacy the prescription drug is obtained from (retail or nonretail); or by the specific national drug code (NDC) given to identify the dosage and packaging of the prescription drug. These categories will be used throughout this report to describe the data received from manufacturers, health insurers, and consumers.

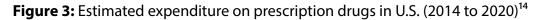
<sup>&</sup>lt;sup>10</sup> Oregon Prescription Drug Program. https://www.oregon.gov/oha/hpa/dsi-opdp/Pages/index.aspx. Accessed Oct. 27, 2023.

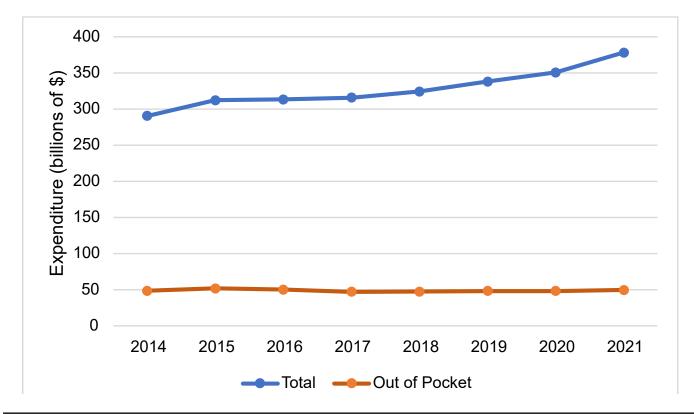
# Prescription drug spending in the U.S. and Oregon

In 2021, U.S. health care spending reached \$4.3 trillion, a 2.7 percent growth from the prior year, and \$378 billion of that was retail prescription drug spending (8.9 percent of total health care expenditures). For 2021, prescription drug expenditures grew by 7.8 percent, increasing at a rate 3.5 times higher than the rate increase for all other health care expenditures. This is double the increase rate from the prior year, according to the Centers for Medicare & Medicaid Services. Figure 3 shows the U.S.

increase in prescription drug expenditures from 2014 through 2021 along with the amount of out-of-pocket costs for consumers. Calendar year 2021 data is the most recent data available.

An estimated 19 million people were unable to pay for their prescription drugs in 2021.<sup>12</sup> The program hears stories of how high costs affect people, particularly those who need expensive prescription drugs to treat cancer, manage diabetes, and address heart conditions.<sup>13</sup> These stories illustrate the effects prescription drug costs have on households around the country and in Oregon.





<sup>&</sup>lt;sup>11</sup> "NHE Fact Sheet." Centers for Medicare & Medicaid Services, Sept. 6, 2023. https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet. Accessed Oct. 27, 2023.

<sup>&</sup>lt;sup>12</sup> Witters, Dan. "In U.S., An Estimated 18 Million Can't Pay For Needed Drugs." Gallup, Sept. 21, 2021. https://news.gallup.com/poll/354833/estimated-million-pay-needed-drugs.aspx. Accessed Oct. 27 2023.

<sup>&</sup>lt;sup>13</sup> Bunis, Dena. "People Share Their Stories: The Human Cost of High Prescription Drug Prices." AARP, Politics & Society, Sept. 28, 2021. https://www.aarp.org/politics-society/advocacy/info-2021/high-prescription-drug-price-stories.html. Accessed Oct. 27, 2023.

<sup>&</sup>lt;sup>14</sup> "Historical." Centers for Medicare and Medicaid, National health expenditure data, Sept. 6, 2023. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical. Accessed Nov. 6, 2023.

### Oregon prescription drug spending

Prescription drug spending and the effects of costs on Oregonians has been an interest for policymakers, health care providers, and the public for several years. The state is a major purchaser of prescription drugs through health benefit plans or direct purchases for Oregonians. Reports show that the Oregon Health Authority (OHA) spent more than \$1.3 billion between January and December 2022 on prescription drugs for those enrolled in the Oregon Health Plan. 15 The total prescription drug spending expectation for 2022 was more than \$16 million for the CAREAssist program (Oregon's AIDS Drug Assistance Program – ADAP) and is expected to be more than \$17 million for 2023.16 Prescription drug spending by the Public Employees' Benefit Board (PEBB) was \$180 million in 2022 for 136,641 members. The Oregon Educators Benefit Board (OEBB), with 132,077 members, recorded \$127 million for the 2021-22 plan year (October 2021 to September 2022). 17,18 The Oregon Youth Authority, Oregon Department of Corrections, and Oregon State Hospital also purchase prescription drugs for the people in their care.

Oregon has a prescription drug assistance program called the ArrayRx Discount Card Program. This state-sponsored program is a partnership between the states of Oregon, Washington, Nevada, and Connecticut serving almost 700,000 people. Part of

the program helps Oregonians and residents of the other states (more than 40,000 people) save on prescription drug costs when they are uninsured, underinsured, or their medication is not covered by their insurance. Prescriptions purchased through the program do not count toward insurance deductibles or out-of-pocket maximums. ArrayRx services also include a broad suite of programs designed to assist states and participating programs with administering their pharmacy programs. Throughout the four states, these include 550,000 group-insured people, managed Medicaid programs serving about 70,000, and vouchers serving more than 13,000. ArrayRx has resulted in more than \$155 million in savings to Oregon and the other participating states through these programs over the past five years.<sup>19</sup>

While we do not have the amounts for all other prescription drug spending for Oregonians, information from the insurers who report to the DPT Program will be shown later in this report.



<sup>&</sup>lt;sup>15</sup> "Pharmacy Utilization Summary Report: January 2022 – December 2022: Total Amount Paid." Drug Use Research & Management Program, DHS Health Systems Division, Oregon State University College of Pharmacy, page 1, July 20, 2023, CAREAssist program data provided from Oregon Health Authority. https://www.orpdl.org/durm/reports/utilization/2023/DUR\_Utilization\_2023\_Q2.pdf. Accessed Oct. 27, 2023.

<sup>&</sup>lt;sup>16</sup> "Background Brief on Prescription Drugs." Legislative Policy and Research Office, September 2014. https://www.oregonlegislature.gov/lpro/Publications/BB2014PrescriptionDrugs.pdf. Accessed Oct. 30, 2023.

<sup>&</sup>lt;sup>17</sup> "Oregon Public Employees' Benefit Board, July Utilization Review." Mercer presentation to the Oregon Health Authority and Public Employees' Benefit Board, page 13, July 18, 2023. https://www.oregon.gov/oha/PEBB/MeetingDocuments/PEBB-Board-Agenda-Attachments-20230718.pdf#page=13. Accessed Oct. 27, 2023.

<sup>&</sup>lt;sup>18</sup> Oregon Educators Benefit Board (OEBB) data provided from Oregon Health Authority in 2023. https://www.oregon.gov/oha/Pages/index.aspx. Accessed Oct. 27, 2023.

<sup>&</sup>lt;sup>19</sup> Oregon Prescription Drug Program and ArrayRx data provided from Oregon Health Authority in 2023. https://www.oregon.gov/oha/hpa/dsi-opdp/Pages/index.aspx. Accessed Oct. 27, 2023.

# Special topic: Cost and coverage of weight-loss medications

In June 2021, the U.S. Food and Drug Administration (FDA) approved Novo Nordisk's injectable drug Wegovy for chronic weight management in obese or overweight adults.<sup>20</sup> The active ingredient of Wegovy, semaglutide, is also marketed by Novo Nordisk under the brand names Ozempic and Rybelsus as an insulin regulator for patients with type 2 diabetes. Semaglutide belongs to a class of molecules called GLP-1 agonists that imitate the hormone GLP-1 (glucagon-like peptide-1). GLP-1 agonists stimulate the body to produce insulin and suppress appetite by creating a feeling of fullness. This class of drugs also includes others marketed by Eli Lilly and Novo Nordisk using the brand names Trulicity (dulaglutide), Victoza (liraglutide), and Saxenda (liraglutide). Novo Nordisk's Saxenda was approved as a drug for weight management in 2014.

In May 2022, the FDA approved Eli Lilly's injectable Mounjaro (tirzepatide) as a treatment for type 2 diabetes.<sup>21</sup> Like Wegovy, Mounjaro imitates GLP-

1, plus the receptors for a different hormone, GIP (glucose-dependent insulinotropic polypeptide). While Mounjaro is currently approved solely for treatment of type 2 diabetes, subsequent studies have shown that it could be even more effective than Wegovy as a weight-loss aid.<sup>22</sup>

Studies suggest that semaglutide and other GLP-1 agonists may be able to treat other conditions, such as heart disease, substance abuse, and dementia.<sup>23</sup> Obesity is a risk factor for many chronic health conditions, so a safe and effective treatment has the potential to provide a massive public health benefit even without additional applications.<sup>24</sup> However, some researchers suggest the health effects of obesity are exaggerated, with much of the related research funded by the weight-loss industry.<sup>25</sup>

The Institute for Clinical and Economic Review (ICER) finalized a cost-effectiveness study of Wegovy for weight loss in October 2023. ICER's study concluded that a fair price for Wegovy as a weight loss aid would be between \$7,500 and \$9,800 per year.<sup>26</sup>

<sup>&</sup>lt;sup>20</sup> "FDA Approves New Drug Treatment for Chronic Weight Management, First Since 2014." U.S. Food & Drug Administration, June 4, 2021. https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weight-management-first-2014. Accessed on Sept. 13, 2023.

<sup>&</sup>lt;sup>21</sup> "FDA Approves Novel, Dual-Targeted Treatment for Type 2 Diabetes." U.S. Food and Drug Administration, May 13, 2022. https://www.fda.gov/news-events/press-announcements/fda-approves-novel-dual-targeted-treatment-type-2-diabetes. Accessed on Sept. 13, 2023.

<sup>&</sup>lt;sup>22</sup> Stokes, Victoria. "Mounjaro More Effective Than Ozempic for Weight Loss, New Research Shows." HealthLine, Aug. 2, 2023. https://www.healthline.com/health-news/mounjaro-more-effective-than-ozempic-for-weight-loss-new-studies-suggest. Accessed Sept. 18, 2023.

<sup>&</sup>lt;sup>23</sup> Scott, Dylan. "Is There Anything Ozempic Can't Do?" Vox, Sept. 13, 2023. https://www.vox.com/policy/2023/9/13/23869823/ozempic-wegovy-semaglutide-diabetes-dementia-research. Accessed Sept. 18, 2023.

<sup>&</sup>lt;sup>24</sup> Scott, Dylan. "The Next Frontier for Ozempic: Health Insurance," Vox, May 26, 2023. https://www.vox.com/policy/2023/5/26/23734216/weight-loss-wegovy-ozempic-prescription-cost. Accessed Sept. 18, 2023.

<sup>&</sup>lt;sup>25</sup> Gibbs, Wayt W., "Obesity: an Overblown Epidemic?" Scientific American, Dec, 1, 2006. https://www.scientificamerican.com/article/obesity-an-overblown-epidemic-2006-12/. Accessed Sept. 18, 2023.

<sup>&</sup>lt;sup>26</sup> Atlas, Steven J.et al. "Medications for Obesity Management: Effectiveness and Value; Final Evidence Report." Institute for Clinical and Economic Review (ICER), Oct. 20, 2022. https://icer.org/wp-content/uploads/2022/03/ICER\_Obesity\_Final\_Evidence\_Report\_and\_Meeting\_Summary\_102022.pdf. Accessed Sept. 13, 2023.

At the time of writing, the list price of Wegovy is \$1,349.02,<sup>27</sup> or about \$16,000 per year. However, the actual cost for insurers and pharmacies is usually lower after discounts and rebates. Data collected by the Oregon Health Authority shows that pharmacies are currently paying an average price around \$568 per month for a Wegovy injector, while data from insurers gave an average allowed amount of \$856 per month for an Ozempic prescription last year.<sup>28</sup>

In March 2023, Novo Nordisk reported a shortage of semaglutide to the FDA for certain formulations of Wegovy and Ozempic, citing increased demand. Some reports show this is from offlabel use for weight loss, which has been a major trend on the social media platform TikTok.<sup>29</sup> While only Wegovy is approved for use as a weight-loss aid for certain obese or overweight adults, doctors may be prescribing Ozempic off-label for weight loss. This could be in part due to its lower list price (\$935.77 versus \$1,349.02 for Wegovy).30 Some patients may be using compounding pharmacies to fill semaglutide prescriptions, which is sometimes permitted for on-patent

medications with a declared shortage in effect.<sup>31</sup> In response, the FDA issued a warning against the use of compounded semaglutide on May 31, 2023, noting that many compounders may be using a different chemical form of semaglutide not assessed for safety or efficacy.<sup>32</sup>

Some insurers have started taking action to limit coverage of Ozempic, citing concerns about the rising cost of covering the drug.



<sup>&</sup>lt;sup>27</sup> "Ozempic Semaglutide Injection 0.5 mg, 1mg, or 2mg." Novo Nordisk, October 2023. https://www.novopricing.com/ozempic.html. Accessed Sept. 13, 2023.

<sup>&</sup>lt;sup>28</sup> Ozempic price is averaged from insurer reports for plan year 2022 for all insurers who reported spending on Ozempic. Wegovy price taken from the Oregon Health Authority Average Actual Acquisition Cost survey: Oregon Health Authority, "Average Actual Acquisition Cost (AAAC) Rate Listing for Brand Drugs, Sept. 12, 2023, https://myersandstauffer.com/client-portal/oregon/#toggle-id-1. Accessed on Sept. 26, 2023.

<sup>&</sup>lt;sup>29</sup> Duboust, Oceane et al. "Ozempic: How a TikTok Weight Loss Trend Caused a Global Diabetes Drug Shortage and Health Concerns." Euronews, March 3, 2023. https://www.euronews.com/next/2023/03/02/ozempic-how-a-tiktok-weight-loss-trend-caused-a-global-diabetes-drug-shortage-and-health-c. Accessed Sept. 18, 2023.

<sup>&</sup>lt;sup>30</sup> "Ozempic Semaglutide Injection 0.5 mg, 1mg, or 2mg." Novo Nordisk, October 2023. https://www.novopricing.com/ozempic.html. Accessed Sept. 13, 2023.

<sup>&</sup>lt;sup>31</sup> "Drug Compounding and Drug Shortages." U.S. Food & Drug Administration, March 24, 2023. https://www.fda.gov/drugs/human-drug-compounding/drug-compounding-and-drug-shortages. Accessed Sept. 18, 2023.

<sup>&</sup>lt;sup>32</sup> "Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss." U.S. Food & Drug Administration, May 31, 2023. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss. Accessed on Sept. 14, 2023.



However, semaglutide is not particularly expensive when compared to many other new drugs, particularly antivirals, cancer drugs, and drugs for auto-immune disorders. The cost challenge is from the large number of patients who could qualify for treatment – around 30 percent of Oregonians self-report obesity as compared to around 10 percent of adult Oregonians diagnosed with type 1 or type 2 diabetes.<sup>33</sup>

At least one Oregon insurer, Kaiser Permanente, has publicly taken action to limit coverage of Ozempic. They issued prescriber guidance limiting coverage to patients with a diagnosis of type 2 diabetes who are unable to use the lower-cost drug Jardiance.<sup>34</sup> While no other Oregon insurer has taken direct action like this in a public-facing way, state data does not show an increase in the number of Ozempic prescriptions covered in Oregon from 2021 to 2022, since Wegovy was approved.<sup>35</sup> While use of Ozempic by insured Oregonians has grown over the last five years, this appears to be driven mostly by diabetes patients switching to Ozempic from earlier therapies like Victoza, Trulicity, and Jardiance. Insurers generally do not cover prescriptions for weight loss, and federal statute expressly bars such coverage in the Medicare and Medicaid programs.<sup>36</sup>

<sup>&</sup>lt;sup>33</sup> "Adult Obesity Prevalence Maps." Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Nutrition, Physical Activity, and Obesity, Sept. 21, 2022. https://www.cdc.gov/obesity/data/prevalence-maps.html. Accessed Sept. 13, 2023. "National and State Diabetes Trends." Centers for Disease Control and Prevention, May 17, 2022. https://www.cdc.gov/diabetes/library/reports/reportcard/national-state-diabetes-trends.html. Accessed Sept. 13, 2023.

<sup>&</sup>lt;sup>34</sup> "Injectable Semaglutide (Ozempic)." Kaiser Permanente Northwest Region Criteria for Drug Coverage, Criteria-Based Consultation Prescribing Program, June 8, 2023. https://healthy.kaiserpermanente.org/content/dam/kporg/final/documents/formularies/nw/kp-ozempic-nw-en.pdf. Accessed Sept. 18, 2023.

<sup>&</sup>lt;sup>35</sup> Insurer reports received by DCBS showed 2,275 enrollees with a covered Ozempic prescription in 2021 and 2,255 in 2022 (a decrease of 20). Some insurers reported an increase in enrollees, offset by decreases from other insurers This may reflect either changes in utilization or consumers moving from one carrier to another. The growth in Ozempic prescriptions is also correlated with a decline in the number of reported prescriptions for Victoza, Trulicity, and Jardiance. Oregon Prescription Drug Price Transparency program, 2023. https://dfr.oregon.gov/drugtransparency/Pages/index.aspx.

<sup>&</sup>lt;sup>36</sup> "Payment for covered outpatient drugs." Social Security, Sec. 1927, [42 USC 1927(d)(2)]. https://www.ssa.gov/OP\_Home/ssact/title19/1927.htm. Accessed Oct. 30, 2023

# Oregon's Drug Price Transparency (DPT) Program



The program continues to engage manufacturers and collect information to inform the annual public hearing and legislative report. In December 2023, the program will hold its fifth public hearing. Program staff members will submit this report to the Legislature by Dec. 15 and post it to the program's website for public access.

Data from consumers, insurers, and pharmaceutical manufacturers is collected and analyzed by program staff members throughout the year. Next year's data will include information reported by pharmacy benefit managers (PBMs) for the aggregated dollar amount of rebate, fee, price protection payment, and any other payments the PBM received from manufacturers that were passed on to insurers or enrollees at the point of sale of a prescription drug, and the amount retained as revenue by the PBM. Data collection from insurers will be expanded to include all state regulated health plans to ensure a more complete and accurate picture of drug costs in Oregon.

Program staff members help pharmaceutical manufacturers with questions, registration, billings, and filing required reports. Efforts to increase manufacturer reporting compliance and review claims of trade secrets have increased due to process

improvements and additional program staff. The program also is working to increase outreach to consumers.

This report summarizes the findings from data collected since the 2022 annual legislative report. Any information directly identifiable to a particular drug or company was not claimed as a trade secret in the manufacturer's submission. Information covering multiple drugs has been de-identified and aggregated so that information claimed to be a trade secret is not disclosed.

### **Consumer price increase notices**

Anyone can provide notification of an increase in the cost of prescription drugs to the DPT Program through phone, email, or an online submission form. The notification form includes information about the consumer's insurance coverage, the drug that increased in price, and when and where the consumer experienced the price increase. The form is available in English, Spanish, Russian, Vietnamese, and Chinese.

During the last year, the department has received only nine price increase notifications from Oregon consumers. The program will be undertaking new strategies to reach consumers and bridge the gap in reporting drug price increases.

The nine reports received in the past year show patient copays from \$10 to \$413. The reports show increases from \$1 to \$280. Three of the reported price increases were more than triple the previous price. Some consumers mentioned that the cost of their medications was causing financial stress. Most of these patients are covered by Medicare. The price increases reported by consumers involved a variety of pharmacies, and most said they did not know why there was an increase. Like last year, a consumer cited the Medicare "donut hole" as the reason for the 387 percent price

increase they experienced (an increase from \$47 to \$229). Another consumer covered by Medicare likely experienced the "donut hole" when their pharmacy changed their copay from \$110.95 to \$370. The term "donut hole" refers to a temporary coverage gap in Medicare drug plans. Once a Medicare enrollee and their plan have spent the coverage limit (\$4,660 for 2023), the Medicare enrollee will pay a copay up to 25 percent for prescription drugs. This "donut hole" ends only when the Medicare enrollee reaches their out-of-pocket max (\$7,400 in 2023).<sup>37</sup>

Here are a few quotes from consumers reporting their price increases:

"Outraged with this price increase!!!"

"Why is the cash price HALF the cost of the insured price?? This is NOT the fault of the pharmacy – insurance is gouging me."

"I have to not buy something else to afford the medication."

We are hopeful for an increase in consumer reporting next year that will allow a more meaningful analysis. Our previous outreach efforts have involved social media advertising and distributing print literature in multiple languages to retail pharmacies. The department remains committed to maintaining consumer engagement with the program and views consumer reporting as an indispensable element of our data collection. The program will continue outreach to Oregonians using a variety of strategies. Program staff members will be looking for suggestions and input to increase consumer reporting, because this reporting helps provide information about the real effect on consumers.

### **Stories from Oregonians**

In addition to price increase reports, the program also asked Oregonians to submit their stories about prescription drug pricing. We have received

a number of responses, with a few consistent threads. You can see all stories submitted in the exhibit to this report and a few of the stories we received in the last year are printed here. The submissions have been lightly edited and any names removed.

Here is a story about having to get a medication from Canada and using "coupons":

"My cat has asthma. His vet prescribed a flovent inhaler. It's the same one used by people, no difference at all ... A Flixotide Evohaler 44 mcg (120 doses) was (with the DISCOUNT) over \$200.00 at Walgreens. \*every two months\*! That's awful and my cat would have died because I couldn't afford \$1,200.00 a year for just one of his meds. ... I went online, found a Canadian 'pet meds' line that would work with my vet via fax to verify the scrip, and mail me the exact same item every 2 months for \$41.00. Yes, that includes shipping from Canada. Same manufacturer. Nothing different at all.

"Then there was the time we lost our health care for my son who has ADHD. The pharmacy was providing his Adderall for our union health care of \$25.00 for 3 months. I tried to refill it once we lost our insurance ... would have been \$1,300.00. We didn't have that, not even close. I called everywhere, and found a 'deal' with coupons for his Adderall for only \$675.00. Wow. I had to borrow from friends to get my son his meds.

"No one is losing money offering our health insurance discounts, and no one is losing money selling me our cat's meds by mail. We are being ripped off by pharmaceutical companies. . . . I cannot believe that in the U.S.A. we are using coupons and pharma commercials advertise that if you can't afford them to call and see what they offer to help. This is nuts. This is not a healthy way to manage getting medications to people. Government should know the exact cost of every item and the markup profit price and our

<sup>&</sup>lt;sup>37</sup> "Costs in the coverage gap." Medicare.gov. https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/costs-in-the-coverage-gap. Accessed Nov. 1, 2023.

privately owned pharma providers should not be raking in record profits off our pain and suffering. Every new drug has input from federal research, federal grant money, and often uses university research. They don't spend their own money to develop any of these drugs, and yet they hide that from you. . . .

"Cap prices, demand transparency, and create an agency where consumers can call and get direct help to find their meds at a reasonable cost or have our gov pick up the balance on their meds. Correlate the pharmacy prices state by state. Collect URLs of where to get discount meds. \*\*Approve mail order from Canada\*\* on everything and let the pharma industry know we aren't going to turn in coupons for heart meds, diabetes injections, cancer treatments, or anything else. That's demeaning, dehumanizing, and disgusting."

Here is someone referring to costs for an older brand name drug, because the cheaper generic drugs do not work for them:

"Thyroid medicine that is not a 'new drug' is \$200 a month if discounts are not available. I have to take this one, none of the cheaper ones work."

Here is a story from someone on Medicaid:

"We are a low-income family on OHP Medicaid. My 28-year-old has multiple chronic illnesses, so I also buy an ACA Obamacare plan so our long-term Kaiser psychiatrist can continue providing care. The OHP Kaiser plan did not cover psychiatry. The OHP mental health is weak with long, long wait times and we'd start way back 10 years ago with diagnosis, etc. In spite of these 2 plans, we struggle with prescription costs. I had to come up with \$426 last month, although I am on Social Security retirement and work as a low paid caregiver. This covered a monthly dose of a self-injected antibody that has given my 28-year-old huge relief from daily migraines, Postural Orthostatic Tachycardia Syndrome (POTS), and depression; the medicine is Ajovy.

Kaiser refuses to do the injection, although they diagnosed anxiety and know the injections cause anxiety. Last month my 28-year-old was ill, but the injection was overdue, and they began having the severe migraines, so they tried the autoinjector and spilled the medicine. Kaiser refused to replace it. OHP refused also, saying Kaiser needed to bill them on the Open Plan Card, which Kaiser refused to do. I had to work extra hours, incurring back pain, and now worry we are over the Medicaid income limits. It is a catch-22 situation. Please help us. Thank you!"

Here are stories about costs for those enrolled in Medicare. The term "donut hole" refers to a temporary coverage gap in Medicare drug plans. Once a Medicare enrollee and their plan have spent the coverage limit (\$4,660 for 2023), the Medicare enrollee will pay a copay up to 25 percent for prescription drugs. This "donut hole" ends only when the Medicare enrollee reaches their out-of-pocket max (\$7,400 in 2023).

"For 2024, my current Plan D with Cigna increased the annual deduction from \$100 to \$145, increased monthly premium from \$54.70 to \$65.20, and changed my Eliquis charge from a \$47 monthly copay to 20 percent of total monthly cost. The current 3 month cost is \$1796.99. It is like being in the 'donut hole' all year."

"I have been taking generic Propranolol capsules once per day for many years. Until this year the prescription was a covered benefit with my insurer, and a 90-capsule refill from the online pharmacy, mailed to my home, costs approximately \$37.87, of which I paid co-insurance of \$16 until I reach my out-of-pocket maximum.

"I turned 65 in September and enrolled in a Medicare Part D plan with an insurer. This policy costs \$12.50 per month and has a \$505 annual deductible. When I price my next refill, 60 mg capsules, 90 day supply through the insurer website, I am quoted the

<sup>&</sup>lt;sup>38</sup> "Costs in the coverage gap." Medicare.gov. https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/costs-in-the-coverage-gap. Accessed Nov. 1, 2023.

following comparison prices at different pharmacies: \$144.65; \$126.34; \$126.34; \$126.34; \$135.19.

"It appears that because I am using insurance, the cost of the drug has been inflated by nearly 400%. This pricing is really alarming when you price the drug using the GoodRx, a discount prescription drug program. A 90 day supply of the same capsules, using the GoodRx discount code, will cost the following at some of the same pharmacies: \$32.85; \$45.84; \$28.94; \$22.44.

"That is a dramatic difference in price. If I use the discount card to purchase the drug, the full year of the prescription will cost less than the cost of 1 refill of the prescription with the Medicare Part D insurance. If this is not price gouging, then I do not know what is.

"I would note that the Medicare Part D program I chose is the least expensive

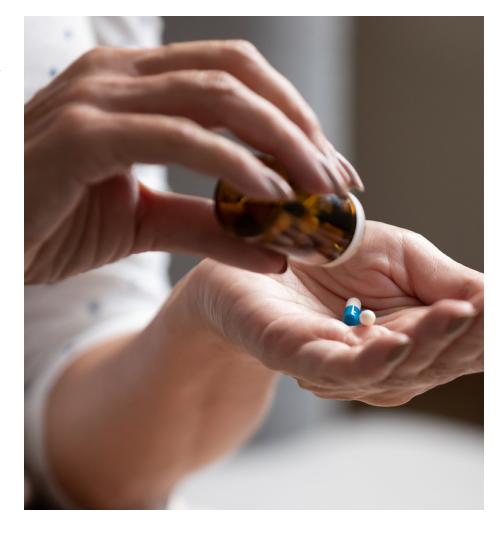
available in Oregon. I cannot avoid having Part D without facing a late enrollment penalty later in life when I would otherwise enroll (presumably when I would be sicker and need more prescription drugs).

"There is nothing fair, or reasonable, about the price inflation using the insurance program. It should be unlawful for drug providers and insurance companies to inflate the cost of prescription drugs based on the use of Medicare Part D insurance."

"I have to use an inhaler, Symbicort. Inhalers are in Tier 3. I have a Medicare Part D drug plan. There is a \$509 deductible for Tier 3 items. For 2024, that deductible is going up to \$549. Then when the deductible is met, I have Silver Scrips, the cost per inhaler has been about \$71.00. I have never understood why there is this big deductible for Tier 3 inhalers.

I'm already paying for Part D premiums and Part B premiums plus a supplement for Part B. Most of this comes out of my Social Security benefits check each month. Please work on this deductible to drop it. I don't have money for that. I am not the only person with this situation."

This report contains significant detail on the drug pricing process, though it also describes how the price set by a manufacturer can be quite different from the price actually paid at the pharmacy counter. The concerns presented by Oregonians are a vital part of our process and will guide our continuing implementation of the Drug Price Transparency Act, as well as future legislative actions.



# **Prescription drug manufacturers**

Prescription drug manufacturers are required to submit reports to the program for new prescription drugs and prescription drug price increases that exceed the threshold for that reporting requirement. The three types of reports are:

- New drug report: Manufacturers are required to submit a new prescription drug report within 30 days of introducing a new prescription drug with a list price of \$670 or more for a 30-day supply or for a course of treatment shorter than one month.
- Annual price increase report: Manufacturers are required to annually submit a price increase report for each prescription drug with a list price of \$100 or more for a 30-day supply or for a course of treatment shorter than one month that experiences a net price increase of 10 percent or more during the previous calendar year.
- 60-day notice price increase report:
   Manufacturers are required to submit a price increase report 60 days before the planned increase takes effect when the threshold is met. A report is required for a brand name prescription

drug when the cumulative price increase is at least 10 percent or \$10,000 within a 12-month period. A report is required for a generic prescription drug when the cumulative price increase is at least \$300, and the increase is also 25 percent or more, within a 12-month period.

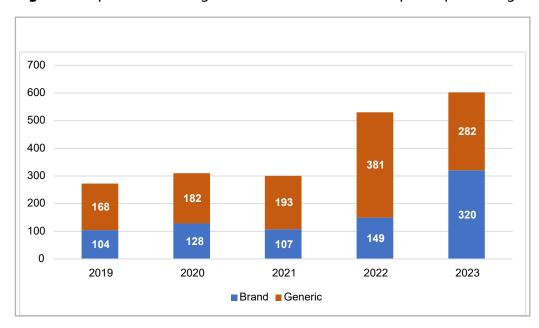
Reporting is required for each qualifying national drug code (NDC) the manufacturer sells. Each unique formulation, dosage, and packaging of a manufacturer's drug gets its own NDC, so the program may receive multiple reports for a single drug if it is manufactured in a variety of dosages or sold in different package sizes.

This report is based on data submitted to the program from Sept. 1, 2022, through Aug. 31, 2023. Any information directly identifiable to a particular drug or company was not claimed as a trade secret in the manufacturer's submission. Information covering multiple drugs has been de-identified and aggregated so that information claimed to be a trade secret is not disclosed.



# **New specialty drug reports**

Figure 4: Report counts for generic and brand name new prescription drugs from 2019 to 2023



New specialty drugs are reported to the program when they are priced at \$670 or more. This was the price threshold set by the federal government to categorize a drug as a "specialty drug" under Medicare Part D in 2019, when the Oregon DPT Program began. Reports for new specialty drugs come in continuously. The federal government has increased this threshold to \$950 in 2024. The program expects to update the rule to link to the federal threshold. Until then, it will remain at the 2019 amount of \$670.

From Sep. 1, 2022, through Aug. 31, 2023, the program received 602 new specialty drug reports. These reports were submitted by 129 different manufacturers, and each report is for a single NDC.

A single drug will generally be sold under several NDCs. For example, a manufacturer may sell two bottles of generic ibuprofen, one with 25 tablets and the other with 50 tablets. In that case, both bottles would have a different NDC, even though they are for the same drug. In our analysis, we will group together NDCs for the same drug from the same manufacturer when describing our data.

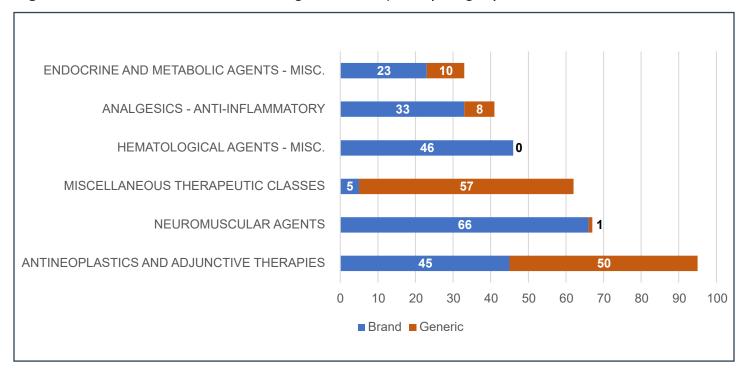
We received new specialty drug reports for 282 generic drugs that came from 59 manufacturers. We also received reports for 320 brand name drugs that came from 84 manufacturers. This information is visualized year to year in Figure 4.

In some parts of this report, we analyze information for a drug at the "product family" level, which includes all NDCs for the same brand name or active chemical agent, rather than individual

NDCs. Manufacturers do not track costs, revenues, or profits for individual NDCs. Instead, they aggregate and track information by "product family" or other methods. Consequently, we generally see identical numbers in the costs, revenue, and profit fields in all reports they submit for NDCs in the same product family. When we say "drug product family," we are referring to a set of NDCs from a manufacturer with the same reported trade name, and "drug" in the same context may be used to refer to a product family rather than an individual NDC.

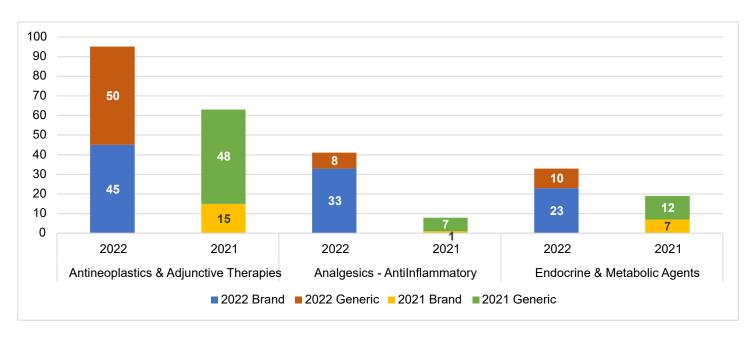
Referencing Figure 5, the most common classes of drugs in these reports were antineoplastic and adjunctive therapy drugs, with 95 reports of drugs falling into this category. Among those 95 reports, 50 were for generic drugs and 45 were for brand name drugs. The second common class of drug in these reports were neuromuscular agents, with 67 reports and only one of these was for a generic drug. The third most common class was hematological agents with 46 reports that were all for brand name drugs. Those not in the top classes were combined and are shown as miscellaneous therapeutic classes.





Visualized in Figure 6 are counts of new specialty drug reports received across three drug families. While the number of new generics in these categories remained about the same each year, reports for brand name drugs experienced a significant increase from 2021 to 2022 across all three drug families. These drug families were chosen because they were also the families with the highest report count from last year's filings.

**Figure 6:** Brand name versus generic new specialty drug report counts for three drug families compared between 2021 and 2022



# Highest WAC prices in new specialty drug reports

The program received new specialty drug reports for drugs with WAC prices ranging from \$49.10 to \$3,500,000. It is possible that a WAC less than \$670 may still require a report to the program, depending on the length of a course of treatment. For example, a drug with a WAC of \$335 for a single dose that requires two doses in one month would cost \$670 for a course of treatment, prompting a

report. However, it is likely that some of the reports we received with lower WAC prices have been submitted in error.

Figure 7 shows the 10 highest WAC prices for new brand name drugs reported to the program this year. It is important to note this is not the price that will be billed to most patients or their insurance company, but is a factor in that price, which is typically calculated as a set percentage of a drug's WAC.

Figure 7: Highest reported WAC for new brand name drugs

Drug	WAC	Therapeutic Class	Manufacturer
Hemgenix	\$3,500,000	Hematological agent	CSL Behring LLC
Elevidys	\$3,200,000	Neuromuscular agent	Sarepta Therapeutics
Skysona	\$3,000,000	Psychotherapeutic and neurological agents	Bluebird Bio Inc.
Zynteglo	\$2,800,000	Hematopoietic agent	Bluebird Bio Inc.
Omisirge	\$338,000	Antineoplastics and adjunctive therapies	Gamida Cell Inc.
Tzield	\$193,900-\$138,500	Antidiabetics	Provention Bio Inc.
Roctavian	\$90,625	Hematological agents	Biomarin Pharmaceutical
Olpruva	\$57,028-\$51,300	Endocrine and metabolic agents	Acer Therapeutics Inc.
Spevigo	\$51,133	Dermatologicals	Boehringer Ingelheim Pharmaceuticals Inc.
Joenja	\$45,000	Miscellaneous	Pharming Healthcare Inc.

The highest WAC reported this year was for a hematological agent, Hemgenix, at \$3.5 million. Hemgenix is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with hemophilia B.<sup>39</sup>

The second-highest reported WAC was for a neuromuscular agent, Elevidys, at \$3.2 million. Elevidys is the first gene therapy for the treatment of pediatric patients 4 to 5 years of age with

Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene who do not have a pre-existing medical reason preventing treatment with this therapy.<sup>40</sup>

Figure 8 shows the 10 highest WAC prices for new generic drugs reported to the program this year. Again, these prices are not necessarily the same as the price billed to patients or insurance.

Figure 8: Highest reported WACs for new generic drugs

Drug	WAC	Therapeutic Class	Manufacturer
Lenalidomide	\$71,990-\$15,118	Immunomodulators	Mylan Pharmaceuticals
Nitisinone	\$43,594	Endocrine and metabolic agents	Analog Pharma Inc.
Edetate calcium disodium injection	\$32,609	Antidotes and specific antagonists	Rising Pharmaceuticals
Bexarotene	\$23,269	Dermatologicals	Amneal Pharmaceuticals
Tasimelteon	\$20,571	Hypnotics/sedatives /sleep disorder agents	Gamida Cell Inc.
Sorafenib	\$15,000-\$10,874	Antineoplastics and adjunctive therapies	TWI Pharmaceuticals/ Teva
Sunitinib Malate	\$14,453-\$12,453	Antineoplastics and adjunctive therapies	Dr. Reddy's Laboratories Inc.
Treprostinil	\$11,460	Cardiovascular agents	Dr. Reddy's Laboratories Inc.
Vigabatrin	\$10,512	Anti-convulsants	Edenbridge Pharmaceuticals Inc.
Indomthacin	\$10,314	Analgesics/ anti-inflammatories	Zydus Pharmaceuticals Inc.

<sup>&</sup>lt;sup>39</sup> "Hemgenix." U.S. Food & Drug Administration, Jan. 4, 2023. https://www.fda.gov/vaccines-blood-biologics/vaccines/hemgenix. Accessed Oct. 30, 2023.

<sup>&</sup>lt;sup>40</sup> "FDA Approves First Gene Therapy for Treatment of Certain Patients with Duchenne Muscular Dystrophy." U.S. Food & Drug Administration, June 23, 2023. https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-treatment-certain-patients-duchenne-muscular-dystrophy. Accessed on Oct. 30, 2023.

The highest WAC reported this year among generic drugs was for an NDC of lenalidomide, an antineoplastic-thalidomide analog. We received reports for lenalidomide from 13 manufacturers, but the most expensive was from Mylan Pharmaceuticals at \$71,990.

DPT's review of generic competition for a drug with several manufacturers showed a price reduction. The program received new drug reports from several manufacturers for the generic drug fingolimod (30 capsules, 0.5 mg). The new drug reports showed WAC prices ranging from \$1,000 to \$8,883.89; however, the current prices from 10 different manufacturers shows a decrease, with WAC prices ranging from \$220.21 to \$2,220.97. The WAC price for generic fingolimod was reduced by 84 percent to 97 percent from its starting price by most manufacturers, while a few are at the same price. Because price decreases are not reported to us, this may be evidence of how competition in the generics market can bring down the price of a drug.

# Public funds in new specialty drug reports

Manufacturers are required to report any funding provided by national, state, local, or foreign government entities used in the basic or applied research for the drug, including funding for preclinical and clinical trials.

Manufacturers overwhelmingly reported receiving no public funding for the drugs reported. Out of the 602 new specialty drug reports received, only three reports provided public funding amounts that were not marked as a trade secret.

An entry for Omisirge (NDC 73441080004), an antineoplastic manufactured by Gamida Cell Inc., reported \$43.8 million in international public funding and included the following description:

"The company has received grants from the Israeli Innovative Authority (IIA) to finance its research and development programs in Israel ... \$35.4 million is royalty-bearing grants and \$2.6 million is non-royalty-bearing grants. In return, the Company is committed to pay IIA royalties at a rate of 3-3.5 percent of future sales of the developed products ... grants received by the Company and the associated LIBOR interest on all such grants totaled to \$43.8 million."

Two reports for Ngenla (NDCs 00069050502 and 00069052002), a growth hormone manufactured by Pfizer, reported \$7.4 million in international public funding and included the following excerpts from Form 10-K filings:

"During the year ended Dec. 31, 2015, OPKO Biologics made a payment of \$25.9 million to ... (Israel) ... in connection with repayment obligations resulting from grants ... to support development of hGH-CTP and the out license of the technology outside of Israel."

"Royalty-bearing grants from the government of Israel for participation in the development of approved projects ... received by OPKO ... from May 31, 2005 (inception date) through June 30, 2013 were \$0, \$0, \$0, \$622,834, and \$5,922,588, respectively."

All other new specialty drug reports either indicated \$0 in public funding or marked their public funding as a trade secret. Of the 49 product families reported, four of them (across six NDCs from three manufacturers) claimed their public funding data as a trade secret.

## Marketing description

Manufacturers are required to submit a description of their planned marketing for a new prescription drug as part of any drug report. This includes the amount the company expects to spend on marketing directly to consumers, as well as on marketing to health care providers. The narrative description is required to include the marketing activities a company plans to engage



in, including, but not limited to, advertising on TV and in magazines, and using peer-to-peer communications such as sponsored speakers at medical seminars and employing sales representatives. Many manufacturers claim marketing strategies and costs are trade secrets. The information not claimed as trade secret or that has been determined to not be exempt from disclosure can be found on the program's data transparency webpages: https://dfr.oregon.gov/drugtransparency/data/Pages/new-drug-reports.aspx#drug.

Here are samples from submissions during the past year with the marketing description data element not claimed as a trade secret:

### **MIRATI THERAPEUTICS INC.**

"There is no direct-to-consumer marketing for Krazati via TV or magazine ads. Promotional activities in support of patients include a patient specific website, www.Krazati.com, search and standard patient educational materials....

"Promotional activities to HCPs include sales representative detailing, speaker programs, congresses and non-personal promotion such as HCP website, www.krazatihcp.com, search, banner advertising, and other digital educational programming in line with the Krazati USPI. Mirati in support of lung cancer patients is providing patient support services as described on www.

miratiandme.com website. Mirati appreciates that the cost of prescription drugs is a concern for many people. Thus, Mirati is committed to responsible pricing of our cancer therapies. We factored in prelaunch research, post launch-sales and operational costs. Mirati believes in pricing our therapies in line with similar therapies and according to the value they provide. Mirati's global pricing focus is to ensure patient access. Krazati is available at a 30-day WAC of \$19,750 and priced in line with comparable targeted cancer therapies." (Krazati® filed by Mirati Therapeutics Inc.)

#### **QOL MEDICAL LLC**

"Congenital sucrase-isomaltase deficiency (CSID) is a rare genetic disorder characterized by a deficiency of the sucrase-isomaltase (SI) enzyme complex within the brush border membrane of the small intestine. Sucraid is an orphan drug and will treat a very limited number of patients in the US population as this affliction occurs in only 1 in every 5,000 people of European descent. This product will not be marketed directly to prescribers or dispensers." (Sucraid® filed by QOL Medical LLC)

#### RIGEL PHARMACEUTICALS INC.

"Rezlidhia (Olutasidenib) ... for adult patients with relapsed or refractory acute myeloid leukemia (AML) ... Rigel's approach for a new product launch is to develop marketing materials for our sales teams to educate healthcare professionals on the appropriate utilization of REZLIDHIA consistent with the US FDA approved indication. Rigel utilizes printed materials, websites, and other digital media to communicate this information to relevant healthcare professionals. We provide patient assistance programs, including a copay assistance program which can be found at www.rezlidhia.com, and our Rigel OneCare program which aids in patient support services, benefit verifications, prior authorizations, temporary and long-term free drug supply, and adherence support. Additional company and product information is included on Rigel's website at www.rigel.com." (Rezlidhia<sup>™</sup> filed by Rigel Pharmaceuticals Inc.)

The marketing description for the two filings below had trade secret claims. The published information only shows the information we determined was not conditionally exempt from disclosure. Any information that appeared to meet the requirements for nondisclosure was identified in *[brackets]* with a description of the information not disclosed.

### **ABBVIE INC.**

"AbbVie's marketing plan for the introduction of SKYRIZI in the gastroenterology market will focus on educating health care professionals (HCPs) and patients (consumers) about the approved use of SKYRIZI and its clinical profile.

"HCP engagement in the introduction of SKYRIZI will involve the development and support of educational material regarding on-label use, peer-to-peer education programs (including seminars), personal and non-personal communications, and a field sales force. We plan to provide drug samples to physician offices, but do not plan to provide gifts or sponsor continuing education programs for HCPs. Moreover, the company's commercial function does plan to sponsor promotional booths at medical conferences.

"Consumer engagement in the introduction of SKYRIZI will involve the development and support for educational materials regarding on-label use including a website, social media, blogs, digital, television, radio, billboards, magazine advertising, and patient in-office materials. Moreover, AbbVie does not plan to provide direct-to-consumer promotional incentives that are different from our patient assistance programs (as that term is used in HB 4005 § 2(5)).

"The total amount spent on the above-described marketing activities is [monetary amount]." (Skyrizi® filed by AbbVie Inc.)

### **VERICEL CORPORATION**

"Product promotion designed to educate health care professionals will occur during medical conferences and during scheduled appointments

with company representatives. Product information and product demonstration will be offered at industry conferences and at individual burn centers at the request of health care professionals. We do not market directly to consumers.

"Vericel does not market directly to consumers, i.e., no promotional incentives or media advertisements on different platforms. The direct-to-consumer marketing spend is 0 (items (i) and (ii)).

"Product promotion designed to educate health care professionals will occur during medical conferences and during scheduled appointments with company representatives. Product information and product demonstration will be offered at industry conferences and at individual burn centers at the request of health care professionals [specific monetary amounts for marketing]." (NexoBrid® filed by Vericel Corporation)

While the program collects this information for all new drug reports, both generic and brand name, we have found that most companies do not engage in any marketing for generic drugs. The scope of promotion for generics is typically limited to listing the drug in wholesaler catalogs. However, biosimilars, which are roughly equivalent to generics in the market for biologics, tend to be marketed more like a brand name.

## **Pricing methodology**

Manufacturers are also required to submit an explanation of the methodology they used to establish the price of the new prescription drug, including a narrative description and explanation of all major financial and nonfinancial factors that influenced the initial price. We found that the price of generic drugs is commonly set as a fixed percentage of the price of the drug's brand name equivalent, while most brand name manufacturers described a holistic multi-factor analysis of economic and clinical factors. Many manufacturers claim this information is a trade secret.

Here are samples from submissions during the last year for the pricing methodology data element not claimed as a trade secret:

#### **BIOVERATIV U.S. LLC**

"... Sanofi (parent company) understands and shares concerns about the affordability of medicines for patients while also recognizing that we are only one of many stakeholders in the health care system. ... While many factors, including decisions affecting patient out-of-pocket spending and insurance coverage, are controlled by other stakeholders in the health care system, we believe we have a responsibility to be a leader in solving issues of patient access and system viability. For our part, we price our medicines according to their value, while contributing to broader solutions that improve patient outcomes and support affordability within the U.S. health care system.

"When we set the price of a new medicine, we hold ourselves to a rigorous and structured process that includes consultation with external stakeholders and considers the following factors:

"A holistic assessment of value, including 1) clinical value and outcomes, or the benefit the medicine delivers to patients, and how well it works compared to a standard of care; 2) economic value, or how the medicine reduces the need - and therefore costs – of other health care interventions; and 3) social value, or how the medicine contributes to quality of life and productivity. Our assessments rely on a range of internal and external methodologies, including health technology assessment (HTA) and other analyses that help define or quantify value and include

patient perspectives and priorities.

"Similar treatment options available or anticipated at the time of launch, in order to understand the landscape within the disease areas in which the medicine may be used.

"Affordability, including the steps we must take to promote access for patients and contribute to a more sustainable system for payors and health care systems.

"Unique factors specific to the medicine at the time of launch. For example, we may need to support ongoing clinical trials to reinforce the value of our medicines (e.g., longer-term outcomes studies), implement important regulatory commitments, or develop sophisticated patient support tools that improve care management and help decrease the total cost of care." (Altuviiio™ filed by Bioverativ U.S. LLC)

#### **BLUEBIRD BIO INC.**

"ZYNTEGLO is an autologous hematopoietic stem cell-based gene therapy indicated for the



treatment of adult and pediatric patients with -thalassemia who require regular red blood cell (RBC) transfusions. ZYNTEGLO has the potential to untether from the health care system patients who, on average, currently require regular red blood cell transfusions every two to five weeks for life and may lose decades of life relative to the general population.

"Bluebird took this profound impact into consideration when pricing the therapy—weighing the therapy's robust and sustained clinical benefit, quality of life improvements for patients and their families, cost savings to the system, and the overall impact on society. We are focused on timely access to this therapy for this patient population." (Zynteglo® filed by Bluebird Bio Inc.)

### FERRING PHARMACEUTICALS INC.

"In establishing the WAC for REBYOTA, Ferring applied an approach based on research evaluating the current market for the product, including inputs from health care practitioners and health plans, as well as the current market for competing products. We evaluated these factors for impact on patient access through formulary coverage, ability to dispense/fill each prescription, and patient affordability." (Rebyota™ filed by Ferring Pharmaceuticals Inc.)

#### **GENENTECH INC.**

"As a company with a long history of pursuing ground-breaking science to bring innovative medicines to patients, we strive to ensure that anyone who is prescribed one of our potentially life-changing medicines can get it – regardless of their ability to pay. We strive for the right balance between ensuring people can access, afford and benefit from the medicines they need while investing in future scientific breakthroughs and therapeutic advancements. We have invested in excess of \$15B per year on R&D – more than any other healthcare company in the world. ...

"We take a long-term, thoughtful approach to pricing that involves several considerations, beyond how safe and effective our medicine might be. In addition to the clinical benefit, which helps us begin to understand a medicine's potential value for patients, providers, payers, and the health care system, we seek to understand and evaluate how our medicine might be different from medicines currently being used, or if it will be the first treatment option available to patients. We gather input from a range of stakeholders such as people living with a particular disease and their care partners, health care professionals, patient advocacy groups, and professional societies as well as legislative and administration officials, to appropriately assess the medicine's value and help ensure we price it right.

"At every step of the way, from research to pricing, Genentech puts patients first. We have a longstanding pricing philosophy that is designed to strike a balance between ensuring patients have rapid, broad, and sustainable access to our medicines, while at the same time preserving our ability to invest in future scientific innovations that drive the important medical breakthroughs that patients depend on. We have brought 21 innovative new medicines to patients over the twelve years in areas such as cancer, neuroscience, respiratory and ophthalmology diseases, as well as devastating rare diseases like hemophilia and spinal muscular atrophy. Additionally, we have been granted 39 FDA breakthrough therapy designations." (Lunsumio™ filed by Genentech Inc.)

The program collects this information for all new drug reports, both generic and brand name. We have found that most generic drugs do not use financial and nonfinancial factors in pricing. For generic drugs, it is common to determine a discounted price from the brand name drug or a comparative price to other generics on the market instead of using other pricing methodologies, such as ones used to price brand drugs.

# **Annual price increase reports**

Manufacturers are required to annually submit a price increase report for any of their drugs with a list price of \$100 or more for a 30-day supply or a shorter course of treatment that experience a net price increase of 10 percent or more from the previous year. Price increase reports are due March 15 each year. Reports are filed for price increases that occurred over the preceding calendar year, so reports received in 2023 reflect increases from the average price of the drug in 2021 to the average price of the drug in 2022.

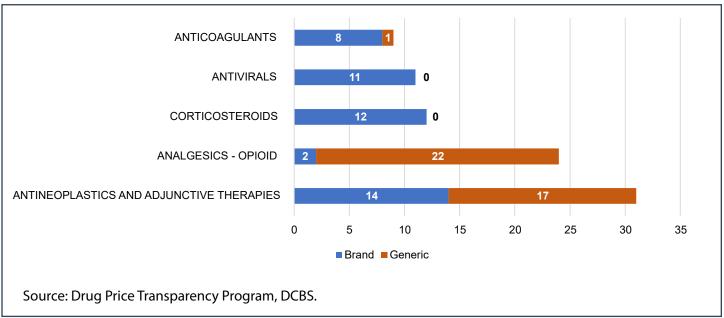
In 2023, the program received 203 annual price increase reports, each one for a different NDC, from 31 different manufacturers. This is a near doubling from the 102 reports we received in 2022.

As described earlier, a single drug will generally be sold under several NDCs. For example, a manufacturer may sell two bottles of generic ibuprofen, one with 25 tablets and the other with 50 tablets. In that case, both bottles would have a different NDC, even though they are for the same drug. In our analysis, we will group together NDCs for the same drug from the same manufacturer when describing our data.

We received annual price increase reports for 95 generic drugs from nine manufacturers. We also received reports for 108 brand name drugs from 25 different manufacturers.

Patient assistance programs were reported on 22 of the brand name drug reports, showing information for 18 patient assistance programs from eight manufacturers. The reports included the number of Oregon participants and the total value all Oregon participants received from the patient assistance program for that year. Participant counts ranged from one Oregon participant to 623 for a total of 2,302 participants. The total benefit amount for the Oregonians participating in each patient assistance program in 2022 ranged from \$171 to \$828,204. These reports showed a total of more than \$2.5 million in benefits for all 2,302 participants, leading to an average of \$1,091.95 savings on prescription

Figure 9: Breakdown for brand name and generic drugs from annual price increase reports by most common classes



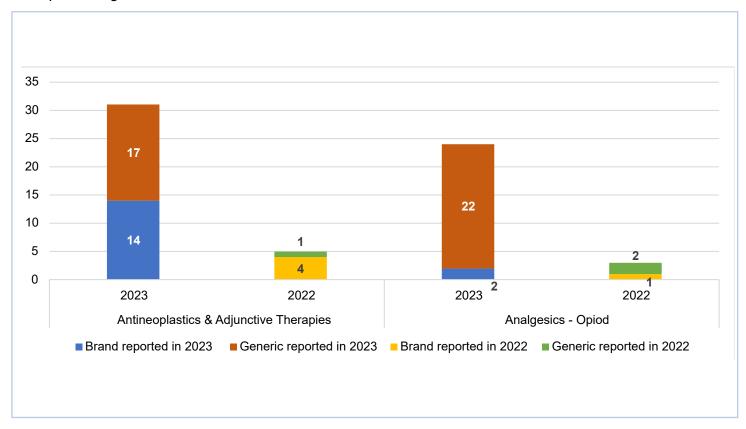
drugs for each Oregon participant. We are not providing the drug names or other details because the number of participants and value of assistance is claimed as a trade secret on most of these reports.

The median reported price increase was 20 percent for generic drugs and 14.9 percent for brand name drugs. The overall median price increase was 15.5 percent.

Referencing Figure 9, the most common class of drugs in these reports was antineoplastics and adjunctive therapies, with 31 total reports. Of those reports, 14 were for brand name drugs and 17 were for generic drugs. The next most common class was opioid analgesics with 24 reports. Two of those were for brand name drugs and 22 were for generic drugs. The third most common class was corticosteroids and all 12 reports were for brand name drugs.



**Figure 10:** Comparison of annual price increase report counts for brand name and generic drugs in the top two drug families



This shows a large increase in the number of annual price increases for generic analgesic opioids with 22 reports received. The number of annual price increase reports greatly increased, with brand name antineoplastics and adjunctive therapies increasing from four to 14, and generic antineoplastics and adjunctive therapies increasing from one to 17.

This information is visualized in Figure 10. These drug families were chosen because they were the families with the highest report count from last year's filings. Shown in Figure 11, the total of 203 price increase reports received in 2023 represents an increase from the 102 received in 2022.

■ Brand ■ Generic

Figure 11: Annual price increase reports from manufacturers 2019 to 2023

# **Recent trends and market dynamics**

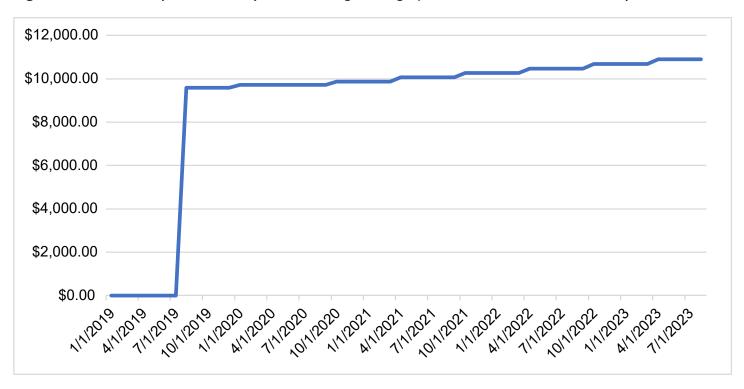
Decreases or increases in the number of reports received by the program, however, do not indicate the degree to which price increases are or are not occurring in the overall market. The program only receives a price increase report when the specified threshold has been met. There may be instances where price increases are significant, but do not meet the program's reporting threshold.

As reported by the office of U.S. Rep. Katie Porter, "The next frontier in the battle to lower drug costs is launch prices." Keytruda, a brand name for the

drug known as pembrolizumab (NDC 00006302604) manufactured by Merck Sharp & Dohme LLC appeared in both the top five greatest increase and most costly drug lists reported by insurers this year. Shown below is Keytruda's price history in dollars. This particular NDC is for the 100 mg/4 mL intravenous solution. Keytruda entered the market on Aug. 2, 2019, at a WAC of \$9,580.40 and rose steadily to \$10,897.12 effective March 30, 2023, where it remains at present, according to the Medi-Span price history database. The price increases are below 10 percent each year, so the manufacturer was not required to file a DPT report for Keytruda.

<sup>&</sup>lt;sup>41</sup>"Skyrocketing: How Big Pharma Exploits Launch Prices to Cash in on Cancer." Office of Rep. Katie Porter, Nov. 2, 2022. https://porter.house.gov/uploadedfiles/skyrocketing\_-\_how\_big\_pharma\_exploits\_launch\_prices\_to\_cash\_in\_on\_cancer.pdf. Accessed Oct. 30, 2023.

Figure 12: Price history review of Keytruda starting at a high price with small increases each year



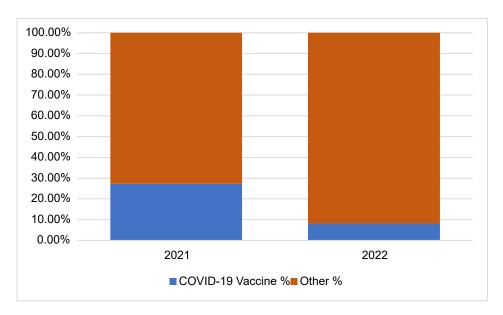
This is just one of many examples. Drugs enter the market at their launch price and increase at varying rates. These are the two components to evaluate: launch price and increase pattern. "Prescription drug prices are too high in the U.S., and these high prices are driven by the financial incentives present under the current system," according to Thomas Waldrop, a policy analyst focused on prescription drug pricing at the Center for American Progress. "The abuse of government-granted monopoly periods and the inability of payers to meaningfully negotiate prescription drug prices has created a system in which drug companies are able to set prices for their product without regard to the value that the drugs provide to patients."<sup>42</sup>

Another important trend to study is the effect COVID-19 had on the prescription drug market for the years 2021 and 2022. The FDA first granted

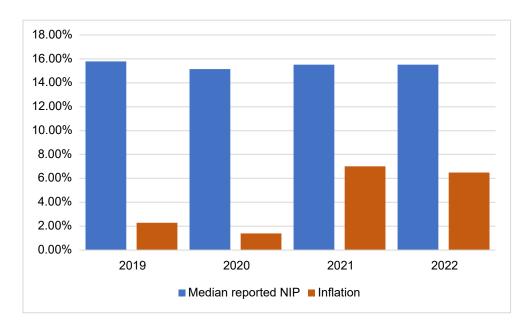
emergency use authorization to the Pfizer-BioNTech vaccine on Dec. 10, 2020, and mass vaccination began four days later. The Moderna vaccine was granted emergency use authorization on Dec. 17, 2020. The Johnson & Johnson (Janssen) vaccine was granted emergency use authorization on Feb. 27, 2021. In 2021, the top 10 most prescribed drugs had a total prescription count of 1,971,160, of which 537,155 (27.3 percent) were for COVID-19 vaccinations. These vaccinations were the most prescribed drug class of 2021, followed by flu vaccinations. In 2022, the top 10 most prescribed drugs had a total prescription count of 1,524,292, of which 124,948 (8.2 percent) were for COVID-19 vaccinations. These vaccinations dropped to ninth-most prescribed drug class of 2022, with flu vaccinations being the most prescribed. This is visualized in Figure 13.

<sup>&</sup>lt;sup>42</sup> Waldrop, Thomas. "Value-Based Pricing of Prescription Drugs Benefits Patients and Promotes Innovation." Center for American Progress, Sept. 13, 2021. https://www.americanprogress.org/article/value-based-pricing-prescription-drugs-benefits-patients-promotes-innovation/. Accessed Oct. 30, 2023.

**Figure 13:** COVID-19 vaccine counts versus the rest of the top 10 most prescribed drugs for the years 2021 and 2022



**Figure 14:** Inflation compared to the median reported net increase percentages (NIP) from drug manufacturers

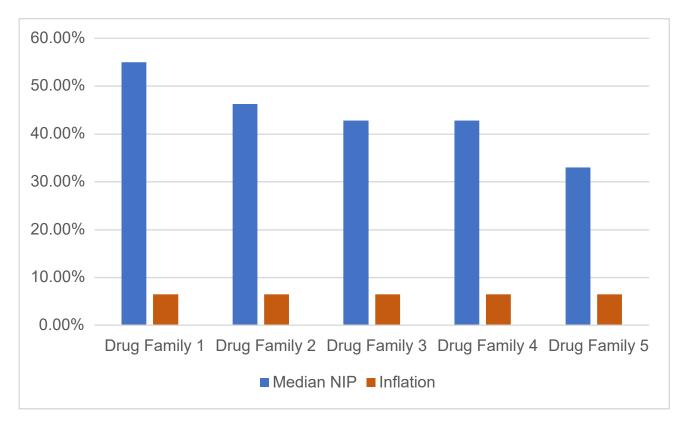


The net increase percentages reported by drug manufacturers were aggregated year to year from 2019 to 2022. Median increase percentages for prescription drugs reported to the program were steady at approximately 15 percent year to year. Inflation was 2.3 percent in 2019, 1.4 percent in

2020, 7 percent in 2021, and 6.5 percent in 2022.<sup>43</sup> Median net increase percentage outpaced inflation by 13.5 percent in 2019 and 13.7 percent in 2020, and by 8.5 percent in 2021 and 9 percent in 2022. This information is visualized in Figure 14.

<sup>&</sup>lt;sup>43</sup> "Consumer Price Index." U.S. Bureau of Labor Statistics, Archived Consumer Price Index Supplemental Files, Nov. 14, 2023. https://www.bls.gov/cpi/tables/supplemental-files/. Accessed Nov. 30, 2023.

**Figure 15:** Inflation in 2022 is compared to the median reported increase percentages for the top five drug families



Net increase percentages were collected from each drug report the program received in 2022. These were divided into their drug families, then the average for each family was calculated. The top five are reported in Figure 15, which shows how the increases for that drug family compare to the 2022 inflation rate.

Drug Family 1 (ADHD/anti-narcolepsy/anti-obesity/ anorexiants) reported a median percent net increase of 55.0 percent, followed by Drug Family 2, (calcium channel blockers) with a 46.3 percent net increase, Drug Family 3 (local anesthetics-parenteral) with a 42.9 percent net increase; Drug Family 4 (musculoskeletal therapy agents) with a 42.8 percent net increase, and Drug Family 5 (antianginal agents) with a 33.0 median percent net increase.

### **Price increase factors**

Manufacturers are required to submit an explanation of the reasons for the annual price

increase of the prescription drug, including a narrative description and explanation of all major financial and nonfinancial factors that influenced the increase in price. Many manufacturers claim this information is a trade secret.

Here are samples from submissions from the past year for the price increase factors data element not claimed as a trade secret:

#### AMERISOURCE HEALTH SERVICES LLC

"Market Conditions; Upon AHP's periodic review of market data for Oxazepam, AHP determined that there was consistent supply chain disruption on bulk supply availability and backorders of AHP unit dose product for 10MG, 15MG and 30 MG doses. As a result of these market conditions, AHP decided to increase WAC from \$198.75 to \$238.50 per carton (or \$1.99 to \$2.39 per unit dose) for the 10MG dose with an effective date of February 1, 2022." (Oxazepan filed by Amerisource Health Services LLC, reporting a 20 percent increase)



#### **CLINIGEN INC.**

"Our price increase was driven by market condition in including an increase in the cost of business and cost of manufacturing. The decision to increase the wholesale acquisition cost of Proleukin was carefully assessed prior to Clinigen taking any action. Clinigen assembled an internal pricing steering committee to examine various market research, competitive pricing, and data sources to evaluate Proleukin's pricing and formulate our new wholesale acquisition cost of the drug. Clinigen has historically kept the price of Proleukin relatively the same however market conditions including the increased cost of operations and manufacturing were key considerations that also factored into our decision. In addition, the overall cost of inflation across all of the facets of manufacturing and maintaining the product (i.e., marketing, personnel, materials, etc.) were also assessed and included in the committee's recommendation." (Proleukin filed by Clinigen Inc., reporting a 10.4 percent increase)

#### **EVOFEM BIOSCIENCES INC.**

"Evofem has experienced unexpectedly high rebate demands from PBMs combined with high demand for patient assistance programs. We had anticipated

Phexxi coverage to be improved by the ACA Preventive Services regulations. However most PBMs are not recognizing Phexxi as a preventive contraceptive product." (Phexxi filed by Evofem Biosciences Inc,. reporting a 11.3 percent increase)

#### **SECURA BIO INC.**

"Copiktra is an orphan drug and one of only 2 pi3 kinase inhibitors on the market. It is currently indicated for Refractory Relapsed Chronic Lymphocytic Leukemia (CLL) and is typically prescribed after all other therapies have been utilized and hospice is the only remaining option. Copiktra has

proven efficacy in heavily pretreated CLL patients that have received multiple lines of therapy. We did a general competitive analysis and these types of therapies have a higher price point. Copiktra pricing is now in line with similar therapies. In addition, the company is still selling this product as a loss as wells as not producing net income on a company basis at this time." (Copiktra filed by Secura Bio Inc., reporting a 25.2 percent increase)

#### **ZYLA LIFE SCIENCES**

"Our pricing is guided by the value our products bring to patients and an understanding of the environment in which we operate. The following financial and nonfinancial factors, along with a narrative description and explanation of these factors, influenced our decisions to take a price action:

- "(1) Covering Operating Expenses. ...
- "(2) Recouping Development Costs. ...
- "(3) Covering and Funding Acquisition Costs. ...
- "(4) Supporting Investment in New Products. ...
- "(5) Supporting Investment in Existing Products. ...

"(6) Discounts and Rebates: We pay rebates and discounts to various stakeholders in the supply chain in connection with the sale of our products, including pharmacy benefits managers, health insurers and health plans, including government payors like Oregon's Medicaid program (known as the Oregon Health Plan), as well as wholesalers and pharmacies. Collectively, these price concessions represent substantial dollars, and we consider them in our decisions around pricing our products.

"(7) Inflation: We consider the rate of annual inflation in our decisions around pricing our products.

"As is well known in the U.S. drug industry, Wholesale Acquisition Cost – WAC (list) prices are not reflective of the final price paid by patients, health plans, PBMs or government payers, nor are they reflective of the net price or profits realized by the drug manufacturer. Each year Zyla analyzes the increasing costs associated with providing our products to patients, including impact of managed care rebate agreements, costs of distribution, GMP manufacturing, regulatory obligations and post-marketing commitments, and other costs associated with commercializing a regulated pharmaceutical product in the U.S. We then determine what, if any, WAC price adjustment is appropriate given the dynamics of our contractual commitments and the competitive environment. This is done on a product-by-product basis. Zyla is committed to maintaining a suite of robust patient access programs, which strive to minimize and, in most cases, completely eliminate the impact of any WAC price adjustment on patient out-of-pocket costs for commercially insured patients. For these reasons, product increases may look similar over time; however, the net price received by the Company may be quite variable in nature. While Zyla follows this process for each on-market drug, the resulting analytical modeling varies depending on the specific drug class, competitive influences, and nature/terms of PBM/payer agreements.

"Zyla products are branded prescription drugs sold in markets where there is significant generic

competition. Therefore, decisions on pricing are made with these considerations in mind. While we make product-by-product WAC price decisions, our price increase factor statement is similar among all products because the process and factors considered when making pricing decisions are similar across all of our products." (Oxaydo filed by Zyla Life Sciences, reporting a 11.5 percent increase)

We receive a wide variety of reasons for increasing the price of a drug with many referring to "the market," "government charges," or "the benefit to patients." As Secura Bio provided above, it noticed that its price was lower than its competitors. Some of this high-level information does not provide the insights the program needs to better understand the reasoning and source of increasing drug prices.

### Largest reported price increases

Manufacturers reported the net percent increase in the WAC price of the drug from 2021 to 2022 in their annual price increase reports this year. To validate the reported percentages, we checked them against the Medi-Span price history database. Across all reports, the median price increase was 20 percent for generic drugs and 14.9 percent for brand name drugs.

The highest reported price increase was 379 percent for Aquasol A, a generic vitamin A solution manufactured by Casper Pharma (NDC 70199002611). According to the Medi-Span database, Aquasol A entered the market at \$575 on Dec. 30, 2020. Then it was increased to \$718.75 on July 10, 2023. This represents a 25 percent increase versus the self-reported 379 percent, indicating a data quality problem. Casper Pharma reported the following as increase factors:

"... Casper Pharma makes pricing decisions regarding the WAC price of a medication after careful consideration of a number of factors, including but not limited to a) the clinical and economic value of the particular therapy; b) the therapeutic category, its market dynamics, and competitor pricing; c) discounts

provided to customers in both the commercial and government channels; d) overall general administration, research and development costs. From 2019 through 2023, Casper expects to invest more than \$2 million in research and development ('R&D') related to the product. Specifically, Casper has invested in R&D activities relating to the following:

- Developing the Product from nutritional to pharmaceutical grade.
- Qualifying a new, upgraded source for the active pharmaceutical ingredient that will be subject to a drug master file, where previously the active ingredient was only available from a nutritional source.
- Eliminating the existing need to include preservatives within the Product's formulation.
- Reformulating the Product to eliminate the need to refrigerate the Product, thereby extending the Product's use in care settings where refrigeration is unavailable.
- Increasing manufacturing capacity and availability
  of the Product throughout the United States to
  address previous supply limitations that resulted in
  the product being in-and-out of supply and markets
  being under served; and
- Supporting a multi-year, multi-center clinical study to determine appropriate dosing of the Product in neonatal treatment contexts."

The second-highest reported price increase was for gemcitabine, a generic antimetabolite manufactured by Amerisource Health Services LLC (NDC 68001034234). According to the Medi-Span database, gemcitabine entered the market at \$7.39 on May 1, 2018, and increased to \$26.40 on Jan. 1, 2022. This represents a 257 percent increase that was backed up by the self-reported amount. As the reason for its price increase, the manufacturer originally wrote "market conditions" on the report. Following compliance efforts, it added this information:

"A periodic business review of AWP and WAC prices across BPL products was carried out in June 2021 following a discovery by BPL of a mismatch between the AWP of the manufacturer-labelled versions of the Drugs and the AWP reported by BPL for BPL-labelled versions of the same drugs. This resulted in price changes that took effect January 1, 2022. The WAC of the below NDC's for Gemcitabine (1GM/10ML, 200 MG/2ML, and 2GM/20ML) was updated to align with the manufacturer-labelled WAC."

The third-, fourth-, and fifth-highest reported price increases all came from Amerisource Health Services LLC. The third being for cisplatin, a generic alkylating agent (NDC 68001028327). According to the Medi-Span database, cisplatin entered the market at \$17.50 on Sept. 12, 2016, dropped to \$14.51 on March 8, 2018, and then rose to \$30 on Jan. 1, 2022. This represents an increase of 107 percent for the year 2022, which is backed up by the self-reported amounts.

The fourth-highest report was for diltiazem hydrochloride, a generic calcium channel blocker (NDC 60687020601). It entered the market at \$39 on Jan. 26, 2017, and rose to \$80.55 on July, 5, 2022. This represents an increase of 107 percent, again backed up by the self-reported amount.

Finally, the fifth-highest reported price increase came from metoprolol tartrate, a generic beta blocker (NDC 62584026701). It entered the market at \$8.52 on Oct. 24, 2007, rose to \$13 on Nov. 29, 2017, rose again to \$14.88 on March 2, 2021, and then again rose to \$28 on Jan. 3, 2022. This represents an increase of 88 percent, backed up by the self-reported amount.

For all three of these drugs, Amerisource again justified the price increases by citing "market conditions." Following compliance efforts, the manufacturer provided some additional information, similar to this, for each:

"A periodic business review of AWP and WAC prices across BPL products was carried out in June 2021 following a discovery by BPL of a mismatch between the AWP of the manufacturer-labelled versions of the Drugs and the AWP reported by BPL for BPL-labelled versions of the same drugs. This resulted in price changes ... updated to align with the manufacturer-labelled WAC as well as the pricing across the different dosages."

# Profits and revenues in annual price increase reports

Manufacturers are required to include the drug's profits and revenues in the previous year in each annual price increase report they file with the program. This year, we analyzed the reported profits and revenues for 42 drug product families – 25 generic and 29 brand name (there are some drug families appearing on both lists) – from 31 different manufacturers.

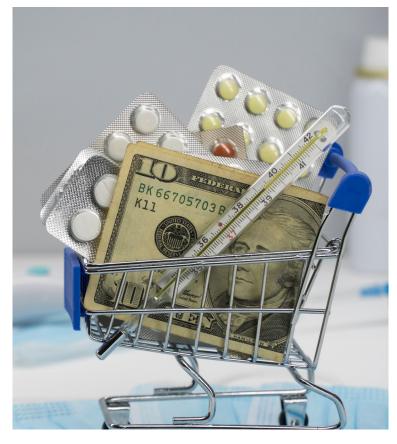
This year, the median profit margin was 23.3 percent for both brand and generic categories, which means that for every dollar of revenue brought in by the drug, 23.3 cents was pure profit. The maximum profit margin reported from brand name drugs this year was 12,800 percent and the minimum was negative 510 percent.

The identities of specific drug and manufacturer names have been removed from this section of the report as an overwhelming majority of profit and revenue information reported this year was claimed as trade secret by the manufacturer. The maximum profit margin from generic drugs this year was 88.8 percent, and the minimum profit margin was negative 25.1 percent. This year, only 5.2 percent of entries reported negative profit margins, and 5.8 percent of entries reported profit margins greater than 80 percent. In 2021, 13.3 percent of entries reported negative profit margins, and 23.5 percent of entries reported profit margins greater than 80 percent.

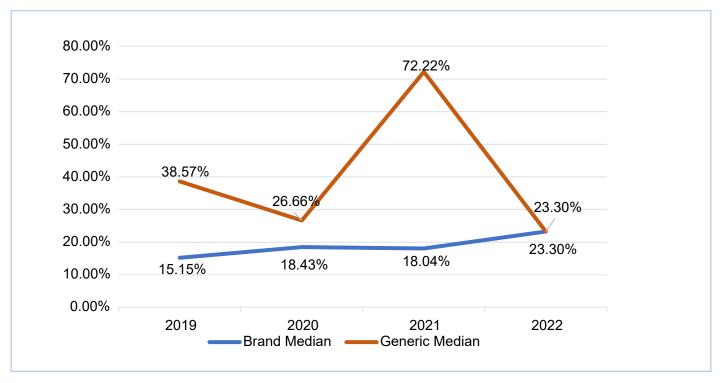
Depicted in Figure 16, generic drugs have historically earned higher profit margins than brand

name drugs, with a median of 38.6 percent versus 15.2 percent in 2019, and a median of 26.7 percent versus 18.4 percent in 2020. In 2021, approximately one-third of generic reports had a profit margin greater than 90 percent. Opioids such as oxymorphone heavily skewed median profit margin numbers for this year. Removing these values from our analysis, the median profit margin for generic drugs in 2021 drops to 46.3 percent. Figure 17 shows the results of the same analysis as Figure 16, but with the oxymorphone entries removed.

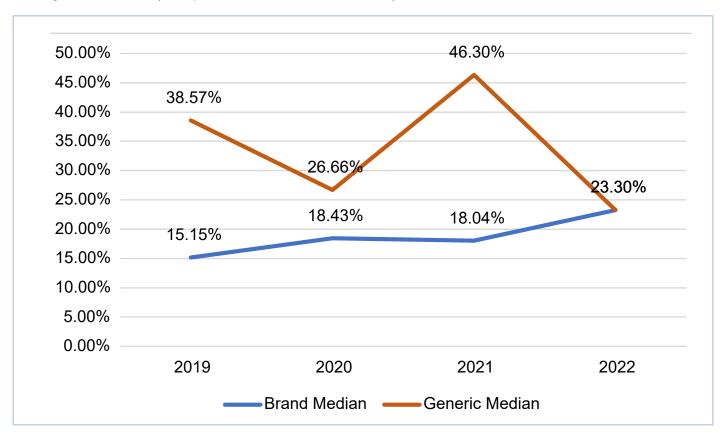
The highest gross profit reported for a drug in 2022 had a profit margin of 61 percent. In total, the 108 brand name drugs we studied this year reported an aggregate \$60 billion in revenue and \$34.8 billion in profit, for an overall profit margin of 57.9 percent. The 95 generic drugs we studied reported an aggregate \$288 million in revenue and \$96 million in profit for an overall profit margin of 33.3 percent. The numbers for profits and revenues this year far surpassed those from last year. A steep increase in report numbers this year and a decrease in entries of "0/0" for "profit/revenue" within those reports may also be contributing to the increase.



**Figure 16:** Median reported profit margins for brand name and generic drugs from 2019 through 2022



**Figure 17:** Median reported profit margins for brand name and generic drugs from 2019 through 2022 with oxymorphone removed from the analysis



# Direct costs in annual price increase reports

Pharmaceutical manufacturers also are required to report the direct costs they incurred in the previous year in each annual price increase report they file with the program. They are required to report direct costs across four categories:

- Manufacturing
- Marketing
- Distribution
- Ongoing safety and effectiveness research

This year, we analyzed the reported costs from 25 unique manufacturers of brand name drugs and nine unique manufacturers of generic drugs.

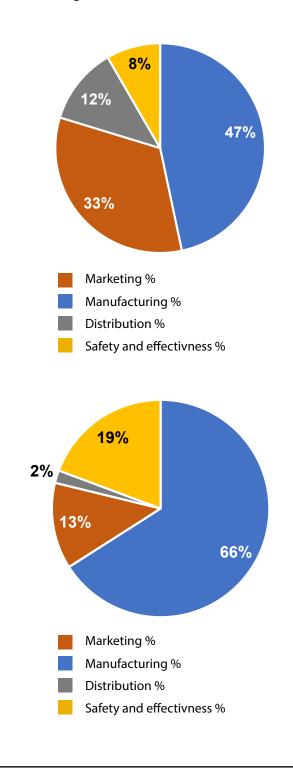
As we saw last year, manufacturers tend to spend more on manufacturing than on marketing, distribution, or safety and effectiveness research.

Among the brand name manufacturers, 47 percent of their costs were manufacturing, marketing accounted for 33 percent, distribution accounted for 12 percent, and ongoing safety and effectiveness research accounted for 8 percent of a product family's reported costs, on average.<sup>44</sup> This information is shown in Figure 18.

Among the generic drug manufacturers, 66 percent of their costs were manufacturing, ongoing safety and effectiveness research accounted for 19 percent, marketing accounted for 13 percent, and distribution accounted for 2 percent of a product family's reported costs, on average. This information is shown in Figure 19.

In total, the 25 manufacturers of brand name drugs reported \$977 million in manufacturing costs, \$692 million in marketing costs, \$238 million in distribution costs, and \$175 million in ongoing safety and effectiveness research costs. The nine manufacturers of generic drugs reported \$70.3 million in manufacturing costs, \$13.7 million in marketing costs, \$2 million in distribution costs, and \$20.6 million in ongoing safety and effectiveness research costs.

**Figure 18 and 19:** Averages of direct costs from annual price increase reports – brand name and generic



<sup>&</sup>lt;sup>44</sup> In some parts of this report, we analyze information for a drug at the product family level, which includes all of the NDCs for the same brand name or active chemical agent, rather than individual NDCs. We found that many manufacturers do not track costs, revenues, or profits for individual NDCs. Instead, they aggregate and track information by product family. Consequently, they provide identical numbers in the costs, revenue, and profit fields in all reports they submit for NDCs in the same product family. When we say drug product family, we are referring to a set of NDCs from a manufacturer with the same reported trade name. In the same context, drug may be used to refer to a product family rather than an individual NDC.

# Public funds in annual price increase reports

Manufacturers are required to report any funding provided by national, state, local, or foreign government entities that was used in the basic or applied research for the drug, including funding for preclinical and clinical trials.

Just as in the submitted new specialty drug reports, manufacturers overwhelmingly reported receiving no public funding for the drugs reported. Out of the 203 annual price increase reports we received, none reported nonzero amounts of public funding.

### **Drug prices in other countries**

When filing an annual price increase report, manufacturers are required to include the 10-highest prices paid for the drug in any country other than the U.S., converted to U.S. dollars. The prices should be reported as an average for the previous calendar year.

This year, they should have reported the average prices over the calendar year 2022.

In the reports filed this year, manufacturers generally did not report any prices from other countries. Out of the 203 annual price increase reports we received, 38 included non-U.S. prices. The remaining 165 reports did not include any non-U.S. prices. Of the prices reported, the average non-U.S. price for most drugs reported (76 percent), were at least a 50 percent discount over the average U.S. WAC and a third of those were at least a 90 percent discount. A few of the reported international prices were higher than the average WAC. Below are some of the drugs and their reported average international price not marked as trade secret compared to the average WAC in Medi-Span.

When reviewing information about prices in other countries, it is important to remember that the final price consumers pay in the U.S. is generally less than the WAC due to discounts applied to the WAC from manufacturers, pharmacy benefit managers, state programs, or insurance companies.

**Figure 20:** A sample of average international prices reported by manufacturers on annual price increase reports for 2022 (filed in 2023)

Drug trade name	Manufacturer name	Medi-Span 2022 average WAC <sup>45</sup>	Average international price reported
Biktarvy	Gilead Sciences Inc.	\$3,583.80	\$1,089.37
Cayston	Gilead Sciences Inc.	\$10,394.56	\$3,151.07
Complera	Gilead Sciences Inc.	\$3,261.53	\$992.78
Cytarabine	Pfizer	\$20.32	\$57.21
Descovy	Gilead Sciences Inc.	\$2,038.83	\$662.97
Fragmin	Pfizer	\$476.54	\$38.08
Genvoya	Gilead Sciences Inc.	\$3,583.80	\$1,031.61
Matulane	Leadiant Biosciences Inc.	\$11,969.11	\$7,751.69
Nerlynx	Puma Biotechnology Inc	\$19,252.81	\$5,531.42
Nipent	Pfizer	\$2,439.07	\$801.31
Odefsey	Gilead Sciences Inc.	\$3,261.53	\$803.05
Oxaliplatin	Pfizer	\$96.00	\$564.22
Prepidil	Pfizer	\$654.78	\$26.35
Solu-Cortef	Pfizer	\$18.50	\$3.70
Solu-Cortef	Pfizer	\$462.76	\$42.62
Solu-Cortef	Pfizer	\$34.24	\$46.07
Stribild	Gilead Sciences Inc.	\$3,759.41	\$1,036.47
Tybost	Gilead Sciences Inc.	\$267.52	\$36.62
Unituxin	United Therapeutics Corp.	\$14,349.60	\$9,385.33
Vemlidy	Gilead Sciences Inc.	\$1,297.69	\$365.24
Zydelig	Gilead Sciences Inc.	\$12,429.83	\$4,046.58

<sup>&</sup>lt;sup>45</sup> Average WAC is daily weighted. Average WAC for 2022 uses formula described in Appendix A.

# Manufacturer compliance and enforcement efforts



While many states have passed transparency laws and implemented drug price transparency programs since 2019, Oregon's law remains one of the most ambitious. Much of the information we collect from manufacturers is not mandated by any other state's reporting program, and no other state has the same authority to assess the validity of trade secret claims.

The quality of information submitted by manufacturers continues to be extremely variable, ranging from reluctance to provide required information to detailed descriptions of a company's plans for a drug's lifecycle. The program frequently sends requests for more information or clarification to companies with insufficient filings, which sometimes results in more complete information. Other times, we receive no response or incomplete responses resulting in notices of noncompliance.

The program has the authority to impose civil penalties on manufacturers who fail to file required reports or respond to program correspondence. Our initial compliance efforts focused on outreach and education, rather than formal enforcement proceedings.

This past year, the program's compliance efforts have progressed to issuing noncompliance warning notices to manufacturers that have not provided the required information on their submitted reports. We have identified noncompliant manufacturers with multiple violations among them and issued noncompliance notices. If the manufacturers do not come into compliance following our initial noncompliance notices, we will prepare a file to send to the division's enforcement unit. The program is focused on getting recent filings into compliance.

To monitor that all prescription drugs are reported accurately, the department has contracted for access to Medi-Span, a database of WAC pricing data. We used algorithmic analysis of WAC data in Medi-Span to identify NDCs that may have required a new drug or annual price increase report. We do further analysis to identify which NDCs should be reported and then notify the manufacturer to come into compliance or provide documentation that a report is not required.<sup>46</sup>

Education efforts and noncompliance warnings have increased compliance with most manufacturers, so these will continue to be our main focus. The department is considering adding fees for manufacturers who register late or submit a report after the due date to increase compliance, which would be added to the manufacturer's annual assessment.

<sup>&</sup>lt;sup>46</sup> Some drugs may not be subject to reporting despite showing up in our analysis of Medi-Span data. For example, specific drugs may not be sold in the state of Oregon (manufacturer only sells to a single provider in a different state) or may be listed in Medi-Span in anticipation of a market launch, but have not actually been offered for sale in the United States.

# Trade secret claims from manufacturer reports

When manufacturers report information to the program, they may mark individual data elements (such as cost and profit data and the narrative description of the pricing factors and marketing) as trade secrets. This prevents the Drug Price Transparency (DPT) Program from immediately publishing the data. Before publicly releasing any part of an individual data element claimed to be a trade secret, the program must conduct a lengthy review of the trade secret claim. The trade secret review encompasses these steps:

- An evaluation of manufacturer's provided justification for the trade secret claim
- A review of common industry practice and knowledge
- Research for the availability of the information claimed to be trade secret

If there are claims where the program finds the information is common knowledge or publicly available, or the claim is not substantiated as required, there are additional steps:

- A trade secret determination is issued to the manufacturer if any part of the data will be published and the manufacturer has 15 days to appeal the program's determination.
- If not appealed, the determination becomes final.
- If appealed, there is an evaluation of the appeal and the program issues a final trade secret determination.
- After a 21-day waiting period, the information determined not conditionally exempt from disclosure is published to the program's transparency site.

Many reports include invalid or unexplained trade secret claims. We met with representatives for the manufacturers submitting reports with these types of claims. Some of the representatives who work for third-party entities stated they were instructed by

the manufacturer to provide as little information as possible and claim trade secrets on all data elements where allowed. All trade secret claims require thorough review and a determination before the program can process the report and publish the data. The program is considering options for preventing the misuse of trade secret claims and its burden on the program as well as removing the option to claim certain data elements as trade secret because they are publicly available.

Across the 602 new specialty drug reports we received in the past year, manufacturers claimed 556 individual data elements as trade secrets on 316 reports. The following data elements were often claimed to be trade secrets:

- · Marketing description, including dollars spent
- · Methodology used to establish the price
- Estimated number of patients per month

Across the 203 annual price increase reports received, manufacturers claimed 1,021 individual data elements as trade secrets on 159 reports. The following data elements were often claimed to be trade secrets:

- Narrative description of the factors that contributed to the price increase
- Direct costs of the drugs (manufacturing, marketing, distribution, and ongoing safety and effectiveness research costs)
- Sales revenue of the drug
- · Profit from the drug
- Participant count of a patient assistance program
- Dollar value of the assistance provided by a patient assistance program

The program has received more than 1,900 reports with more than 10,500 data elements claimed as trade secrets since the program began. We will continue to review these claims to determine whether the program can publish the information. Information from manufacturers that has been published is available on the DPT Program website at https://dfr.oregon.gov/drugtransparency/data/Pages/new-drugreports.aspx.

# Health insurance companies

Each year, as part of Oregon's rate review process, health insurance companies report lists of the top 25 most prescribed drugs, the 25 drugs with the highest total health plan spending, and the 25 drugs with the greatest increase in year-over-year-plan spending. These reports are mandatory for health plans in the small group and individual markets. We also receive some voluntary reports for other market segments, such as Medicaid and large-group plans.

For 2023, the program received reports from these companies:

- BridgeSpan Health Company
- Health Net Health Plan of Oregon Inc.
- Kaiser Foundation Health Plan of the Northwest
- · Moda Health Plan Inc.
- PacificSource Health Plans
- · Providence Health Plan
- Regence BlueCross BlueShield of Oregon
- · Samaritan Health Plans Inc.
- UnitedHealthcare Insurance Company/ UnitedHealthcare of Oregon Inc.

The types of plans included in each company's report are listed in Appendix B. Altogether, the data reported covers prescription drug claims for around 750,000 individuals, representing about a quarter of all Oregonians.

Following program reporting guidance, insurance companies combine all claims for all drug products with the same name, including versions with different or modified release dosages. For example, if a drug is sold in 50 mg tablets and 100 mg extended-release tablets, both would be grouped together. Then, they totaled the following:

 The number of prescriptions for those drugs in 2022

- The money spent by them and their policyholders on those drugs in 2022
- The difference between the total amounts spent in 2021 and in 2022 (the year-over-year increase)

From these values, they made lists of the 25 drugs with the highest numbers of prescriptions, the 25 drugs with the most money spent, and the 25 drugs with the largest year-over-year increases. They made separate lists for generic drugs, brand name drugs, and specialty drugs, and submitted all the top-25 lists to Oregon's DPT Program.

After receiving the lists from the health insurance companies, the DPT Program worked on combining the data to get a picture of prescriptions and spending across Oregon. The program took the lists submitted by all nine companies and totaled the number of prescriptions, the amount of money spent, and the year-over-year spending differences for every drug. Our final lists show the top-10 drugs in each category, aggregated from the data for all nine insurers.

The DPT Program curated the insurer information within the limits of its knowledge and database resources to combine drug entries and related information. It relied heavily on the Medi-Span drug database to assess the quality of the reported data and to improve it, if possible. The combined prescription counts and dollar amounts in the lists should be considered approximations because they represent only the data slices reported to the DPT Program by the health insurance companies in their lists.

### Plan spending on prescription drugs

Collecting information on drug spending compared to total premiums allows the DPT Program to measure the percentage of plan spending directed to prescription drugs versus all other costs – including all other medical claims, plan

administration, profit, and financial reserves.
The data presented in these charts represents prescription drug spending in the small employer, large employer, and individual market segments. It does not include data for the Public Employees' Benefit Board (PEBB), Oregon Educators Benefit Board (OEBB), Medicare, or Medicaid, because most insurers did not submit data for these markets.

Figure 21 shows plan spending on prescription drugs as a percentage of total premiums collected. The blue bar on the bottom represents plan spending on pharmaceuticals, while the orange bar on the top represents all other spending, including funds directed to profits or reserves. The

bars have been ordered from highest to lowest pharmaceutical spending.

BridgeSpan had the highest share of spending with 58.8 percent of its total collected premium spent on pharmaceuticals. Moda had the secondhighest share of spending, with 26.8 percent of its total collected premium spent on pharmaceuticals. As with last year, BridgeSpan's pharmaceutical spending percentage is twice the spending of the second-highest company (last year it was UnitedHealthcare). Discussion about this topic in the next few charts will explain why BridgeSpan is an outlier.

Figure 21: Plan spending on prescription drugs as a percentage of premiums collected

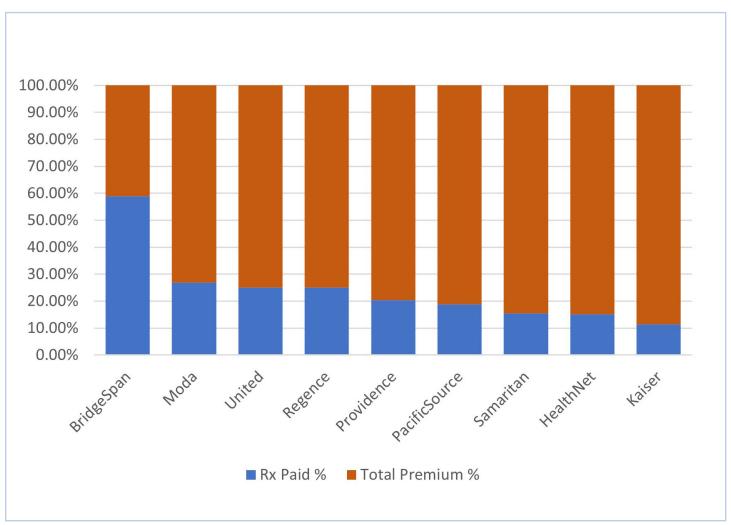
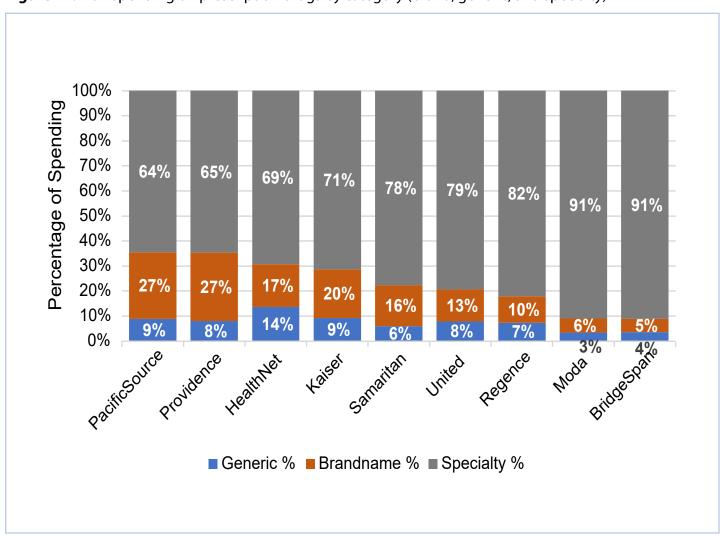


Figure 22 shows spending on each drug category as a percentage of total spending on prescription drugs. In the insurer data collection, the DPT Program asked insurance companies to report data divided into three drug categories: (1) generic drugs, excluding specialty; (2) brand name drugs, excluding specialty; and (3) specialty drugs. For the program's purposes, specialty drugs are defined as those having a list price of \$670 or more for a course of treatment lasting 30 days or less. In the chart below, the gray bars represent specialty drug spending, the orange bars represent spending on branded drugs,

and the blue bars represent spending on generic drugs. The companies are ordered from lowest to highest spending on specialty medications as a percent of prescription drug benefits paid.

Across the board, all plans spent the most on specialty drugs and the least on generic drugs; however, this is opposite to the actual volume of prescriptions. Generic drugs constitute the vast majority of prescriptions written, while specialty drugs represent a fraction of prescriptions, despite driving the majority of spending.

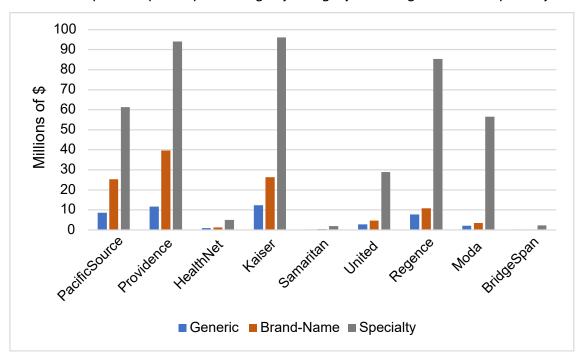
Figure 22: Plan spending on prescription drugs by category (brand, generic, and specialty)



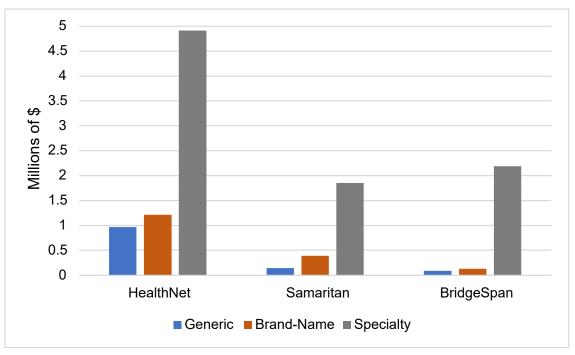
Again, BridgeSpan stands out with 91 percent of prescription spending in the specialty category (Moda also had 91 percent of spending in this category). This is due to a small population prescribed a specialty medication that was the driver of BridgeSpan's high overall pharmaceutical spending, a fact highlighted more clearly in Figure

23 below. On the other end of the spectrum, PacificSource reported the overall least spending on specialty drugs (64 percent) versus overall most spending on brand name and generic drugs (27 percent and 9 percent, respectively). Figure 24 shows the three smaller companies for better visibility.

Figure 23: Amounts spent on prescription drugs by category (brand, generic, and specialty) for all insurers



**Figure 24:** Amounts spent on prescription drugs by category (brand, generic, and specialty) for the three smallest insurers



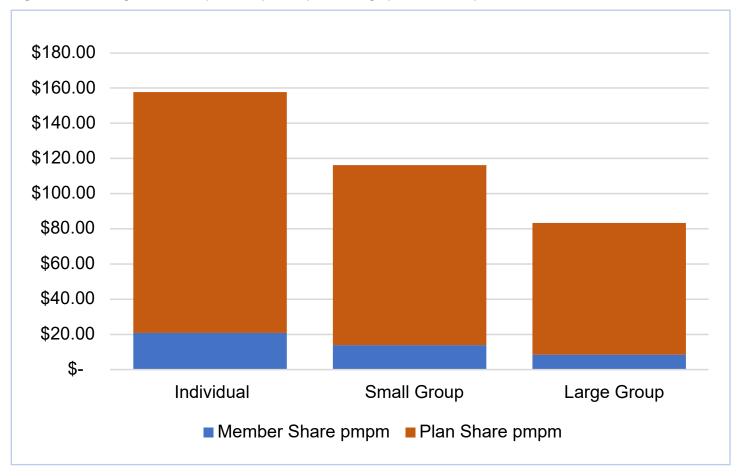
As the DPT Program continues to refine the data it collects from insurers, it will be able to give more meaningful analysis in coming years.

That said, there is at least one significant conclusion the program can draw from this data: High-cost specialty drugs present a significant financial risk for insurance companies with small enrollment. The three companies with the least spending were Samaritan, BridgeSpan, and HealthNet. Their combined spending on pharmaceuticals was \$11.9 million, which is not even 10 percent of the total spending by Providence, which had the most total pharmaceutical spending at \$145.3 million. The difference in spending between those three plans is driven by a very small number of patients and could easily have been reversed if specific consumers chose to enroll in different plans.

### **Consumer cost sharing**

The data the program has collected on consumer cost sharing allows it to present an analysis regarding insured consumer's cost burden for prescription drugs. Figures 25 and 26 below show dollars spent on a per-member, per-month basis for individual, small group, and large group insurance plans across all nine insurers studied. This data shows the average monthly cost sharing for prescriptions paid by consumers (member share) and the average monthly amount covered by insurance (plan share). The program can compare the consumer burden per plan type in dollars and relative percentages as it did with its analysis of pharmaceutical spending by prescription type.

Figure 25: Average amount spent on prescription drugs per member per month



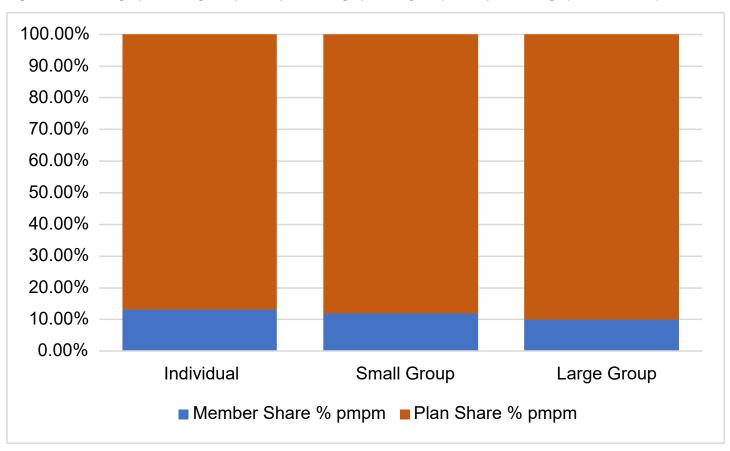
Overall, individual market plans spent the most per member, averaging \$157.72 in total spending per member, per month. Of that \$157.72, \$20.79 was shouldered by the plan member and \$136.93 was covered by the plan. Small-group plans spent the second most per member, per month at an average of \$116.20. Of that, \$13.86 was shouldered by the plan member and \$102.34 was covered by the plan. Finally, large-group market plans spent the least per member, per month, at \$83.47. Of this, \$8.38 was shouldered by the plan member and \$75.10 was covered by the plan.

Several factors may be contributing to this difference. In general, employer-sponsored plans in the small- and large-group markets tend to have a larger number of young, healthy enrollees. As a result, claims costs for prescription drugs are likely

to be lower in the group markets due to lower incidence of chronic conditions.<sup>47</sup> Individual plans may also have less market power, and thus have less ability to negotiate lower prices or higher rebates from manufacturers and wholesalers.

After comparing the member burdens between individual, small group, and large group market plans on an absolute basis showing the costs in Figure 25, the program compares those values on a relative basis in Figure 26. Of the total spent on average for individual plans, 13.2 percent was shouldered by the member. Of the total spent on average for small-group plans, 11.9 percent was shouldered by the member. Of the total spent on average for large-group plans, 10 percent was shouldered by the member.

Figure 26: Average percentage of prescription drug spending on prescription drugs per member, per month



<sup>&</sup>lt;sup>47</sup> Boersma, Peter et al. "Prevalence of Multiple Chronic Conditions Among US Adults, 2018." Centers for Disease Control and Prevention, Preventing Chronic Disease, vol. 17, Sept. 17, 2020. https://www.cdc.gov/pcd/issues/2020/20\_0130. htm. Accessed Oct. 30, 2023.

#### Rebates

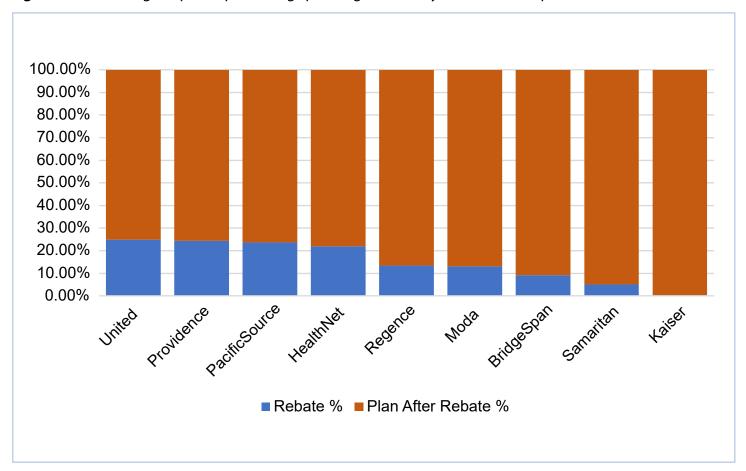
The price of a drug is influenced by many factors, but manufacturer rebates are one of the most significant. Rebates are paid to insurers and negotiated by intermediary companies known as pharmacy benefit managers (PBMs). Typically, a manufacturer will pay a rebate for a portfolio of drugs, rather than on a drug-by-drug basis. Insurance companies use these rebates to lower premiums. Due to the medical loss ratio standards of the Affordable Care Act, insurers are barred from taking profits beyond a specified threshold.

Specific rebate amounts are kept a closely guarded secret by PBMs. In many cases, PBMs do not share this information with their client insurance companies.

As a program, we have always collected pricing information from insurers "net of rebates" to the maximum extent possible. We have also collected data on the total amount of rebates collected by each insurer as compared to dollars spent on pharmaceuticals.

In Figure 27, the blue bars represent the percentage of costs that were covered by rebates, while the orange bars represent the remaining cost paid by the insurance companies. Manufacturer rebates and other price concessions were reported by insurance companies as well as the total dollars paid by carrier after rebates. Amounts from individual, large-group, and small-group spending were added together. The bars are ordered from highest to lowest amount of rebates.

Figure 27: Percentage of prescription drug spending covered by rebates versus plan cost

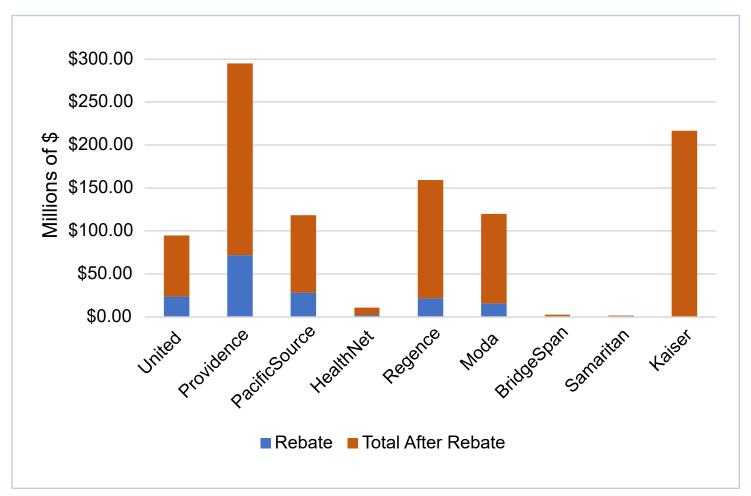


This year, UnitedHealthcare reported the highest percentage of rebate compared to total spent at 24.8 percent. UnitedHealthcare Insurance Company is an affiliate of Optum Rx, a PBM and pharmacy. Providence and PacificSource came in second and third with 24.3 percent and 23.7 percent, respectively. Kaiser reported the lowest amount of rebates with 0.3 percent. Kaiser had the lowest rebate percentage last year as well. It should be noted, however, that Kaiser also reported the lowest overall spending on prescription drugs – so low rebate values do not necessarily connect to higher pharmaceutical spending. BridgeSpan also reported relatively low rebate amounts, at 9.2 percent of total prescription drug spending. Again, the program does not have sufficient data to suggest whether

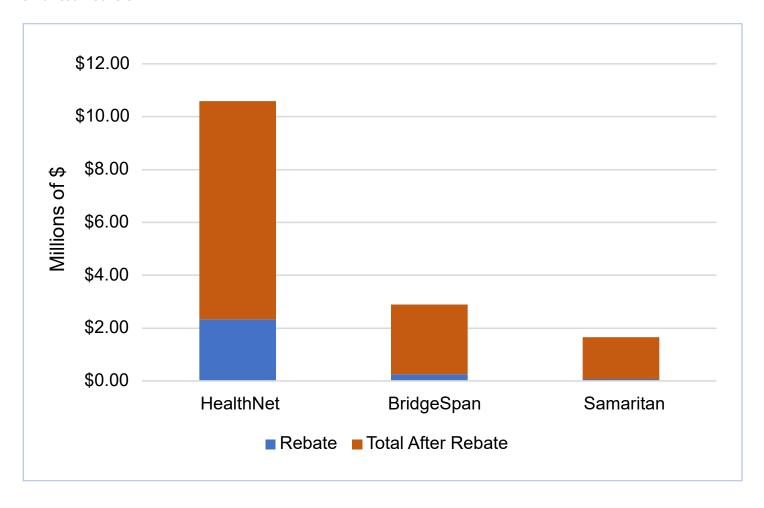
this is correlated with BridgeSpan's high spending on specialty drugs, or whether rebates are available for those drugs.

Referencing Figure 28, the highest amount of rebate was from Providence with \$71.72 million. The second-highest amount reported was from PacificSource at \$28.06 million, and the third highest amount reported was \$23.55 million. Figure 29 shows the amounts for the three smallest for better visibility. Samaritan had the lowest rebate amount reported at \$84,547. Manufacturer rebates and other price concessions were reported by insurance companies, as well as the total dollars paid by carrier after rebates. Amounts from individual, large-group, and small-group spending were added together.

Figure 28: Amounts of prescription drug spending covered by rebates versus plan cost for all insurers



**Figure 29:** Amounts of prescription drug spending covered by rebates versus plan cost for the three smallest insurers



# **Most prescribed drugs**

The most frequently prescribed class of drugs reported for 2022 was vaccines, with 346,168 prescriptions (124,948 being for the mRNA COVID-19 vaccines produced by Moderna and Pfizer-BioNTech, and 221,220 being for formulations of the flu vaccine). For benefit year 2019, there were 342,608 reported flu vaccine prescriptions. For benefit year 2020, there were 383,665 reported flu vaccine prescriptions. Finally, for benefit year 2021, there were 231,714 reported flu vaccine prescriptions. This indicates a slight decrease of flu vaccine prescriptions this year compared to last.

The next most prescribed classes of drugs

reported for 2022 were antidepressants (with 246,044 total prescriptions between two types of antidepressants, a decrease of 15,823 prescriptions from last year). Following that, the thyroid agent Levothyroxine Sodium, aka Euthyrox, Levoxyl, Synthroid, and Tirosint, was the thirdmost commonly prescribed (with 169,336 total prescriptions).

The drugs on this year's most-prescribed table that were also on last year's are: the COVID-19 vaccines, the influenza vaccines, Atorvastatin Calcium, Levothyroxine Sodium, Lisinopril, Amphetamine-Dextroamphetamine, Metformin HCl, and Bupropion HCl.

**Figure 30:** Top 10 most prescribed drugs

Drug	Class	Prescriptions
Influenza virus vaccine Includes brand names: Afluria, Fluarix, Flulaval, and Fluzone	Vaccines	221,220
Levothyroxine Sodium Includes brand names: Euthyrox, Levoxyl, Synthroid, and Tirosint	Thyroid agents	169,336
Atorvastatin Calcium Includes brand names: Atorvaliq and Lipitor	Antihyperlipidemics	166,505
Lisinopril Includes brand names: Prinivil, Qbrelis, and Zestril	Antihypertensives	161,174
Amphetamine- Dextroamphetamine Includes brand names: Adderall and Mydaysis	ADHD/anti-narcolepsy/ anti-obesity/anorexiants	156,001
Albuterol Sulfate Includes brand names: ProAir, Proventil, and Ventolin	Anti-asthmatic/bronchodilator agents	141,372
Metformin HCl	Antidiabetics	137,692
Bupropion HCl	Antidepressants	126,612
COVID-19 (SARS-CoV-2) mRNA virus vaccine Moderna and Pfizer-BioNTech	Vaccines	124,948
Sertraline HCI Includes brand name: Zoloft	Antidepressants	119,432

### Most costly drugs

Insurer reporting of the costliest drugs reflects the drugs with the highest total payments made on behalf of covered members, including payments made by insurance companies and member cost sharing, such as copays and coinsurance. As has been the case for the prior three years, more money was reported spent on anti-inflammatory analgesics than on any other drug class. Most drugs in this class are monoclonal antibodies and are used in the treatment of a variety of inflammatory autoimmune conditions, including arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, and plaque psoriasis.

Most of the spending was for Humira, which has been responsible for more plan spending than any other drugs for five years running. In 2022, companies reported \$75.24 million in spending on Humira, a decrease of about \$1.73 million as compared to reported spending in 2021 (\$76.97 million). The program does not have sufficient information to analyze the reason for this decrease, which could be a result of changing market conditions or changes in the underlying population represented by this data set. The lack of drugs biosimilar to Humira has allowed it to be priced so high, but around July 2023, a cohort of adalimumab biosimilars entered the market. This is not reflected in this year's report, but may be in the 2024 report.48



Another notable drug responsible for high levels of plan spending was Stelara, a dermatological with \$28,957,943 reported in spending. Another is Keytruda, an antineoplastic and adjunctive therapy with \$28,248,898 reported in spending.

Drugs on this year's most costly table that were also on last year's are: Adalimumab (Humira), Ustekinumab (Stelara), Pembrolizumab (Keytruda), Bictegravir-Emtricitabine-Tenofovir (Biktarvy), Etanercept (Enbrel), Elexacaftor-Tezacaftor-Ivacaftor (Trikafta), Secukinumab (Cosentyx), and Vedolizumab (Entyvio).

<sup>&</sup>lt;sup>48</sup>"Amgen's Amjevita Remains the Frontrunner in the US Adalimumab Biosimilars Market, Despite Increased Competition." Spherix Global Insights, Sept. 14, 2023. https://www.globenewswire.com/news-release/2023/09/14/2743506/0/en/Amgen-s-Amjevita-Remains-the-Frontrunner-in-the-US-Adalimumab-Biosimilars-Market-Despite-Increased-Competition-According-to-Spherix-Global-Insights.html. Accessed Oct. 30, 2023.

Figure 31: Top 10 most costly drugs

Drug	Class	Total annual plan spending
Adalimumab Brand name: Humira	Analgesics/anti-inflammatory	\$75,241,110
Ustekinumab Brand name: Stelara	Dermatologicals	\$28,957,943
Pembrolizumab Brand name: Keytruda	Antineoplastics and adjunctive therapies	\$28,248,898
Bictegravir-Emtricitabine- Tenofovir Alafenamide Fumarate Brand name: Biktarvy	Antivirals	\$26,988,465
Etanercept Brand name: Enbrel	Analgesics/anti-inflammatory	\$22,017,823
Elexacaftor-Tezacaftor-Ivacaftor Brand name: Trikafta	Respiratory agents	\$21,559,651
Secukinumab Brand name: Cosentyx	Dermatologicals	\$18,723,855
Vedolizumab Brand name: Entyvio	Gastrointestinal agent	\$17,655,131
Infliximab-dyyb Brand name: Inflectra	Gastrointestinal agent	\$16,516,923
Risankizumab-rzaa Brand name: Skyrizi	Dermatologicals	\$15,517,811

# Drugs with the greatest increases in health plan spending

This list shows the 10 drugs with the largest year-over-year increase in plan spending, as well as the amount of that increase.

The drugs on this year's greatest increase in plan spending table that were also on last year's are: Pembrolizumab (Keytruda), Risankizumab-rzaa (Skyrizi), Elexacaftor-Tezacaftor-Ivacaftor (Trikafta), Semaglutide (Rybelsus/Ozempic), and Ustekinumab (Stelara).

Figure 32: Top 10 drugs with the greatest increases in plan spending

Drug	Class	Year-over-year increase
Pembrolizumab Brand name: Keytruda	Antineoplastics and adjunctive therapies	\$11,840,653
Risankizumab-rzaa Brand name: Skyrizi	Dermatologicals	\$8,385,287
Infliximab-dyyb Brand name: Inflectra	Gastrointestinal agents	\$5,489,239
Elexacaftor-Tezacaftor-Ivacaftor Brand name: Trikafta	Respiratory agents	\$4,417,699
Immune Globulin (Human) IV Brand name: Gammagard	Passive immunizing and treatment agents	\$4,312,556
Adalimumab Brand name: Humira	Analgesics/anti-inflammatory	\$3,682,844
Dupilumab Brand name: Dupixent	Dermatologicals	\$3,333,668
Semaglutide Brand name: Rybelsus/Ozempic	Antidiabetics	\$3,238,534
Ustekinumab Brand name: Stelara	Dermatologicals	\$3,077,394
Brentuximab Vedotin Brand name: Adcetris	Antineoplastics and adjunctive therapies	\$3,020,976

# **Policy recommendations**

Prescription drug costs continue to be an issue for Oregonians. With the information reported, the program is learning several things about prescription drugs, such as the factors contributing to high costs, the drugs that are the costliest for health insurers, and what drugs are of most concern to Oregonians. The data received over the previous years of the program help identify areas for program improvements, and better understanding of drug pricing.

This report is required by the Prescription Drug Price Transparency Act, which also requires proposed recommendations for legislative changes to contain the cost of prescription drugs and reduce the effects of price increases. Some of this year's recommendations propose improvements to the program that would provide more quality data to better inform policy decisions.

### **Manufacturer reporting**

# <u>Recommendation 1: Expanded reporting</u> requirements for patient assistance programs

The program currently receives information on patient assistance programs as part of our annual price increase reports, so we only received information on 18 patient assistance programs from eight manufacturers in 2023. While this limited information showed more than \$2.5 million in benefits for 2,302 Oregonians, it is only a small fraction of the estimated more than 200 patient assistance programs available and is not enough for meaningful analysis. Patient assistance programs include manufacturer "coupons" and other payments that reduce a patient's out-of-pocket cost to fill a prescription.

Patient assistance has been a source of controversy in recent legislative sessions. Drug manufacturers argue that patient assistance helps patients whose insurance does not fully cover the cost of a needed medication. Insurance companies argue

that patient assistance undermines their efforts to control health care costs by incentivizing patients to use expensive brand name drugs even when a generic alternative is available. Patient advocates have also argued for a ban on "copay accumulators" (insurance plan designs that do not credit third-party payments, such as patient assistance, against an individual's deductible or out-of-pocket maximum).

However, as currently structured, the program's patient assistance program reporting is poorly matched to the market landscape. New drug reports do not require any patient assistance program reporting, and most price increase reports are for generic drugs, which would be extremely unlikely to maintain a patient assistance program.

As recommended in previous reports, the program recommends the Legislature consider removing the patient assistance program reporting requirement from the program's price increase reports, and instead require all manufacturers to report annually on all patient assistance programs they maintain or fund. This will both remove the reporting requirement in the program's price increase reports while also allowing the program to develop comprehensive data on the use of patient assistance. This deeper and more informed analysis will help the program and the Legislature to better understand the roles of patient assistance and copay accumulators in developing future policy.

# Health insurer and pharmacy benefit manager (PBM) reporting

Recommendation 2: Require insurers and PBMs to report on their use of "copay accumulator" programs

Much of the recent discourse around manufacturer funded patient assistance has been driven by the increased use of "copay accumulator" programs in Oregon. This term refers to a practice in which an insurer will not count third-party payments, such as manufacturer coupons, against a consumer's annual cost-sharing limits. In other words, a patient who uses patient assistance to access a high-cost medication would still need to meet their deductible using personal funds after they would have otherwise met their deductible using patient assistance.

Insurers argue that copay accumulators are an effective strategy to lower overall prescription drug spending and reduce premiums for their members, in part because manufacturer assistance may drive patients to continue using high-cost medications even when equally effective generic or biosimilar alternatives are available. Copay accumulators are a way insurers try to counteract this incentive to lower overall costs and reduce premiums for the wider population of consumers. Patient advocates argue that this imposes steep financial burdens on patients - especially for patients who must meet their deductible before coverage kicks in – and may result in some patients going without needed medications. To provide an adequate analysis of the issue and its effect on drug pricing, additional transparency in this area is needed.

Accordingly, as a corollary to expanded reporting on patient assistance programs, the program recommends the Legislature require insurers and PBMs report data regarding their "copay accumulator" programs in Oregon. Data elements could include (1) which plans are subject to copay accumulator programs; (2) what drugs are subject to copay accumulators; (3) how much additional revenue is generated by copay accumulators; and (4) how revenue generated by copay accumulators is allocated by insurers and PBMs.

#### **Global recommendations**

# Recommendation 3: Transparency across the pharmaceutical supply chain

The price of a prescription drug is influenced by

numerous factors. This includes the interactions and financial negotiations between pharmaceutical supply chain entities. Oregon has enacted several policies that address prescription drug price transparency across parts of the supply chain; however, there are still gaps in transparency.

The program recommends the Legislature consider additional transparency measures across the pharmaceutical supply chain. These would include entities with no reporting or regulatory oversight, such as wholesalers and pharmacy services administrative organizations (PSAOs), to fully understand what influences and contributes to the price of the drug. New transparency measures would also include aspects of the pharmaceutical supply chain that may affect the cost to consumers such as coupons, discounts, fees, incentive programs, assistance programs, list price, markups, and rebates. Understanding how these entities and cost factors influence the supply chain and ultimately the costs consumers face is necessary to developing policy recommendations to address these issues.

# Recommendation 4: Consider an expansion of bulk purchasing and implementing state manufacturing of prescription drugs to ensure leverage of the state's purchasing power

In 2020, the California Legislature authorized the creation of a state-operated generic drug manufacturer, CalRx. This new entity will contract with other generic manufacturers and act as a relabeler, with the long-term goal of establishing its own manufacturing capacity. CalRx would supply generic medications to the citizens of the state where the open market has failed to produce an adequate supply of fairly priced pharmaceuticals.

CalRx mirrors the structure of several other recent generic manufacturing initiatives. These include Civica Rx, a nonprofit generic manufacturer established by a coalition of philanthropies and health systems, and Cost Plus Drug Company, a generic manufacturer offering low-cost "cash only" pharmaceuticals directly to consumers. While all of these entities are commonly described as drug manufacturers, most of their activity is more in line with bulk purchasing and relabeling of drugs.

The first project for CalRx is to contract with Civica Rx to manufacture the three most commonly used long-acting and rapid-acting types of insulin (biosimilar insulin) at a lower cost to Californians. Test runs of the manufacturing is expected to begin soon and Civica Rx is expected to file for FDA approval in 2024.

The Oregon Prescription Drug Program (OPDP) is a statutorily defined program operated by the Oregon Health Authority (OHA). In cooperation with other states and through an interstate agreement, OPDP participates in a regional drug purchasing consortium, recently rebranded as ArrayRx. OPDP does not have authority to establish its own multistate purchasing entity. As in last year's report, the program continues to recommend the Legislature grant this authority and direct OPDP to further expand the program's ability to leverage purchasing power for prescription drugs purchased by public and commercial entities. Doing so would help open opportunities for the adoption of a state contracted manufacturing or direct bulkpurchasing model.

In making this recommendation, bulk purchasing must be understood as two separate functions. There is a purchaser – a wholesaler who must do the actual purchasing and acquisition to take possession of the drugs. The second is a payment and claims administration service for payers and is commonly provided by PBMs.

Additionally, the program recommends the Legislature explore a directive to the state Medicaid program to purchase drugs through OPDP for both the fee-for-service and coordinated care organization (CCO) delivery systems to truly leverage bulk purchasing of prescription drugs and PBM services. This model would also realize other

financial efficiencies including state supplemental rebates for a uniform preferred drug list (PDL) and eliminate the need for the state's 16 CCOs to separately manage drug benefits.

Finally, the program recommends the establishment of a centralized office of pharmacy purchasing to provide coordination and oversight of all state purchasing to ensure Oregon is leveraging all of the state's position in the marketplace.

### Price increase notice reporting

Recommendation 5: Update reporting thresholds to align 60-day notice and annual increase reporting

Reporting thresholds for the drug price transparency program vary depending on the type of report. To simplify how to calculate when a report is required, the program recommends changing the comparison date to two years prior for 60-day price increase notices and annual increase reports.

Instead of a daily weighted average price comparison for the annual increase report, a report would be required if the price on Dec. 31 of the year that just ended is more than 10 percent higher than the price on Dec. 31 two years earlier.

Instead of a 365-day review period for the 60-day price increase notice, a report would be required if the price on the date of the planned increase for a brand name drug will be more than 10 percent (or 25 percent for a generic drug) higher than the price two years earlier, similar to California's review period. The program also recommends removing the requirement that the generic drug price also be \$300 or more for a 60-day notice. These updates would make it easier to explain and calculate when a report is required.

# Drug policies in other states



The following section does not represent official recommendations from the department, but rather an overview of what drug policies in other states have pursued to reduce the cost of prescription drugs on consumers, businesses, and the state. These items provide additional considerations for the Legislature in continuing to build and shape the program.

State legislatures across the country have continued to work on policies aiming to control the cost of prescription drugs in their state. The topics addressed by state legislation over the past few years include:<sup>49</sup>

 Drug affordability review: Establishing a regulatory body or process to review the affordability of specific prescription drugs and, in some cases, authority to limit prices. The following states have prescription drug affordability boards or other review processes – Colorado, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New York, Oregon, and Washington.

- Drug importation and bulk purchasing: States examining or establishing a drug importation program from Canada are Colorado, Florida, Maine, New Hampshire, New Mexico, Texas, and Vermont. HHS has regulations for implementation of these programs. Some states are looking into or setting up bulk purchasing for their state or in combination with other states
- Delaware, Nevada, and New Mexico.
- Price transparency: There are 21 states that require reporting on drug price information from specified pharmaceutical supply chain entities, such as pharmaceutical manufacturers, wholesale distributors, and PBMs.
- Coupons and cost sharing: There are 28 states regulating or prohibiting the use of discounts or coupons or limiting cost sharing on insulin drugs.
- Pharmacy benefit managers: All 50 states are regulating or providing additional transparency on the actions of PBMs, such as preventing discrimination against certain protected entities, or preventing PBMs from being able to hold a pharmacy or pharmacist responsible for any fees related to certain processes.

<sup>&</sup>lt;sup>49</sup> Torrey, Zoe. "State Drug Pricing Laws: 2017-2023." National Academy for State Health Policy, Oct. 13, 2023. https://www.nashp.org/rx-laws/. Accessed Oct. 30, 2023.

### **Conclusion**

Oregon's Prescription Drug Price Transparency Program has been collecting and analyzing information received from drug manufacturers, health insurers, and consumers for five years. The program is working to deepen the state's understanding of the factors that influence prescription prices and how drug prices affect Oregonians.

Based on the information collected, the program has made the following key findings in this report:

- Most health insurers reported receiving between 10 percent and 25 percent of total pharmaceutical spending in rebates. UnitedHealthcare reported the highest rebates received as a percentage of prescription spending at 24.8 percent. Samaritan and Kaiser reported the lowest rebates received, at 5.1 and 0.3 percent, respectively. The program does not have sufficient data to suggest whether there are any correlations between rebates and spending within the prescription drug data.
- Humira, manufactured by AbbVie Inc., continues to be the most costly drug contributing to more plan spending than any other drug for five years running. In 2022, health insurance companies in Oregon reported \$75.24 million in spending on Humira.
- Antineoplastics and adjunctive therapies, which are used to treat cancer, were the most frequent category of new specialty drugs reported to the program. The highest wholesale acquisition cost (WAC) for a brand name drug was \$3.5 million for Hemgenix, a treatment for hemophilia B.
- The largest price increases were for generic drugs.
   The median price increase reported for generic drugs was 20 percent, and the median price increase reported for brand name drugs was 14.9 percent. The largest price increase reported to the program in 2022 was a 25 percent increase from \$575 to \$718.75 for Aquasol A, a generic vitamin A solution manufactured by Casper Pharma.

- The program received drug reports from several manufacturers for the generic drug fingolimod (30 capsules, 0.5 mg). The new drug reports showed WAC prices ranging from \$1,000 to \$8,883.89. In looking at the current prices of these drugs from 10 different manufacturers, they have been reduced by most manufacturers and now have WAC prices ranging from \$220.21 to \$2,220.97. The WAC price for generic fingolimod was reduced by 84 percent to 97 percent from its starting price by most manufacturers, while a few are at the same price. Because price decreases are not reported to the program, this may be evidence of how competition in the generics market can bring down the price of a drug.
- The quality of information submitted by manufacturers was extremely variable, ranging from refusals to provide any information to generalized descriptions to detailed information of a company's reasons for increasing the price of a drug. This continues to be an issue when attempting to determine the reasons why a drug is priced high when it comes to market or when price increases are reported to the program. For context, the program has received more than 1,900 reports with more than 10,500 data elements claimed as trade secrets since 2019. Of that total, 475 reports with 1,577 data elements claimed as trade secret have been received since last year's report.
- The program's compliance efforts have progressed to issuing noncompliance warning notices to manufacturers to address manufacturer behavior and the volume, variances, and complexities mentioned above. If the manufacturers do not come into compliance following our initial noncompliance notices, the program will prepare a file to send to the division's enforcement unit.

Information collected from this year and previous years continues to be valuable to further understanding and contribute to ongoing efforts to address the effects of costly prescription drugs on Oregonians.

#### Resources

For more information about the Drug Price Transparency Program, visit https://dfr.oregon.gov/ drugtransparency.

For information about the Prescription Drug Affordability Board, visit: https://dfr.oregon.gov/pdab/.

#### Health insurance issues and access

If you have issues with your insurance company about prescription drug coverage, contact the Division of Financial Regulation Consumer Advocacy Team at 888-877-4894 (toll-free) or email DFR.InsuranceHelp@dcbs.oregon.gov.

Oregonians can enroll for free into the ArrayRx Discount Card Program https://www.oregon.gov/oha/HPA/dsi-opdp/Pages/index.aspx and save on prescription drug costs when they are uninsured, underinsured, or their medication is not covered by their insurance. For more information, call 800-913-4146 (toll-free).

If you are uninsured, contact the Oregon Health Insurance Marketplace or the Oregon Health Authority for more information on the health insurance plans that may be available to you.

## For information on a specific drug

- U.S. Food and Drug Administration https:// www.accessdata.fda.gov/scripts/cder/daf/index. cfm
- U.S. National Library of Medicine https:// pubchem.ncbi.nlm.nih.gov/

# For general information on prescription drugs

 U.S. Food and Drug Administration – https:// www.fda.gov/drugs/drug-informationconsumers/find-information-about-drug



# Appendix A – Average annual price increase formula

A net increase percentage compares the average price of a drug from one year to the average price the next year.

Suppose the list price of a brand name prescription drug was \$500 for the first 100 days of 2020, then rose in price to \$600 on the 101st day and remained at that price for the remaining 266 days of the year. The drug's average list price in 2020 is the average of these list prices, \$500 and \$600, considering how much time the drug spent at each price.

So, this drug's average list price in 2020 is

$$\frac{100 \times \$500 + 266 \times \$600}{366} = \$572.68$$

Suppose the drug had another price increase on Jan. 25, 2021, from \$600 to \$640, and then remained at that list price for the remaining 341 days of the year. The drug's average list price in 2021 is

$$\frac{24 \times \$600 + 341 \times \$640}{365} = \$637.37$$

Note: 2021 was a leap year with 366 days. We counted every one of those days and we divided by all 366 here instead of 365. Since 2021 was not a leap year, we divided by 365 when computing the drug's average list price in 2021.

To find the 2021 net increase percentage, we compare the average price in 2020 to the average price in 2021.

The drug's average list price in 2021, \$637.37, is 11.3 percent higher than its average list price in 2020 – \$572.60:

So, the 2021 net increase percentage for this drug is 11.3 percent, and the reporting manufacturer is required to file an annual price increase report for this prescription drug.

In general, the formula for computing a 2021 net increase percentage is

\$(average 2021 list price) – \$(average 2020 list price)

\$(average 2020 list price)

# Appendix B – Types of plans for insurer reports received in 2023

The program received reports from these companies that included the types of plans listed for each:

- BridgeSpan Health Company
  - Individual
- Health Net Health Plan of Oregon, Inc.
  - Large group
  - Small group
- Kaiser Foundation Health Plan of the Northwest
  - Individual
  - Large group
  - Small group
- Moda Health Plan, Inc.
  - Individual
  - Large group
  - Small group
- PacificSource Health Plans
  - Individual
  - Large group
  - Small group
- Providence Health Plan
  - Individual
  - Large group
  - Small group

- Regence BlueCross BlueShield of Oregon
  - Individual
  - Small group
- Samaritan Health Plans, Inc.
  - Large group
  - Small group
- UnitedHealthcare Insurance Company / UnitedHealthcare of Oregon, Inc.
  - Large group
  - Small group