



Prescription Drug Price Transparency
Results and Recommendations – 2022
(As required by House Bill 4005 (2018))



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 the Department of Consumer and Business Services. Visit dfr.oregon.gov.

About the Drug Price Transparency Program:

Oregon's Drug Price Transparency Program 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 <https://dfr.oregon.gov/drugtransparency>. We encourage consumers to report price increases to us online at <https://dfr.oregon.gov/rxdrugprices> or contact the program at rx.prices@dcbs.oregon.gov or leave a message at 503-947-7200 (or toll-free at 833-210-4560).

Additional report information:

This report is based on all data submitted to the program through Aug. 31, 2022, 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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Introduction



This 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 impact of price increases. This report provides information about prescription drug impacts 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
- 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

Prescription drugs are vital to both longevity and quality of life for many Oregonians. 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 because they do at the cost of other needs and there is a reduction in quality of life which can, and often does, affect overall health. Affordability and access remain of high concern to consumers and lawmakers alike. Oregon's Prescription Drug Price Transparency Act in 2018 (House Bill 4005) created the Drug Price Transparency Program to provide accountability by disclosing specific pricing information from pharmaceutical manufacturers, health insurers, and consumers.¹ The Drug Price Transparency Program gathers information each year about new drugs and high-cost drugs that are reported to the program.

A 2021 poll by the Kaiser Family Foundation found that 60 percent of adults in the U.S. take at least one prescription drug and 25 percent take at least four per day. Of those prescribed medications, 29 percent of Americans reported not taking their medications as prescribed due to cost. They do this by not filling their medication, using an over-the-counter medication instead, or cutting the pills in half.²

Program overview

The program continues to engage manufacturers and collect information to inform the public hearing and legislative reports. In December 2022, the program will hold its fourth 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. Program staff help pharmaceutical manufacturers with questions, registration, billing, and filing required reports. Efforts to increase manufacturer reporting compliance and review trade secret claims have increased due to process improvements and additional program staff. The program also is working to increase outreach to consumers in 2023.

Results

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



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

² Hamel, Liz et al. "Public Opinion on Prescription Drugs and Their Prices." Kaiser Family Foundation Polling, Oct. 20, 2022. <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>. Accessed Sept. 19, 2022.



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

- The majority of insurers spend about 20 percent to 30 percent of all plan spending on prescription drugs, with Kaiser and Health Net reporting the lowest percent spending on prescription drugs at 13 percent and 17 percent, respectively. BridgeSpan was the exception with a higher percentage spent on prescription drugs above national data.
- Most health insurers reported receiving between 10 percent and 20 percent of total pharmaceutical spending in rebates. Health Net reported the highest rebates received as a percentage of prescription spending at 21 percent. Moda and Kaiser reported the lowest rebates received, both about 5 percent. The program does not have sufficient data to suggest whether there are any correlations between rebates and spending within the prescription drug data.
- Humira continues to be the most costly drug contributing to more plan spending than any other drug for four years running. In 2021, health insurance companies in Oregon reported \$76,966,470 in spending on Humira.
- Antineoplastics and adjunctive therapies, which are used to treat cancer, were the most frequent category of new high-cost drugs reported to the program. The highest wholesale acquisition cost

(WAC) for a brand name drug was for Janssen Biotech's Carvykti, a treatment for multiple myeloma cancer. It had a reported WAC of \$465,000.

- The six largest price increases were for generic drugs. The median price increase reported for generic drugs was 19.9 percent, and the median price increase reported for brand name drugs was 13.4 percent. The largest price increase reported to the program in 2022 was a 2,527 percent increase for a generic of naproxen manufactured by Hikma Pharmaceuticals. The last historical WAC price for this drug was \$34.13 in 2012, and its new WAC, as of Feb. 2, 2021, is \$896.44.
- 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 1,500 reports with more than 9,000 data elements claimed as trade secrets.
- 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 impact 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 impact 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. 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 carriers 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 "co-pay 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.

Accordingly, 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 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 co-pay accumulators in developing future policy.

Health insurer reporting

Recommendation 2: Expand reporting to more insurers

Under the Prescription Drug Price Transparency Act, health insurance companies are required to submit specified information about prescription drug spending and use, including the top 25 most costly drugs and the top 25 most prescribed drugs, as part of the annual rate filing process. Because companies are required to submit rate filings only if they offer individual or small group health benefit plans, some health insurers that do not participate in these markets are not required to submit these reports. This may result in an incomplete picture of health plan spending on drugs in Oregon.

We recommend legislators consider separating the health insurance company reporting requirement from the rate review process and require it as a separate annual report from all health benefit plan issuers in Oregon.

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 working to address prescription drug price transparency. Manufacturers are required to report to DCBS when price increases or new high-cost drugs occur. Health insurers are subject to regulatory oversight from DCBS including monitoring costs to consumers and reporting of

drug information. Other entities in the supply chain, such as pharmacy benefit managers (PBMs), are required to register with DCBS and follow state laws regarding their interactions with pharmacies. PBMs are also required to report on rebates to the Oregon Health Authority. Reporting requirements also exist for entities such as hospitals and providers as Oregon monitors the cost growth benchmark for rising health care spending.

These policy measures address pieces of transparency across the supply chain; however, there are still gaps in transparency. We recommend the legislature consider transparency across the pharmaceutical supply chain, particularly to entities with no reporting or regulatory oversight, to fully understand what influences and contributes to the price of the drug. This includes aspects of the pharmaceutical supply chain that may impact 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: Continue to consider implementing an "upper payment limit" for certain drugs

During the 2021 session, the legislature authorized creation of the Prescription Drug Affordability Board within DCBS. Working with the data developed by Oregon's Drug Price Transparency Program, the board is empowered to study drug costs and perform affordability reviews of certain high cost-drugs. However, the board's ability to act on the findings of an affordability review by setting an upper payment limit for a drug in Oregon was removed from the final bill.

As a concept, an upper payment limit would be a state-level analog to the pharmaceutical rate setting that exists in some form in most wealthy nations, or the recently created price "negotiation" authority created for Medicare by the federal

Inflation Reduction Act of 2022. Several other states have also established drug affordability boards, and two of these state entities have upper payment limit authority. However, no state has attempted to implement or enforce an upper payment limit, and the actual affect of such a decision is untested. Without additional information, it is impossible to assess whether this expanded authority would provide benefit to the people of Oregon.

We recommend that the legislature continue to examine the use of upper payment limits, including the potential for legal challenges and operational difficulties in implementation of the policy.

Recommendation 5: 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 state to create a state operated generic drug manufacturer, CalRx. This new entity is directed to contract with other generic manufacturers and act as a relabeler, with the long-term goal of establishing its own manufacturing capacity. CalRx would provide a supply of 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 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 multi-state purchasing entity. We 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 both 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, we recommend 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, we recommend 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.

Consumer notification reporting

Recommendation 6: Protection of consumer-reported information

Consumer reports on the price increases of the prescription drugs they take is an essential component to the program. When consumers report to the program, they submit specific

information about the drug they are reporting on, which the program uses to compare against the information submitted by drug manufacturers and health insurers. Also, consumers report their ZIP code, health insurance information, and the reasons for the price increase.

This information is important for policymakers and stakeholders to know what is being reported to the department from the consumer perspective; however, collectively, the information could potentially identify a consumer. We recommend clarifying that the personally identifiable information collected will be protected from public disclosure.

Program improvements

Recommendation 7: Data sharing between state agencies working on drug pricing

We have previously recommended that the state consider expanded transparency for more pharmaceutical supply chain entities. Despite gains in transparency due to the work of this program and others, many aspects of drug pricing remain quite opaque. This is particularly true of manufacturer rebates and PBMs. Other than a drug's "list" price, rebates are likely the largest single factor influencing the actual cost of a given drug to the health care system. Drug manufacturer rebates are negotiated by PBMs, and are kept a closely held secret – in many cases, a PBM may keep rebate information secret from their client insurance companies.

As part of its work to support Oregon's Sustainable Health Care Cost Growth Benchmark, the Oregon Health Authority (OHA) has begun to collect information on rebates from PBMs. We recommend that the state agencies that collect drug pricing information, including DCBS and OHA, collaborate to share critical information where it is already being collected by one or the other. This data sharing will reduce compliance and regulatory burden on reporting entities by avoiding duplicative work, and enable better, more informed analysis by both agencies.

Background

Prescription drugs are vital to both longevity and quality of life for many Oregonians. 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 because they do at the cost of 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. Oregon's Prescription Drug Price Transparency Act in 2018 (House Bill 4005) created the Drug Price Transparency Program to provide accountability by disclosing specific pricing information from pharmaceutical manufacturers, health insurers, and consumers.³ The Drug Price Transparency Program gathers information each year about new drugs and high-cost drugs that are reported to the program.

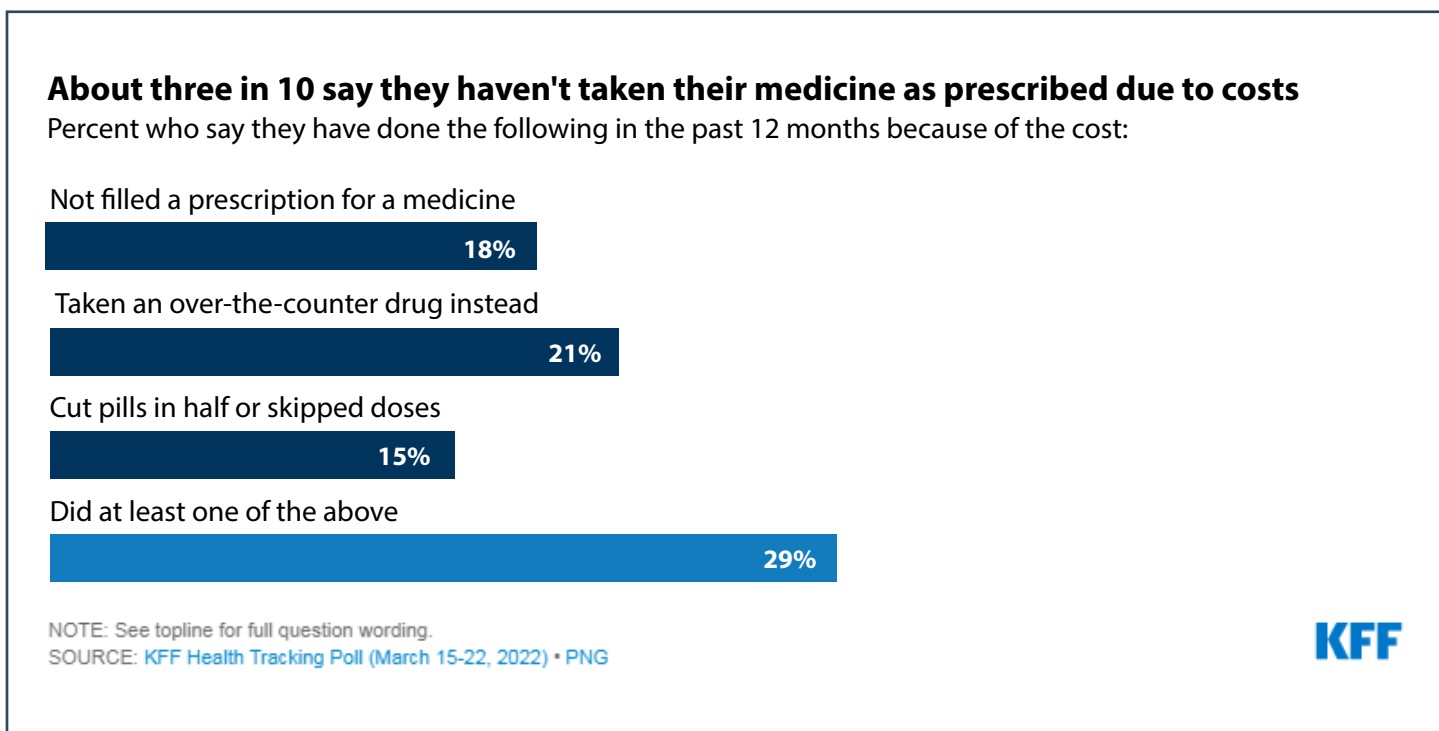
A 2021 poll by the Kaiser Family Foundation found that 60 percent of adults in the U.S. take at least one prescription drug and 25 percent take at least four per day. Of those prescribed medications, 29 percent of Americans reported not taking their medications as prescribed due to cost. They do this by not filling their medication, using an over-the-counter medication instead, or cutting their pills in half.⁴



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

⁴ Hamel, Liz et al. "Public Opinion on Prescription Drugs and Their Prices." Kaiser Family Foundation Polling, Oct. 20, 2022. <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>. Accessed Sept. 19, 2022.

Figure 1: Percent of people who have not taken prescribed medication due to cost



Source: Kaiser Family Foundation⁵

Overview of prescription drugs

A prescription drug is a substance approved by a health care practitioner to provide a therapeutic benefit to a person for a specific disease or condition and is required to be purchased from a pharmacy.⁶ A prescription drug can be either a brand name drug or generic drug. Brand name prescription drugs are covered by a patent, which 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.⁷ Generic drugs typically cost

less than brand name drugs and are used more frequently due to their reduced cost.

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. Many high-cost new 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

⁵ Hamel, Liz et al. "Public Opinion on Prescription Drugs and Their Prices." Kaiser Family Foundation Polling, Oct. 20, 2022. <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>. Accessed Sept. 19, 2022.

⁶ "Prescription Drugs and Over-the-Counter (OTC) Drugs: Questions and Answers." U.S. Food & Drug Administration, Nov. 13, 2017. <https://www.fda.gov/drugs/questions-answers/prescription-drugs-and-over-counter-otc-drugs-questions-and-answers>. Accessed Sept. 19, 2022.

⁷ "Questions, Answers, and Facts About Generic Drugs." U.S. Food & Drug Administration, Nov. 21, 2017. <https://www.fda.gov/drugs/resources-you-drugs/questions-answers-and-facts-about-generic-drugs>. Accessed Sept. 19, 2022.

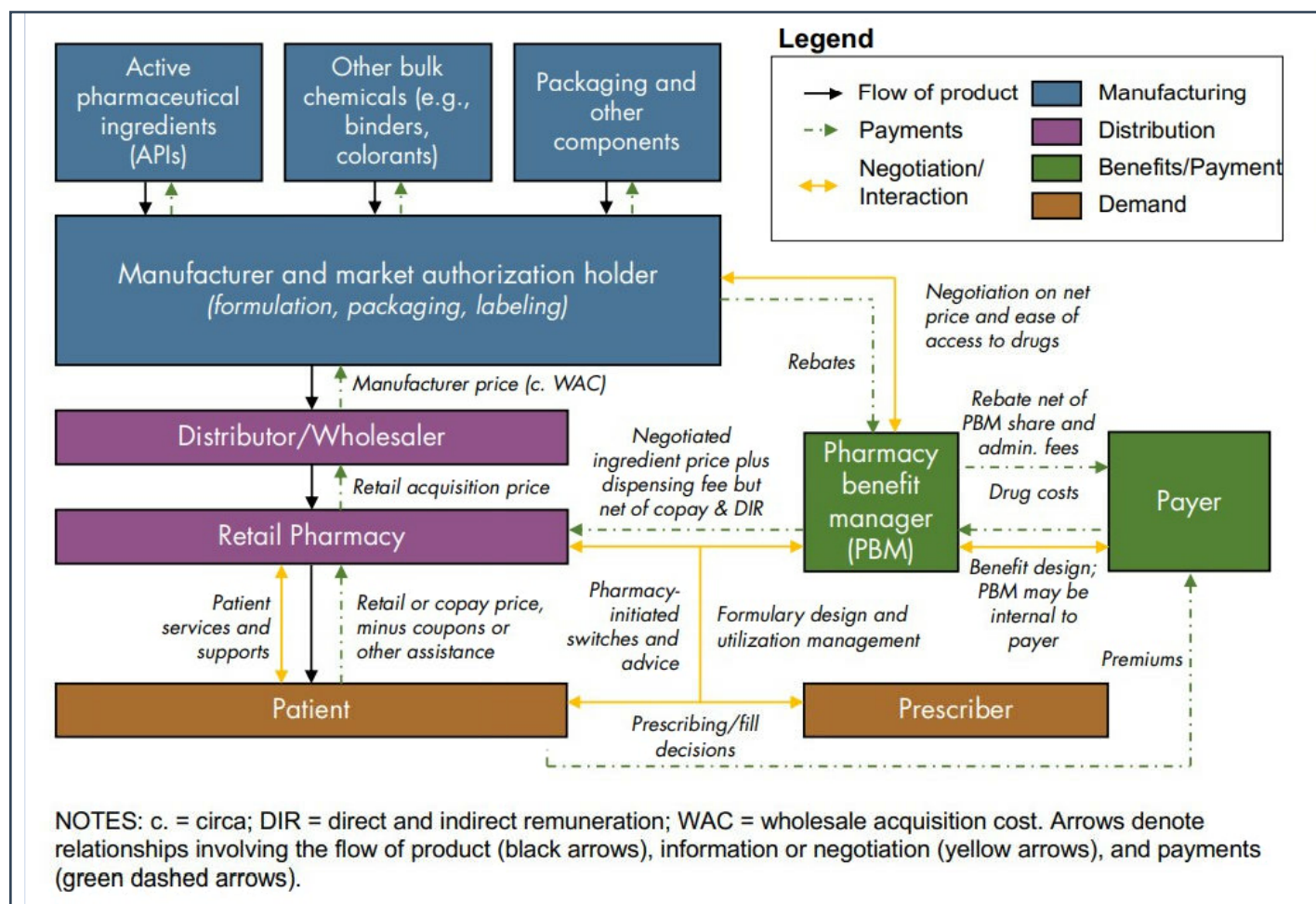
human growth hormone would technically be considered biologics under current law if they were developed today.⁸

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 prescription drugs can be priced, such as the average wholesale price (AWP) and the average manufacturer price (AMP), that are used as starting points for

negotiating drug prices between pharmaceutical supply chain entities.

The price someone pays at the pharmacy is determined through a complex set of factors throughout the pharmaceutical supply chain, that works to supply consumers with drug products. Manufacturers, wholesale distributors, pharmacies, pharmacy benefit managers (PBM), health insurance companies, medical providers, and consumers make up the majority of the actors involved in the pharmaceutical supply chain.

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



Source: RAND Corp. and U.S. Department of Health and Human Services⁹

⁸ 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 Sept. 19, 2022.

⁹ Mulcahy, Andrew W. and Kareddy, Vishnupriya. "Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships." RAND Corporation, 2021. <https://aspe.hhs.gov/sites/default/files/documents/0a464f25f0f2e987170f0a1d7ec21448/RRA328-1-Rxsupplychain.pdf>. Accessed Sept. 19, 2022.

The price a consumer pays at the pharmacy can be influenced by the industry practices and financial negotiations between pharmaceutical supply chain entities, as well as what type of health insurance coverage the consumer has. Figure 2 shows an 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.

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 to purchase the drug. Many health insurance companies will require a co-pay or co-insurance payment when the consumer pays for the prescription drug at the pharmacy. A co-pay is a flat fee, such as \$10 per prescription, and co-insurance is a percentage of the drug cost, such as 20 percent of the drug price, that is paid to receive a prescription drug. 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 co-pay 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 co-pay or co-insurance.

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 types of categories will be used throughout this report to describe the data received from manufacturers, health insurers, and consumers.

Prescription drug spending in the United States and Oregon

In 2020, U.S. health care spending reached \$4.1 trillion, a 9.7 percent growth, and \$348.4 billion of that was retail prescription drug spending.¹⁰ It is estimated that prescription drug spending accounts for approximately 13.9 percent of health care spending, 9.2 percent in retail pharmacies and an estimated 4.5 percent nonretail by a physician or in a health care facility.¹¹ While growth in overall U.S. health care and prescription drug spending has slowed in recent years, many Americans continue to struggle paying for prescription drugs.

An estimated 19 million persons were unable to pay for their prescription drugs in 2021.¹² The program hears stories of how high costs impact people, particularly those who need prescription drugs to treat cancer, manage diabetes, and address heart conditions.¹³ These reports illustrate the impact that prescription drug costs have on households around the country and in Oregon.

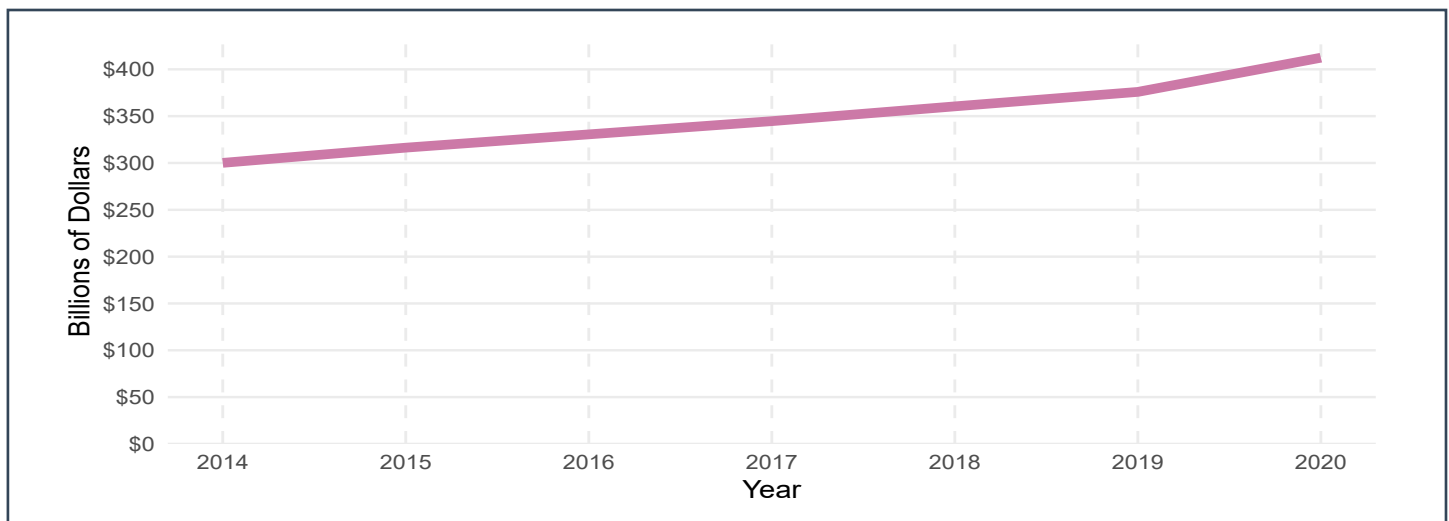
¹⁰ "National Health Spending in 2020 Increases Due to Impact of COVID-19 Pandemic." Center for Medicare & Medicaid Services, Office of the Actuary, Dec. 15, 2021. <https://www.cms.gov/newsroom/press-releases/national-health-spending-2020-increases-due-impact-covid-19-pandemic>. Accessed Sept. 19, 2022.

¹¹ Conti, Rena M., PhD, Turner Ann, MA, and Hughes-Cromwick, Paul, MA. "Projections of US Prescription Drug Spending and Key Policy Implications." JAMA Health Forum. Jan. 29, 2021. <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2776040>. Accessed Sept. 19, 2022.

¹² 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 Sept. 19, 2022.

¹³ 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 Sept. 19, 2022.

Figure 3: Estimated expenditure on prescription drugs in U.S. (2014 to 2020)



Source: Department of Consumer and Business Services, 2022.

Data: Centers for Medicare and Medicaid. National Health Expenditures, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical>, visited September 2022.

Oregon prescription drug spending

Prescription drug spending and the effects of costs on Oregonians has been a growing interest for policymakers, health care providers, and the public in recent 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 \$1.1 billion between July 2020 and June 2021 on prescription drugs for those enrolled in the Oregon Health Plan.¹⁴ The total prescription drug spending expectation for 2021 and 2022 is \$21 million for the CAREAssist program (Oregon's AIDS Drug Assistance Program – ADAP).¹⁵ Prescription drug spending

by the Public Employees' Benefits Board (PEBB) was more than \$226 million in 2021 for 138,567 members. The Oregon Educators Benefit Board (OEBB), with 132,475 members recorded \$165 million for the 2020-21 plan year (October 2020 to September 2021).^{16,17} The Oregon Youth Authority, Oregon Department of Corrections, and Oregon State Hospital also purchase prescription drugs for the people in their care.

In 2022, Oregon rebranded its prescription drug assistance program from the Oregon Prescription Drug Program to the ArrayRx Discount Card Program. This state-sponsored program is a partnership between the states of Oregon,

¹⁴ "Pharmacy Utilization Summary Report: January 2021 – December 2021: Total Amount Paid." Drug Use Research & Management Program, DHS Health Systems Division, Oregon State University College of Pharmacy, page 1, July 21, 2022, CAREAssist program data provided from Oregon Health Authority, November 2022. https://www.orpdl.org/durm/reports/utilization/2022/DUR_Utilization_2022_Q2.pdf. Accessed Nov. 9, 2022.

¹⁵ "Background Brief on Prescription Drugs." Legislative Policy and Research Office, September 2014. <https://www.oregonlegislature.gov/lpro/Publications/BB2014PrescriptionDrugs.pdf>. Accessed Sept. 19, 2022. CAREAssist program data provided from Oregon Health Authority in November 2022.

¹⁶ "Well-Being Strategy Development: Update: PEBB PMAC." Mercer presentation to the Oregon Health Authority and Public Employees' Benefit Board, page 40, July 19, 2022. <https://www.oregon.gov/oha/PEBB/MeetingDocuments/Board-Agenda-Attachments-202207.pdf>. Accessed Sept. 19, 2022.

¹⁷ OEBB data provided from Oregon Health Authority in November 2022.

Washington, and Nevada. It can help Oregonians 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.

Although we do not have the amounts for all other prescription drug spending for Oregonians, we do have information from the insurers who report to us later in this report.

Oregon study on hormone replacement therapy drug costs for men and women

Senate Bill 711 (2021) directed DCBS to conduct a study of disparities in the cost of hormone replacement drugs between those for men and those for women.¹⁸ This information is from the executive summary of the study. The report and executive summary are available at <https://dfr.oregon.gov/drugtransparency/Pages/other-legislative-reports.aspx>.

The Oregon Drug Price Transparency Program within DCBS carried out the study by analyzing the expected patient costs (copay, coinsurance, and deductibles) recorded in retail pharmacy insurance claims for hormone replacement drugs from the Oregon All Payer All Claims Reporting Program (APAC) from the years 2018, 2019, and 2020. A total of 1,290,452 claims from 159,932 different claimants were included in the study.

Claimants who were exclusively identified as “female” in the pharmacy claims data (F claimants) paid an average of \$5 more per claim than claimants who were exclusively

identified as “male” (M claimants). On average, F claimants paid \$32.45 per claim and M claimants paid \$27.76 per claim.

Though their average cost per claim was lower, M claimants made more claims on average, leading to a slightly higher average total cost per claimant over the three-year period from 2018 to 2020. On average, an M claimant had 9.5 claims and paid a total of \$262.43, while an F claimant had 7.8 claims and paid a total of \$252.94.

Some claimants in the data had claims without gender information or had more than one gender identification across multiple claims. We will refer to these claimants as “UV”, for “Unknown or Various.” On average, a UV claimant paid \$16.96 per claim, had 15.8 claims, and paid a total of \$267.15.

F claimants were responsible for paying 31 percent of their claim costs, compared to 20 percent for M claimants and 30 percent for UV claimants. The rest of the cost was paid by insurance.



¹⁸ “Hormone Replacement Therapy Drug Costs Study 2022, As Required by Senate Bill 711 (2021).” Department of Consumer and Business Services, Sept. 7, 2022, OEBS data provided from Oregon Health Authority, November 2022. https://www.oregonlegislature.gov/citizen_engagement/Reports/DFR-Cost-Study-Report.pdf. Accessed Oct. 28, 2022.



Our analysis suggests that the differences between average costs per claim for F claimants and M claimants can be attributed to a small number of high-cost claims, among which F claimants were disproportionately represented.

The top 5 percent highest cost claims cost \$134 or more to the claimant. In total there were 64,597 claims in the top 5 percent. Of those claims, 90 percent were made by F claimants, compared to 82 percent by F claimants in the full data set. Further, for four out of the five most common drugs in the top 5 percent of claims, virtually all of those high-cost claims were made by F claimants.

The data collected for this study is insufficient to directly tie this apparent disparity solely to a patient's gender. These differences could be due to other factors, such as the medical condition being treated, the relative list price of the drug, the delivery mechanism of the drug (such as intravenous versus oral), or the benefit design of the patient's insurance (for example, formulary placement). Due to this, it is difficult to make specific legislative recommendations to address disparities based solely on the conclusions of this study. Additional research and analysis would be needed to be able to identify the cost drivers that create this apparent disparity,

and to make legislative recommendations to address any disparity in the cost of prescription drugs due to gender.

We recommend additional research into the following questions:

- What is driving the disparities in cost sharing? Why do claimants pay a higher share of the cost of claims for estrogens and progestins than for testosterone?
- Why do M claimants make more claims than F claimants? Are there barriers preventing F claimants from getting the drugs they need?
- Why are drugs used by F claimants, such as estradiol and conjugated estrogens, so often the highest-cost claims?
- Why do some claimants have multiple gender flags in their APAC claims data? How should those gender flags be interpreted?

We would also recommend a broader survey of prescription drug claims spanning all therapeutic classes, without limiting our query to claims for hormone replacement drugs. This could help identify whether the apparent disparity is present for non-hormone replacement.

Oregon Drug Price Transparency Program



The program continues to engage manufacturers and collect information to inform the public hearing and legislative reports. In December 2022, the program will hold its fourth 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. Program staff help pharmaceutical manufacturers with questions, registration, billing, and filing required reports. Efforts to increase manufacturer reporting compliance and review trade secret claims have increased due to process improvements and additional program staff. The program also is working to increase outreach to consumers in 2023.

This report summarizes the findings from data collected since the 2021 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 from the public can provide notification of an increase in the cost of prescription drugs to the Drug Price Transparency 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 seven price increase notifications from Oregon consumers. The program will be undertaking new strategies in the next year to reach consumers and bridge the gap in reporting drug price increases.

The seven reports received since last year show patient co-pays from \$57 to \$1,670. Most consumers mentioned that the price of their medications was causing financial stress. Most also stated that the reasons for the increase are insurance/formulary related. Many of these patients are using Medicare. The price increases reported by consumers involved a variety of pharmacies, and a few said they did not know why there was an increase. One consumer told us that their medication, which increased from \$25 to \$109, was essential for them to live and that the cost increase was causing a lot of financial stress. One consumer cited the Medicare “donut hole” (the coverage gap created by drug plan limitations) as the reason for the 311 percent price increase they experienced (an increase from \$42 to \$173).

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 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 received a number of responses with a few consistent threads. All of the consumer stories we have received this year that we had permission to share will be available in a separate document as an exhibit.

Below are some of the stories we received. They have been lightly edited and the names removed:

"We have insurance through my husband's work. Most of the time we utilize GoodRx for our prescription drugs because of the cost savings compared to our pharmacy benefits we receive from our insurance. All of our prescriptions have increased in price – anywhere from \$20 per prescription to as much as \$300. The largest increase we experienced was for our daughter's EpiPen. The price was so expensive for an EpiPen that we were unable to refill the prescription. I believe that without government regulations in place to keep medications affordable for middle class, working Americans, the cost of drugs will only continue to rise. Our future will be where most medications will be unaffordable for the majority of Americans. Those of us that are working and contributing to society should be able to afford medication treatment prescribed by their doctor without having to choose between food, paying rent, etc., or their medications."

"Insulin costs hundreds of dollars. Type one diabetic for 37 years, trying to take insulin to save my life!! Yet Narcan is free. Do you see a problem with this?"

Ampyra costs hundreds of dollars. I have had multiple sclerosis for 26 years. I fall multiple times per day. Ampyra reduces my risk of falling, drastically. Affording the med is not easy to come by. Right now, for example, I have none. So I do not move to not fall. Yet Methadone is free. Do you see a problem with this?"

Methalphenadate is listed as a CONTROLLED substance, yet without it I am asleep all day! So each morning I have to ask myself: Am I awake so I can walk for exercise and to control my blood sugar numbers or am I asleep all day?"

The answer is simple to me, but I am biased because I want to live!!"

"Adderall XR is extremely hard to get insurance to cover. Not covered, (it) was \$300 per month for my 30-day supply. Then insurance wouldn't cover the dosage prescribed to me. I got tired of fighting to get it, so I told my doctor I was done taking it."

"I have to carry an EpiPen with me as I am allergic to bees. My insurance will not cover the cost at \$750.00, and I can't afford that price. What I finally did was get an Rx prescription for epinephrine and three syringes, all for under \$40.00. So the med is high but that pen, at more than \$700, is way out of line!"

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.

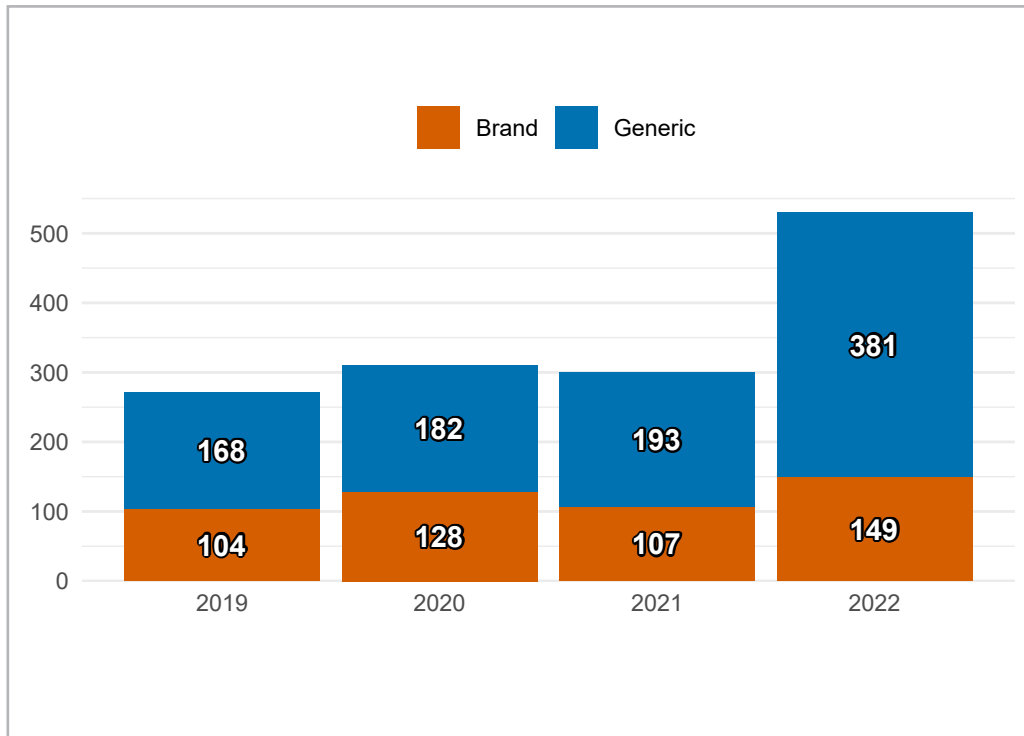
- **60-day notice price increase report:** Manufacturers are required to submit a price increase report 60 days before the planned increase takes effect when the threshold is met. A report is required for a brand name prescription drug when the cumulative price increase is at least 10 percent or \$10,000 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 through Aug. 31, 2022. 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 high-cost drug reports

Figure 4: Reports for generic and brand name new prescription drugs 2019-22



Source: Drug Price Transparency Program, DCBS.

New high-cost drugs are reported to the program when they are priced at \$670 or more. This is the price threshold set by the federal government to categorize a drug as a “specialty drug” under Medicare Part D. Reports for new high-cost drugs come in continuously.

Between Oct. 4, 2021, and Aug. 31, 2022, the program received 530 new high-cost drug reports, each one for a different NDC. These reports were submitted by 114 different manufacturers.

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.

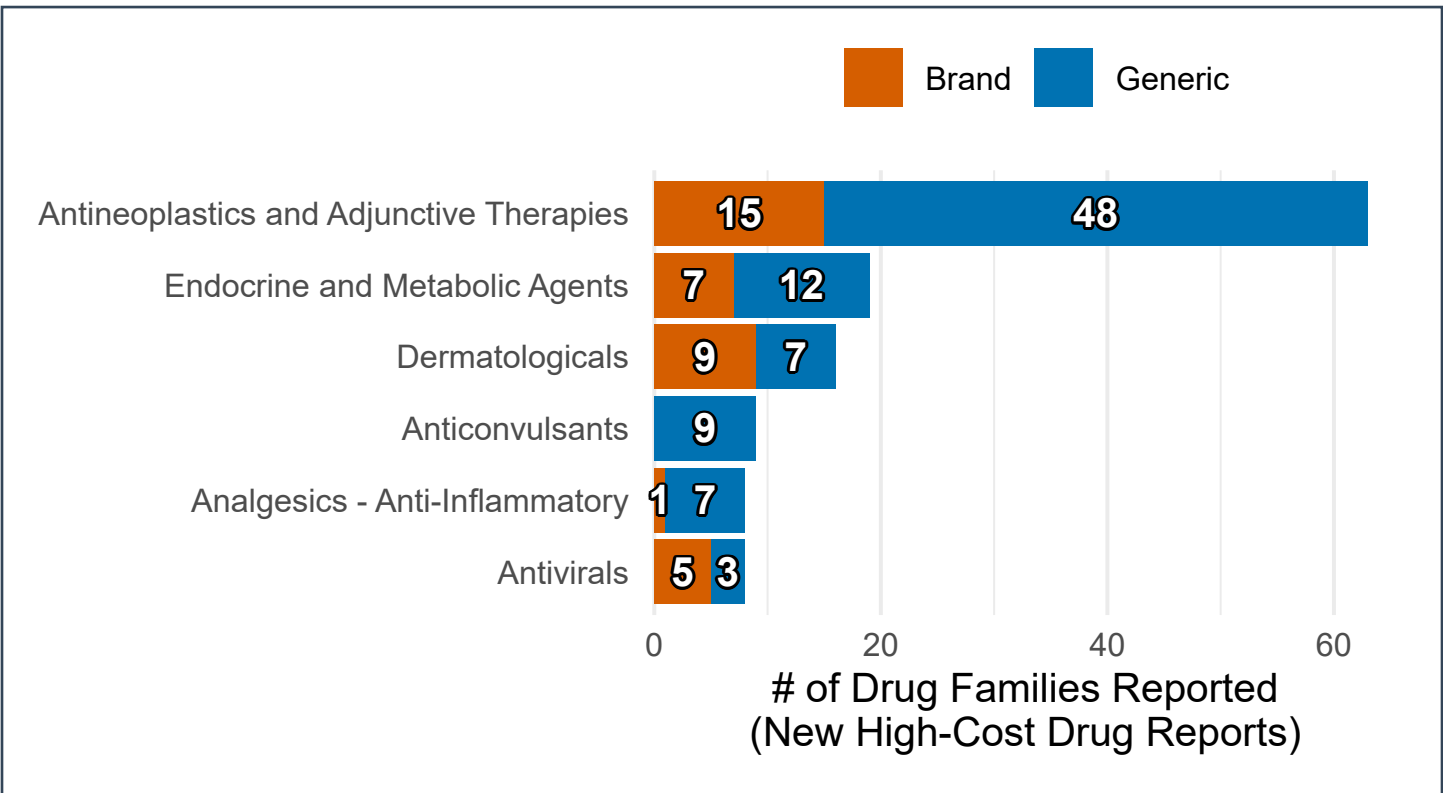
We received new high-cost drug reports for 173 generic drugs that came from 54 manufacturers. We also received reports for 84 brand name drugs that came from 66 manufacturers.

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. 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, and “drug” in the same context may be used to refer to a product family rather than an individual NDC.

The most common classes of drug in these reports were antineoplastic and adjunctive therapy drugs, with 63 reported product families. We received reports for 15 different brand name drugs (21 NDCs from 13 manufacturers) and 48 generics (86 NDCs from 22 manufacturers) in this class. Other common classes were endocrine and metabolic agents, with 19 reported product families (38 NDCs from 17 manufacturers), dermatologicals, with 16 reported product families (24 NDCs from 13 manufacturers), and anticonvulsants, with nine product families (27 NDCs from five manufacturers).

Figure 5: Distribution of brand name and generic new high-cost drugs by most common classes



Source: Drug Price Transparency Program, DCBS.

Highest WAC prices in new high-cost drug reports

The program received new high-cost drug reports for drugs with wholesale acquisition costs (WACs) ranging from \$2.39 to \$465,000. 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 WACs have been submitted in error.

The chart below 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.

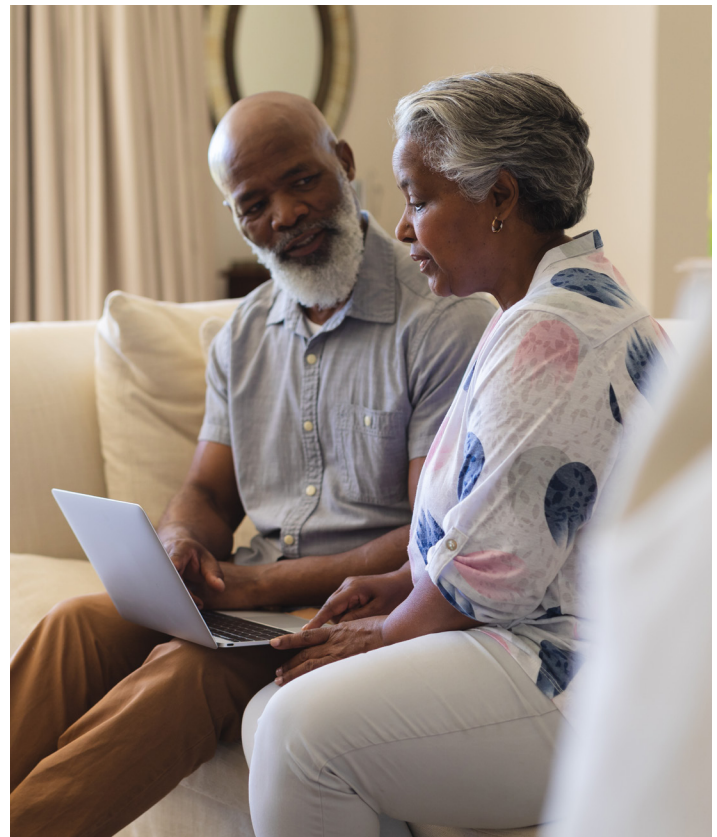


Figure 6: Highest reported WACs for new brand name drugs

Drug	WAC	Therapeutic Class	Manufacturer
Carvykti	\$465,000	Antineoplastics and Adjunctive Therapies	Janssen Biotech
Amvuttra	\$115,875	Psychotherapeutic and Neurological Agents	Alnylam Pharmaceuticals INC.
Livmarli	\$46,500	Gastrointestinal Agents	Mirum Pharmaceuticals
Vijoice	\$32,500	PIK3CA-Related Overgrowth Spectrum (PROS) Agents	Novartis
Cortrophin	\$31,851	Endocrine and Metabolic Agents	Ani Pharmaceuticals INC.
Isturisa	\$2,518 - \$30,823	Endocrine and Metabolic Agents	Recordati Rare Diseases, INC.
Pyrukynd	\$25,760	Hematological Agents	Agios Pharmaceutical INC.
Exkivity	\$25,000	Antineoplastics and Adjunctive Therapies	Takeda Pharmaceuticala America, INC
Epclusa	\$24,920	Antivirals	Gilead Sciences, INC.
Tyvaso DPI	\$20,906	Cardiovascular Agents	United Therapeutics Corporation

Source: Drug Price Transparency Program, DCBS.

The highest WAC reported this year was for a chimeric antigen receptor T-cell (CAR-T) therapeutic, named Carvykti, manufactured by Janssen Biotech. This mirrors the reports from last year, when the highest reported WAC was also for a CAR-T therapy (Abecma, \$419,000). CAR-T therapies are a relatively new technology that uses engineered versions of a patient’s own white blood cells to destroy targeted substances in the body, such as cancer cells.¹⁹ Carvykti has a per-dose price of \$465,000. This is a CAR-T treatment for multiple

myeloma, a cancer of plasma cells that affects the immune system.²⁰

The second-highest reported WAC was for Amvuttra, with a per-dose price of \$115,875. This is a ribonucleic acid interference (RNAi) therapeutic approved for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis, a rare genetic condition caused by the buildup of a specific protein in the body.²¹ RNAi therapies are a new type of targeted cellular drugs that block the expression of certain genes.²²

¹⁹ “CAR T-cell Therapy and Its Side Effects.” American Cancer Society, March 1, 2022. <https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/immunotherapy/car-t-cell1.html>. Accessed Nov. 9, 2022.

²⁰ “Carvykti Approval Marks Second CAR T-cell Therapy for Multiple Myeloma.” National Cancer Institute, Cancer Currents Blog, March 30, 2022. <https://www.cancer.gov/news-events/cancer-currents-blog/2022/fda-carvykti-multiple-myeloma>. Accessed Nov. 9, 2022.

²¹ “Alnylam Announces FDA Approval of AMVUTTRA™ (vutrisiran), an RNAi Therapeutic for the Treatment of the Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis in Adults.” Alnylam20, June 13, 2022. <https://investors.alnylam.com/press-release?id=26776>. Accessed Nov. 9, 2022.

²² “FDA Approves First-of-its Kind Targeted RNA-Based Therapy to Treat a Rare Disease.” U.S. Food & Drug Administration, Aug. 10, 2018. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-its-kind-targeted-rna-based-therapy-treat-rare-disease>. Accessed Nov. 9, 2022.

Figure 7: Highest reported WACs for new generic drugs

Drug	WAC	Therapeutic Class	Manufacturer
Pyrimethamine	\$9,653 - \$32,175	Antimalarials	Oakrum Pharma, LLC
Pyrimethamine	\$7,695 - \$25,650	Antimalarials	Teva
Nitisinone	\$4,360 - \$21,797	Endocrine and Metabolic Agents	Analog Pharma, INC
Sorafenib Tosylate	\$20,240	Antineoplastics and Adjunctive Therapies	Mylan Pharmaceuticala INC
Lenalidomide	\$15,118 - \$20,157	Immunomodulators	Teva
Sunitinib Malate	\$4,889 - \$17,022	Antineoplastics and Adjunctive Therapies	Teva
Sunitinib Malate	\$4,884 - \$17,003	Antineoplastics and Adjunctive Therapies	Mylan Pharmaceuticals INC
Sorafenib Tosylate	\$15,535	Antineoplastics and Adjunctive Therapies	Dr. Reddy's Labratories, INC
Everolimus	\$12,895 - \$13,556	Antineoplastics and Adjunctive Therapies	Mylan Pharmaceuticals INC
Isoproterenol HCl	\$5,450 – \$11,250	Antiasthmatic and Bronchodilator Agents	Auromedics Pharma

Source: Drug Price Transparency Program, DCBS.

Figure 7 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.

The highest WAC reported this year among generic drugs was for an NDC of pyrimethamine, an antimalarial drug manufactured by Oakrum Pharma. This drug reported multiple NDCs that have a WAC price range of \$9,653 to \$32,175, depending on the NDC. This drug is listed as one of the World Health Organization’s Essential Medicines – drugs considered to be effective to meet important health system needs worldwide.²³

The highest reported WAC for a single dose of a generic drug was for sorafenib tosylate,

manufactured by Mylan Pharmaceuticals, with a per-dose price of \$20,240. This drug is intended for the treatment of an advanced renal cell carcinoma, unresectable hepatocellular carcinoma.

Public funds in new high-cost drug 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.

Manufacturers overwhelmingly reported receiving no public funding for the drugs reported. Out of

²³ “Pyrimethamine.” World Health Organization. <https://list.essentialmeds.org/medicines/384>. Accessed Nov. 9, 2022.

the 530 new high-cost drug reports we received, only five reported nonzero amounts of public funding that were not marked as a trade secret.

A report for Rapivab (NDC 72769018103), an antiviral drug manufactured by Biocryst Pharmaceuticals, reported \$234,800,000 of U.S. public funding and stated the following:

“The U.S. Department of Health and Human Services (“BARDA/HHS”) awarded us a contract for the advanced development of peramivir for the treatment of influenza. The contract was later modified and peramivir clinical development shifted to focus on intravenous delivery and the treatment of hospitalized patients, and intended to fund completion of the Phase 3 development of i.v. peramivir for the treatment of patients hospitalized with influenza. The contract modification also provided funding to support the filing of an NDA to seek regulatory approval for i.v. peramivir in the U.S.”

A report for Fyarro (NDC 80803015350), an anticancer treatment for malignant perivascular epithelioid cell tumor (PEComa) manufactured by AADI Bioscience, reported \$2,814,437 of U.S. public funding.

A report for Illuccix (NDC 74725010025 and NDC 74725010064), a radioactive diagnostic agent manufactured by Telix Pharmaceuticals, reported receiving \$13,161,406 of international public funding and stated the following:

“Australian tax incentive (for entire program) for FY 2021. Some used for R & D.”

Finally, a report for Vivjoa (NDC 74695082318), an antifungal drug manufactured by Mycovia Pharmaceuticals, reported receiving \$275,000 of U.S. public funding and stated the following:

“\$275,000 was received from the Department of Health and Human Services (National Institute of Allergy and Infectious Diseases) and was used for research and development purposes.”

All other new high-cost drug reports either indicated \$0 in public funding, marked their public funding as a trade secret, or indicated both. Of the 257 product families we received reports for, 13 of them (across 18 NDCs from 11 manufacturers) claimed their public funding data as a trade secret. The program will not agree with trade secret claims for information that is publicly available, and zero-dollar entries in a data element with a trade secret claim are generally a noncompliance issue.

These manufacturers incorrectly marked their public funding data as a trade secret in every new high-cost drug report they submitted this year:

- **Accord Biopharma** (1 NDC)
- **Averitas Pharma** (3 NDCs)
- **B Braun Medical** (2 NDCs)
- **Biogen** (1 NDC)
- **Bioxcel Therapeutics** (2 NDCs)
- **BPI Labs** (1 NDC)
- **Casper Pharma** (1 NDC)
- **Chiesi USA** (3 NDCs)
- **Mallinckrodt Pharmaceuticals** (1 NDC)
- **Mirum Pharmaceuticals** (1 NDC)
- **Piramal Critical Care** (2 NDCs)

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.

Here are samples from submissions during the last year for the marketing description data element that included the amount spent not claimed as a trade secret:

ARDELYX, INC

“Ardelyx reported general and administrative expenses (G&A) of \$72,303,000 for 2021. Marketing expenses for IBSRELA (tenapanor) are included in the G&A expenses along with many other commercial and non-commercial operating expenses.

- *Marketing messaging will emphasize the unique, first-in-class mechanism of action of IBSRELA (tenapanor), and the clinical data that demonstrates significant improvement in abdominal pain, bloating and constipation with a quick onset of action and sustained efficacy.*
- *IBSRELA will be positioned as a first-in-class NHE3 inhibitor that provides a new therapeutic option for adults with IBS-C.*
- *This positioning and messaging focus will establish IBSRELA, with its new mechanistic*

approach, and triple-acting effect, as a meaningful new medicine in the treatment toolkit for HCPs who treat adult patients with IBS-C. Sales force focus is on the HCPs who treat patients with IBS-C.” (IBSRELA[®] filed by ARDELYX, INC.)

CTI BIOPHARMA CORP

“\$267,381,746.00. VONJO will be promoted by our commercial field team to healthcare professionals to educate them on our product. We will use various means of promotion including in-office visits, virtual meetings, ad campaigns, and digital marketing.” (VONJO[®] filed by CTI BIOPHARMA CORP)

TELIX PHARMACEUTICALS US INC

“Telix will market Illuccix[®] through a variety of channels, including sales conversations with health care professionals, digital banners, email marketing, patient education, professional associations, trade shows, and public relations. Telix participates in Medicaid and agrees to provide outpatient drugs to 340B covered entities at significantly reduced prices. Approximately \$4M spent on marketing.” (Illuccix[®] filed by TELIX PHARMACEUTICALS US INC.)

CERONA THERAPEUTICS, INC

“The marketing plan for Floxuridine will focus on providing key product information such as the package insert and ordering information via the company web site. Cerona Therapeutics does not have current plans to promote Floxuridine directly to consumers during its market introduction. Cerona Therapeutics will support patient access through a patient assistance program, information for which is made available through the company website. Cerona Therapeutics’ 2022 expenses for professional promotion to support the launch of Floxuridine will be less than \$100,000, and will not include spend on DTC advertising.” (Floxuridine[®] filed by CERONA THERAPEUTICS, INC.)

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 drugs' 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:

PADAGIS US LLC

"Padagis considered a number of different factors when determining pricing for Vigabatrin Tablets 500mg. A significant objective of Padagis in establishing its WAC price at \$10,511.89 was to ensure a meaningful reduction in WAC when compared to the RLD, Sabril®. Based on information available to Padagis, the WAC for Sabril® was \$18,571 at the time Padagis introduced its AB-rated generic equivalent to the market. Padagis' WAC price at introduction represents a reduction in price of 43%. When establishing such discounted pricing for the new prescription drug, Padagis considered a variety of factors, including its ability to: (i) recover the costs incurred in bringing this drug to market, including but not limited to costs to evaluate the legal landscape surrounding to the potential drug, costs for studies and developing analytical methods, and costs for ANDA preparation, submission and regulatory approval; (ii) cover manufacturing costs and material costs, including

the cost of sourcing API; (iii) cover supply and distribution costs; (iv) compete with other available AB-rated generics; and (v) earn a reasonable return on investment. The product is priced to deliver value to the market as compared to the Brand referenced drug." (Vigabatrin filed by PADAGIS US LLC.)

GLOBAL BLOOD THERAPEUTICS, INC

"Global Blood Therapeutics, Inc. (GBT) does not conceptualize its pricing decisions by considering a specific set of financial and/or non-financial factors. A range of considerations impacted its decision to set the wholesale acquisition cost for OXBRYTA Tablets for Oral Suspension. The following list of financial and nonfinancial factors ... impacted its pricing decision: The direct and indirect cost and burden of sickle cell disease in the patient population ... The value and impact of OXBRYTA Tablets for Oral Suspension for patients, their families and society, including its clinical benefit relative to existing treatments for sickle cell disease, and the anticipated cost savings GBT's believes OXBRYTA Tablets for Oral Suspension will bring to the health care system. The impact on net revenues, and the need to fund operations, which includes production, supply, and other operational and administrative costs. GBT's commitment to and investment in developing medicines for sickle cell disease, including costs associated with developing OXBRYTA Tablets for Oral Suspension, as well as anticipated future investments in research and development. ... The price of OXBRYTA Tablets for Oral Suspension as compared to treatments for other orphan drugs, which require a significant investment for a smaller eligible patient population. The list price (or Wholesale Acquisition Cost – WAC) for Oxbryta tablets for oral suspension will be \$10,417 per month. The net price for approximately 65 percent of payers will be about \$8,000 per month, after mandatory government discounts. ... GBT's responsibility as a publicly traded company to maximize value for its stockholders and maintain a sustainable and profitable business. GBT's expectations of exclusivity and timing of potential generic competition to OXBRYTA Tablets for Oral Suspension." (Oxbryta® filed by GLOBAL BLOOD THERAPEUTICS, INC.)

ADMA BIOLOGICS, INC

“Using the Pricing Strategy AssessmentSM (PSASM) framework, ADMA has developed a comprehensive pricing strategy for ASCENIV, a new intravenous immunoglobulin therapy indicated for primary immunodeficiency derived from hyperimmune donors containing enhanced levels of neutralizing antibodies to RSV, by examining the role of price in the processes of managing, prescribing and utilization of this product. ASCENIV offers a unique option for immunocompromised patients requiring immune globulin therapy who are at greater risk of developing RSV or other respiratory viral infections. High level of RSV neutralizing antibodies, zero serious bacterial infections, fewer hospital days, overall efficacy in RSV patients and safety were perceived major advantages. As outcomes of its unique antibody profile, ASCENIV's higher concentration of antibodies to RSV and multiple other respiratory viruses may result in preventing disease progression from upper to LRTIs and related complications and improving survival in high risk immunocompromised patients with RVIs” (ASCENIV[®] filed by ADMA BIOLOGICS, INC.)

DR. REDDY'S LABORATORIES, INC

“Sorafenib Tablets 200mg, 120ct (ANDA #216073) is the generic equivalent of an existing innovator product and is being marketed in the generic multi-source space. Accordingly, establishing the WAC price at \$15,534.96 constitutes a significant reduction in the WAC pricing of the referenced listed drug, Nexavar which, upon information and belief, was \$22,192.80 at the time Dr. Reddy's introduced Sorafenib Tablets 200 mg, 120ct into the market, representing a 30 percent reduction in price. Dr. Reddy's WAC pricing will enable it to: i) recoup the costs

it incurred in evaluating the economic and/or intellectual property landscape surrounding a prospective Sorafenib Tablets 200 mg product, sourcing the active pharmaceutical ingredient (API), sourcing excipients, conducting R&D to achieve the acceptable formulation of the product, conducting biostudies, conducting stability studies, developing analytical methods, paying GDUFA and facility fees, submitting the ANDA and responding to FDA deficiencies and inquiries; ii) cover its manufacturing costs; iii) cover the cost of any associated patent litigation, including legal and expert witness fees, if any; iv) cover distribution costs; v) provide rebates and discounts as required by partners in the supply chain; vi) compete with numerous other available generics; and vii) earn a reasonable return on investment.” (Sorafenib filed by DR. REDDY'S LABORATORIES, 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 2022 reflect increases from the average price of the drug in 2020 to the average price of the drug in 2021.

In 2022, the program received 102 annual price increase reports, each one for a different NDC, from 21 different manufacturers. This is a decrease from the 143 reports we received in 2021.

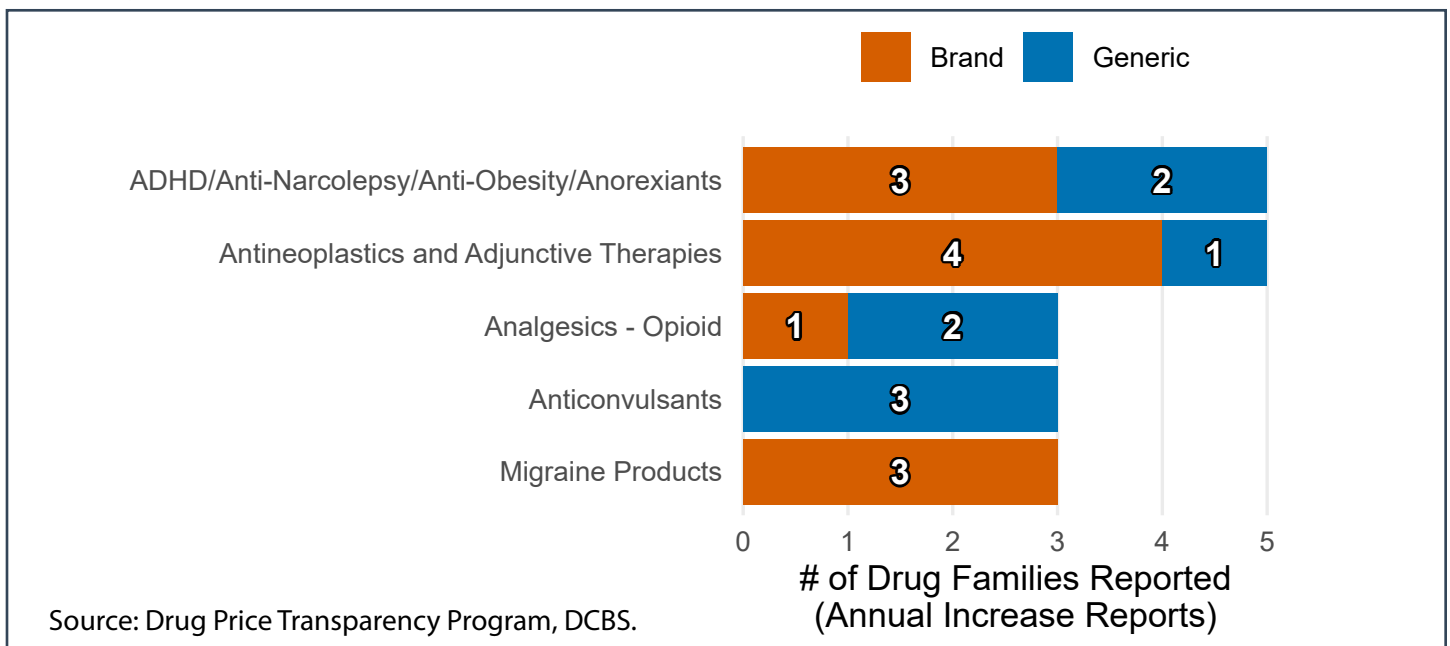
As described earlier, a single drug will generally be sold under several NDCs. For example, a manufacturer may sell two bottles of generic ibuprofen, one with 25 tablets and the other with 50 tablets. In that case, both bottles would have a different NDC, even though they are for the same drug. In our 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 22 generic drugs from five manufacturers. We also received reports for 27 brand name drugs from 16 manufacturers. Patient assistance programs were reported for 10 of the brand name drugs from six manufacturers.

The median reported price increase was 19.9 percent for generic drugs and 13.4 percent for brand name drugs.

The most common classes of drug in these reports were ADHD/anti-narcolepsy/anti-obesity/anorexiants drugs and antineoplastic and adjunctive therapy drugs, both with five reported product families. We received reports for three different brand name ADHD/anti-narcolepsy/anti-obesity/anorexiants drugs (nine NDCs from three manufacturers) and two generics (three NDCs from two manufacturers). For antineoplastics and adjunctive therapies, we received reports for four different brand name drugs (five NDCs from four manufacturers) and one generic drug (one NDC for fluorouracil from Amerisource Health Services).

Figure 8: Breakdown for brand name and generic drugs from annual price increase reports by most common classes



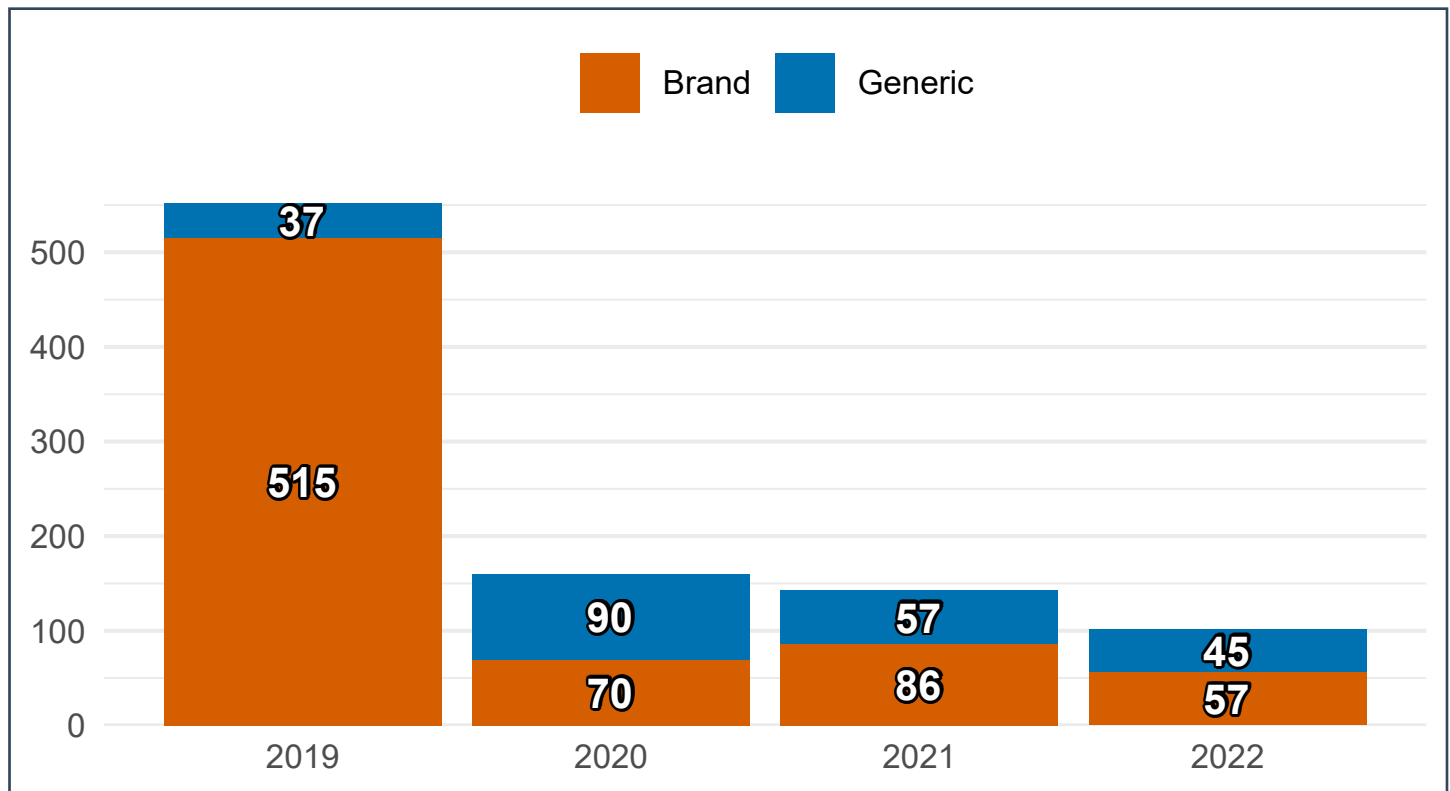
The next most common classes, each with reports for three different drugs, were opioid analgesics (20 NDCs from three manufacturers), anticonvulsants (four NDCs from Amerisource Health Services), and migraine products (three NDCs from two manufacturers).

Recent trends and market dynamics

The total of 102 price increase reports received in 2022 represents a decrease from the 143 received in 2021. This trend is generally consistent with long-term data from the overall market, which has seen a decline in total WAC increases. Decreases 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. This is evidenced in other reports on price increases showing differing frequencies for the number of price increases that have occurred.²⁴ A recent study evaluating drug prices showed a rise in the median launch price of more than 8,000 percent from 2008 to 2021, \$2,115 to \$180,087.²⁵ Cancer drugs are among the highest priced

Figure 9: Annual price increase reports from manufacturers 2019-22



Data Source: Oregon Drug Price Transparency Program

²⁴ Bosworth, Arielle, Sheingold, Steven, Finegold, Kenneth, De Lew, Nancy, and Sommers Benjamin D. “Price Increases for Prescription Drugs, 2016-2022.” Assistant Secretary for Planning and Evaluation, Office of Health Policy, Issue Brief, HP-2022-27, Sept. 30, 2022. <https://aspe.hhs.gov/sites/default/files/documents/d850985c20de42de984942c2d8e24341/price-tracking-brief.pdf>. Accessed Nov. 9, 2022.

²⁵ Rome, Benjamin S., Egilman, Alexander C., and Kesselheim, Aaron S., “Trends in Prescription Drug Launch Prices, 2008-2021.” *Journal of American Medicine*, 327 (1), 2145-2147, June 7, 2022.

prescription drugs. A review of the Food and Drug Administration and other government data sources show that self-administered cancer drugs had an increase in launch prices of 25.8 percent when comparing 2017 and 2021 inflation-adjusted prices.²⁶

Additionally, projections expect that prescription drug spending will increase in the coming years in part due to faster price growth.²⁷ Prescription drug spending growth in 2020 was increased by 3 percent which was a slower rate than 2019 due to “slower overall utilization and an increased use of coupons.”²⁸ It is projected that over 2023 and 2024 retail prescription drug spending will increase to 4.7 and 5.1 percent due to faster price growth and increased utilization.²⁹

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 that this information is a trade secret.

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

SECURA BIO, INC

“Management determined that the WAC of the drug was significantly below its respective peers, and relative to the overall value provided. Secura Bio, Inc. (“Secura”) acquired the worldwide rights to Copiktra

on September 30, 2020. ... The company's clinical investments resulted in positive clinical study results in patients with peripheral T-cell lymphoma that were reported publicly in December 2020 and which led to the inclusion of Copiktra into the relevant treatment guidelines issued by the National Cancer Care Network. Peripheral T-cell lymphoma is a rare but extremely difficult to treat form of lymphoma that historically has not had effective treatment options. Since inception in early 2019, Secura has not generated profits or positive cash flow in any time period, and as of December 31, 2021 had incurred over \$200 million of net losses and had less than \$10 million of cash on hand. ... Adjusting the pricing of Copiktra to be comparable with many of the other approved therapies for chronic lymphocytic leukemia and small lymphocytic leukemia helps to ensure that Secura will be able to continue to provide access of this important therapy to patients, and continue its clinical investments to expand the universe of patients who can benefit from the use of Copiktra.” (Copiktra[®] increased by 15.5 percent filed by SECURA BIO, INC.)

AMNEAL PHARMACEUTICALS

“Amneal made the decision to increase the WAC prices of several products after careful consideration of the company's pricing principles and internal and external factors that impact pricing. While all factors are taken into consideration when making pricing decisions, each factor is considered independently and their impact on pricing varies by product. Increases in manufacturing and distribution costs, availability, and pricing of competitive products, negotiated agreements with payers and changes to discounts/ rebates paid to insurers, GPOs, PBMs, wholesalers,

²⁶ Porter, Rep. Katie. “Skyrocketing: How Big Pharma Exploits Launch Prices to Cash in on Cancer.” Office of US Representative Katie Porter. Nov. 2, 2022. https://porter.house.gov/uploadedfiles/skyrocketing_-_how_big_pharma_exploits_launch_prices_to_cash_in_on_cancer.pdf. Accessed Nov. 9, 2022.

²⁷ “National Health Expenditure Projections 2021–2030: Forecast Summary.” Centers for Medicare & Medicaid Services. <https://www.cms.gov/files/document/nhe-projections-forecast-summary.pdf>. Accessed Nov. 9, 2022.

²⁸ “National Health Expenditures 2020 Highlights.” Centers for Medicare & Medicaid Services. <https://www.cms.gov/files/document/highlights.pdf>. Accessed Nov. 9, 2022.

²⁹ “National Health Expenditure Projections 2021–2030: Forecast Summary.” Centers for Medicare & Medicaid Services. <https://www.cms.gov/files/document/nhe-projections-forecast-summary.pdf>. Accessed Nov. 9, 2022.

or pharmacies, and increased operating costs have all played varying roles in Amneal’s pricing of its products.” (oxyMORphone HCl increased by 19.9 percent filed by AMNEAL PHARMACEUTICALS.)

PUMA BIOTECHNOLOGY, INC

“A number of factors go into the pricing of NERLYNX including manufacturing, sales and marketing costs, and investments in continued research and development. The changes in WAC pricing have been driven by several factors: 1) Narrowed patient population – NERLYNX gained FDA approval based on the two-year iDFS benefit observed in the ITT population of the ExteNET trial, which enrolled an “all-comers” patient population. ... As the ExteNET trial data matured and overall survival results including sub-group analysis were published in 2020, it was recognized that HR+ patients with a high risk of recurrence consistently derive the greatest benefit. Although NERLYNX remains the only approved treatment for the broad extended adjuvant population, our focus is on the high-risk patient population who will likely receive the greatest benefit which is a much smaller patient population than our broader ITT label at launch. The WAC increases reflect this understanding of the impact of NERLYNX in the high-risk patient population and is more consistent with pricing seen in treatments where the intended population is also small. 2) Commitment to patients – Despite 340b chargeback increases of over 5-fold since launch, we have maintained our steadfast support of current cancer patients: a. ~15 percent of Nerlynx in the U.S. is provided free of charge to patients in need. This support is expected to continue to increase. b. We estimate that our co-pay support has tripled over the last several years. Total support since launch will approach \$20 million at the end of 2022. ... 3) Expense Management – Puma is a small biotech company that has yet to be profitable. Given these realities, we have aggressively reduced

operating expenses over the last two years. ... In addition to the above, we offer off-invoice discounts on many purchases, as well as rebate opportunities to some purchasers. We have regular contact with our vendors to explore additional options. We remain committed to ensuring that price is never a barrier to patient care.” (Nerlynx[®] increased by 14.42 percent filed by PUMA BIOTECHNOLOGY, INC.)

CURRAX PHARMACEUTICALS LLC

“Currax pricing reset includes both multifaceted financial and non-financial rational: inherited business challenges which originated with the prior NDA holders, ability to meaningfully increase patient access to Contrave, evolving Contrave market dynamics and substantial investments in Contrave research initiatives. Obesity is the number two preventable cause of death in the U.S. and the number of individuals who are obese, or overweight is growing year over year. In this growing market, Currax is continually analyzing its ability to maintain product capacity to ensure demand can be fulfilled. Increased supply chain costs at all levels, including but not limited to transportation, purchase of active pharmaceutical ingredients, and overall production has been impactful. Increased competition in the market and fluctuations in the labor market are other considerations. Currax is dedicated to effectively managing these type of market dynamics to



ensure patients can maintain appropriate access to *Contrave*.” (*Contrave* increased by 9.2 percent filed by CURRAX PHARMACEUTICALS LLC.)

We receive a wide variety of reasons for increasing the price of a drug with many referring to “the market” or “government charges” or “the benefit to patients.” As Secura Bio provided above, they noticed that their price was lower than their competitors and they felt their product has more value. Most of the information provided is vague, high-level, or does not even address why there was a price increase. This information ends up not providing the insights the program looks for to more fully 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 2020 to 2021 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 23.2 percent for generic drugs and 13.4 percent for brand name drugs.

The highest reported price increase was 2,527 percent for a generic of naproxen manufactured by Hikma Pharmaceuticals (NDC 00054363063). Hikma Pharmaceuticals reported to the program on the factors contributing to this increase:

“increased costs incurred with significant capital investment required in new manufacturing equipment in order to produce quantities sufficient to meet expanded market needs. These increases are required to meet operating costs and involve only a small number of our products -- approximately one percent of our U.S. portfolio of more than 700 medicines of different doses and strengths. Please note that prices of more than 90 percent our products stayed the same or experienced a price decrease during 2021. This drug (with this same NDC) was discontinued in 2012 and out-licensed to a 3rd party by Roxane Laboratories, Inc., a company Hikma acquired. Such license expired on 12/31/2020 and this is Hikma's re-entry into the market with this product. This is initial pricing on Hikma's version of the drug. Technically, this is a price increase because of the letter of the law; for Hikma, this is more akin to a new drug launch.”

According to Medi-Span, the last WAC price for this drug in 2012 was \$34.13, and its new WAC as of Feb. 2, 2021 is \$896.44.

The second- and third-highest reported price increases were for two NDCs of generic isradipine capsules manufactured by Epic Pharma (NDCs 42806026301 and 42806026401). For the NDC 42806026301, the previous WAC price for this drug was \$96.90 (about 97 cents per capsule). It had been that price since 2015. On July 7, 2021, Epic Pharma increased its WAC price by 908 percent to \$976.37 (about \$9.76 per capsule).

For the NDC 42806026401, the previous WAC price from 2015 was \$141.71 (about \$1.42 per capsule). On July 7, 2021, Epic Pharma increased its WAC price by 597 percent to \$987.53 (about \$9.88 per capsule).

Epic Pharma reported to the program the following for the factors contributing to these increases:



“Our price increase was related to our increased discomfort, understanding, and expenses arising from statewide increases in taxation for narcotics.”

The fourth-highest reported price increase was for a generic of trimethoprim manufactured by Mayne Pharma (NDC 51862048601). Over the course of 2021, Mayne Pharma increased the WAC price of this NDC by 500 percent. Since 2016, the WAC price for this drug had been \$31.05. On March 29, 2021, Mayne Pharma increased its WAC price by 200 percent to \$93.15, and on Sept. 8, 2021, Mayne Pharma increased its WAC price by another 100 percent to \$186.30.

In each price increase report to the Drug Price Transparency Program, manufacturers must report the factors that contributed to the price increase. In this report, Mayne Pharma only entered “change in market dynamics” for those factors. When the

program reached out to request clarification, Mayne Pharma did not respond.

The fifth- and sixth-highest reported price increases were for two NDCs of generic benzphetamine hydrochloride manufactured by Epic Pharma (NDCs 42806008130 and 42806008101). The WAC price of the NDC 42806008130 was \$75 at the start of 2021. On July 1, 2021, Epic Pharma increased the WAC by 420 percent to \$390.

The WAC price of the NDC 42806008101 was \$210 at the start of 2021. On July 1, 2021, Epic Pharma increased the WAC by 352 percent to \$950. Epic Pharma reported the same factors contributing to these increases as they reported for the isradipine NDCs discussed above:

“Our price increase was related to our increased discomfort, understanding, and expenses arising from statewide increases in taxation for narcotics.”

Figure 10:

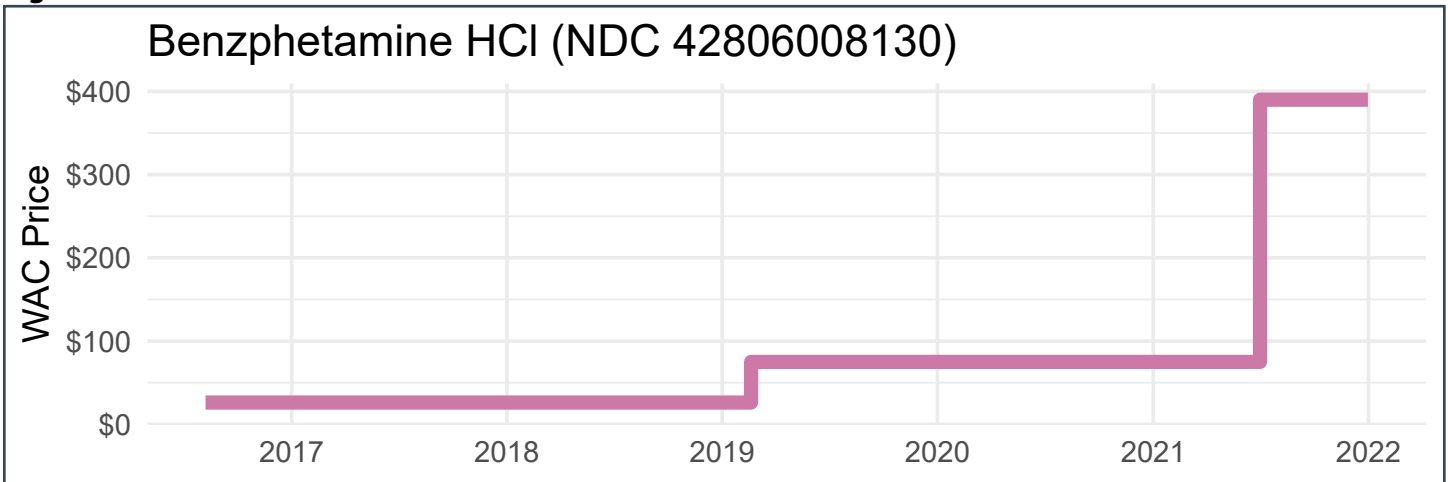
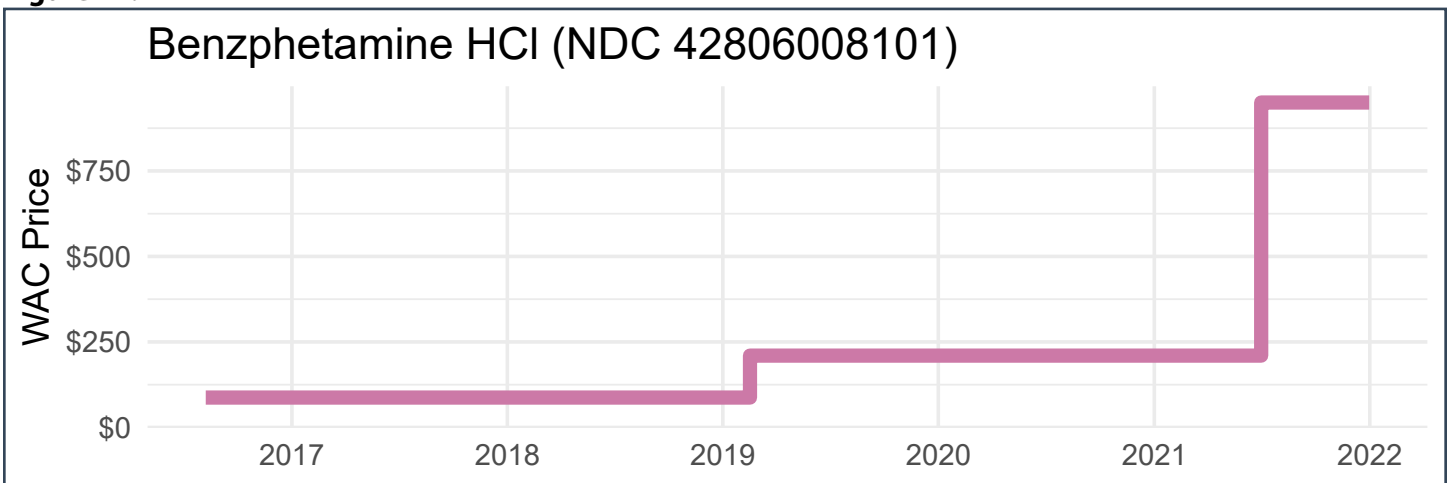


Figure 11:



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 39 drug product families (22 generic and 17 brand name) from 17 manufacturers.

Among the generic drugs, 65 percent reported positive profits (11 product families). The best performing generic drug had a profit margin of 96.3 percent. The median profit margin for generic drugs was 60.2 percent.

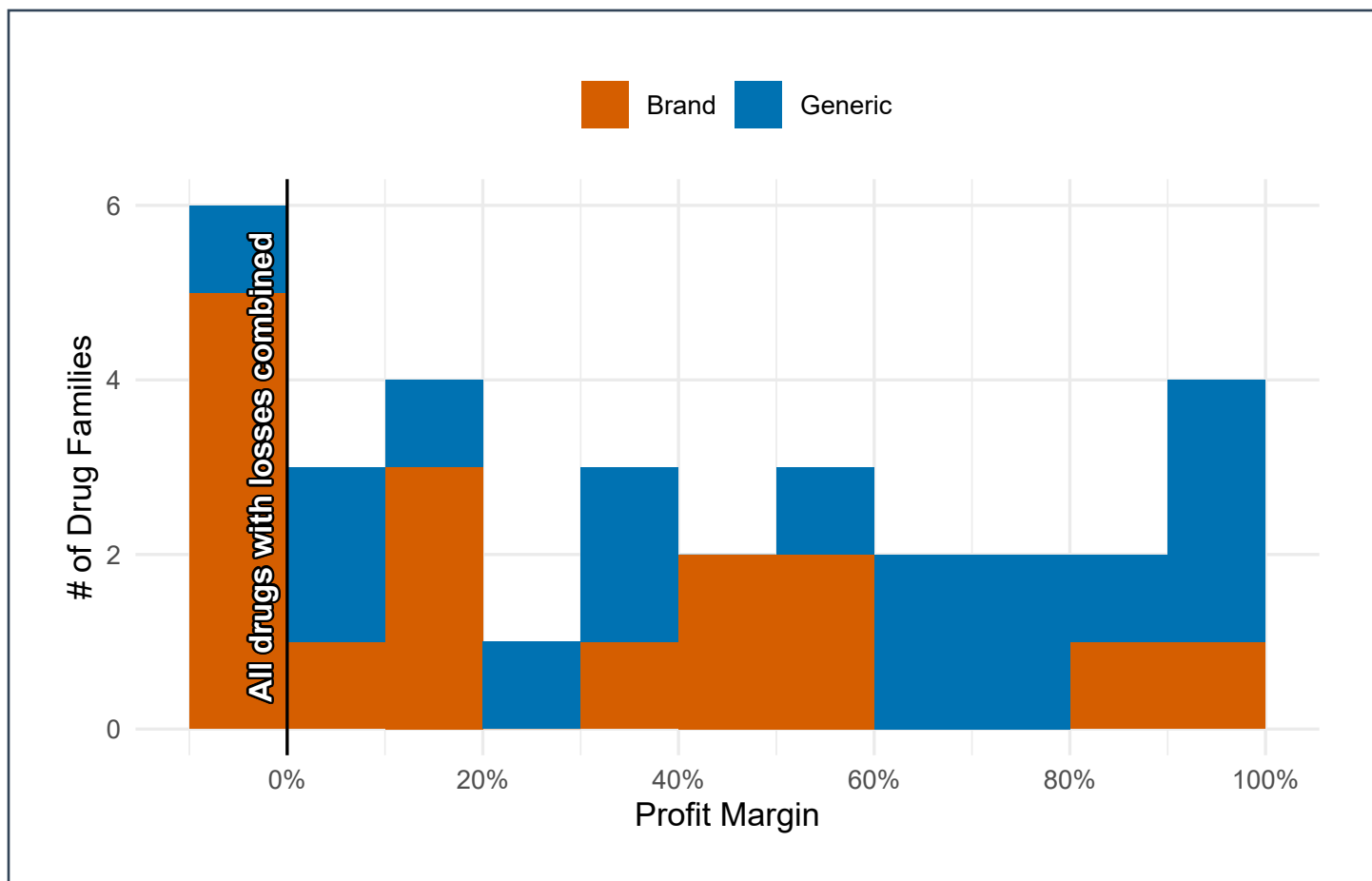
Among the brand name drugs, 65 percent reported positive profits (15 product families). The best performing brand name drug had a profit margin

of 93 percent. The median profit margin for brand name drugs was 15.6 percent.

A 93 percent profit margin means that, for every dollar of revenue brought in by the drug, 93 cents was pure profit. A drug with a 93 percent profit margin would make back its annual costs 14 times over.

This year, generic drugs tended to have higher profit margins than brand name drugs. This is similar to what we saw in last year's reports. However, two brand name product families had unusually high (more than 80 percent) profit margins this year. One explanation for some generic drugs' high profit margins is that marketing and research costs for generic drugs are generally low compared to brand name drugs.

Figure 12: Histogram of the reported profit margins for brand and generic drugs



United Therapeutics Corporation reported \$202,300,000 in revenue and \$188,100,000 in profit for Unituxin, amounting to a 93 percent profit margin. According to Medi-Span, the average WAC of the NDC 66302001401 for Unituxin over the calendar year 2020 was \$11,631.58, and the average WAC over 2021 was \$13,008.62, representing a price increase of 11.8 percent from 2020 to 2021.

Harmony Biosciences reported \$305,440,000 in revenue and \$249,992,000 in profit for Wakix, amounting to an 82 percent profit margin. According to Medi-Span, the average WAC of the NDC 72028004503 for Unituxin over the calendar year 2020 was \$2,907.74, and the average WAC over 2021 was \$3,240.45, representing a price increase of 11.4 percent from 2020 to 2021. The other reported NDC for Wakix, 72028017803, increased in price by the same percentage.

We can compare this year's numbers to last year's report. About three-quarters of the drug product families reported positive profits (39 product families). This means that last year about one-quarter of the drug product families (14 product families) reported negative profits. Half of the drugs reported profit margins of 31 percent or higher. Last year, the median profit margin was 31 percent, compared to 37.8 percent this year.

In total, the 22 generic drugs we analyzed this year reported \$52.8 million in revenue and \$45.5 million in profit, with an overall profit margin of 86.1 percent. The 17 brand name drugs we analyzed reported \$1.66 billion in revenue and \$666.9 million in profit, with an overall profit margin of 40.1 percent. Last year, the 53 drugs we analyzed reported \$2 billion in revenue and \$339 million in profit, with an overall profit margin of approximately 17 percent.

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 potential categories:

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

This year, we analyzed the reported costs for 46 drug product families (22 generic and 24 brand name) from 20 manufacturers.

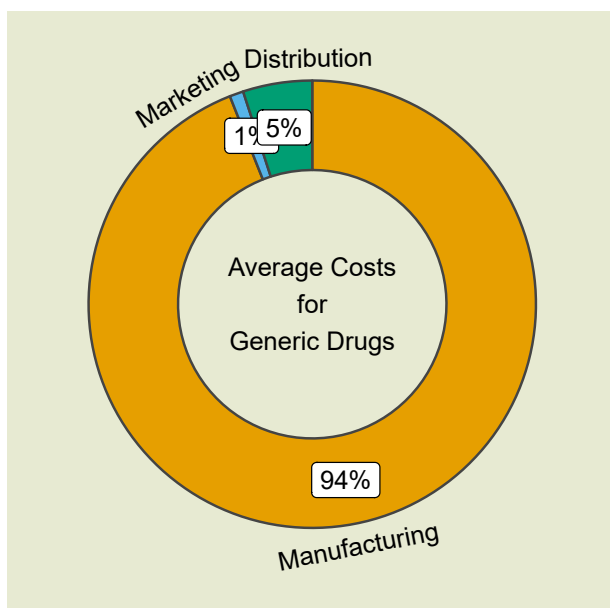
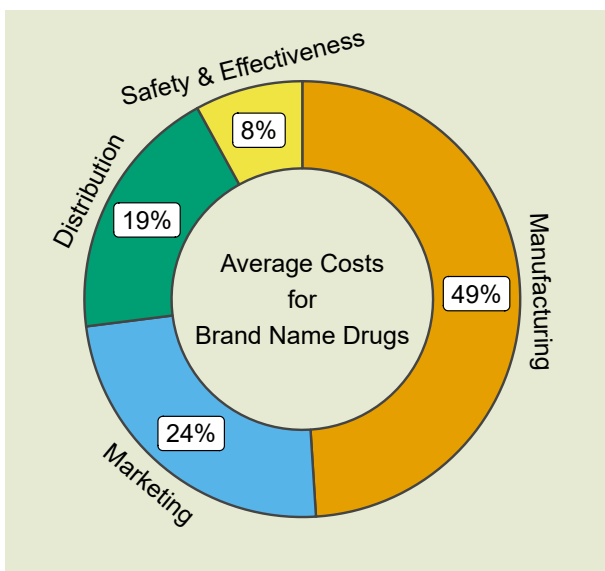
As we saw last year, manufacturers tend to spend more on manufacturing than on marketing, distribution, or safety and effectiveness research. Manufacturers tend to spend the least on ongoing safety and effectiveness research.

Among the brand name drugs, manufacturing accounted for 49 percent, marketing accounted for 24 percent, distribution accounted for 19 percent, and ongoing safety and effectiveness research accounted for 28 percent of a product family's reported costs, on average.³⁰

Among the generic drugs, manufacturing accounted for 94 percent, marketing accounted for 1 percent, distribution accounted for 5 percent, and ongoing safety and effectiveness research accounted for little to none of a product family's reported costs, on average.

³⁰ 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, and "drug" in the same context may be used to refer to a product family rather than an individual NDC.

Figures 13 and 14: Averages of direct costs from annual price increase reports – brand name and generic



In total, the 24 brand name drugs reported \$338 million in manufacturing costs, \$189 million in marketing costs, \$93 million in distribution costs, and \$12 million in ongoing safety and effectiveness research costs. The 22 generic drugs reported \$6 million in manufacturing costs, \$83 thousand in marketing costs, \$2 million in distribution costs, and zero in ongoing safety and effectiveness research costs.

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 high-cost drug reports, manufacturers overwhelmingly reported receiving no public funding for the drugs reported. Out of the 102 annual price increase reports we received, none reported nonzero amounts of public funding that were not marked as a trade secret. All reports either indicated \$0 in public funding or marked their public funding as a trade secret (or both). As noted above, the program will not agree with trade secret claims for information that is publicly available, and zero-dollar entries in a data element with a trade secret claim are generally a noncompliance issue.

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 United States 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 2021.

In the reports filed this year, manufacturers generally did not report any prices from other countries. Out of the 102 annual price increase reports we received, only six included non-U.S. prices. The remaining 96 reports did not include any non-U.S. prices.

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 refusals to provide any 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.

To monitor that all prescription drugs are reported accurately, the department has contracted with a private vendor 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.³¹

³¹ 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.

The program will continue to focus on education efforts and noncompliance warnings to increase compliance with the reporting requirements of the Prescription Drug Price Transparency Act.

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 Program from immediately publishing the data. Before publicly releasing an individual data element claimed to be a trade secret, the program must conduct a lengthy review of the manufacturer's provided justification for the trade secret claim, make a determination that the data element should be released, and give the manufacturer an opportunity to appeal the program's decision.

Many reports include invalid or unexplained trade secret claims. We met with representatives for the manufacturers submitting reports with this type of claim. 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. Insufficient trade secret claims still 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.

Across the 530 new high-cost drug reports we received in the last year, manufacturers claimed 504 individual data elements as trade secrets. The following data elements were often claimed to be trade secrets:

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

Across the 102 annual price increase reports we received, manufacturers claimed 635 individual data elements as trade secrets. 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 1,500 reports with more than 9,000 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 Drug Price Transparency Program website at <https://dfr.oregon.gov/drugtransparency/data/Pages/new-drug-reports.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 receive some voluntary reports for other market segments, such as Medicaid and large group plans.

For 2022, 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 825,000 individuals, representing around 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 both 50 mg tablets and 100 mg extended-release tablets, both would be grouped together. Then, they totaled the following:

1. The number of prescriptions for those drugs in 2021
2. The money spent by them and their policyholders on those drugs in 2021
3. The difference between the total amounts spent in 2020 and in 2021 (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 of these top 25 lists to Oregon’s Drug Price Transparency Program.

After receiving the lists from the health insurance companies, the Drug Price Transparency 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.

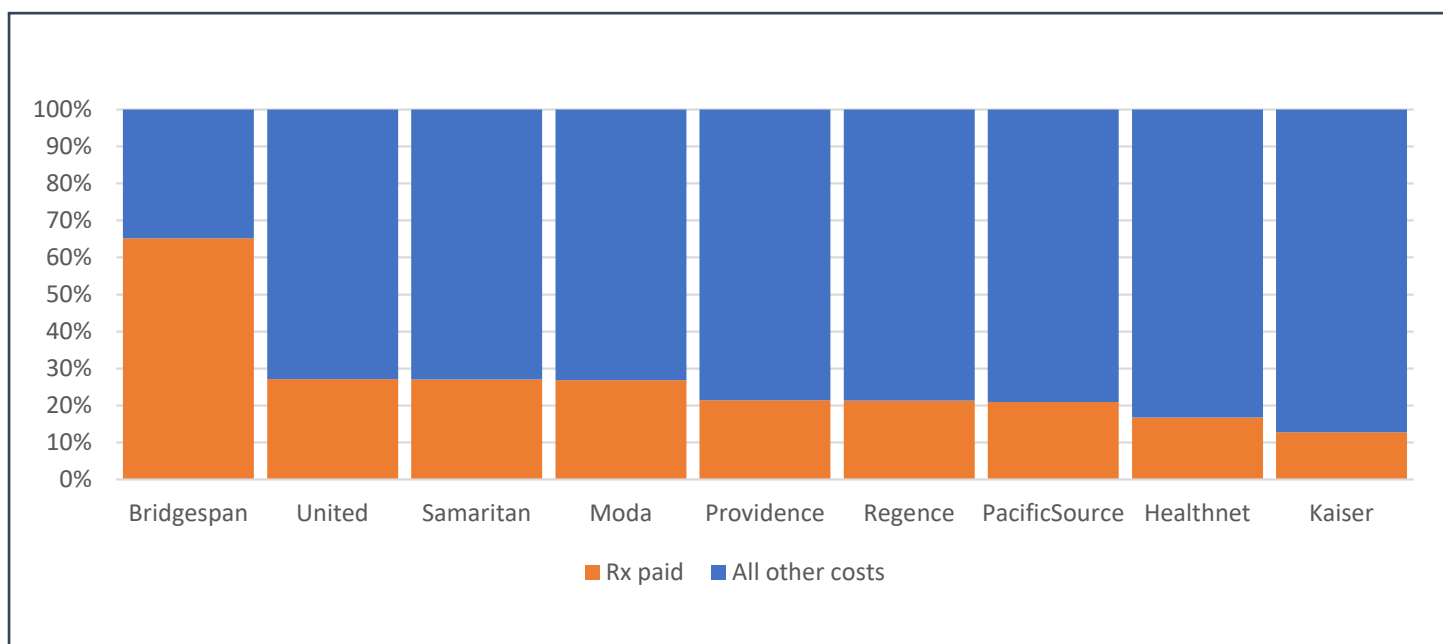
The Drug Price Transparency Program curated the insurer information within the limits of its knowledge and database resources to combine drug entries and related information. We relied heavily on the Medi-Span drug database to assess the quality of the reported data and to improve it, if possible. The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

Plan spending on prescription drugs

This year, we began collecting more specific information on drug spending as compared to total premiums collected. This allows us to measure the percentage of plan spending directed to prescription drugs, as opposed to 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 carriers did not submit data for these markets.

The first chart shows plan spending on prescription drugs as a percentage of total premiums collected. The orange bar on the bottom represents plan spending on pharmaceuticals, while the blue 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.

Figure 15: Plan spending per member per month on prescription drugs as a percentage



Kaiser and Health Net reported the lowest percent spending on prescription drugs, at 13 percent and 17 percent, respectively. All other carriers reported spending between 20 percent and 30 percent on prescription drugs, which is in line with national data suggesting that 22.2 cents of every dollar spent on healthcare goes to prescription drugs.³² However, BridgeSpan was the exception with a higher percentage spent on prescription drugs above national data.

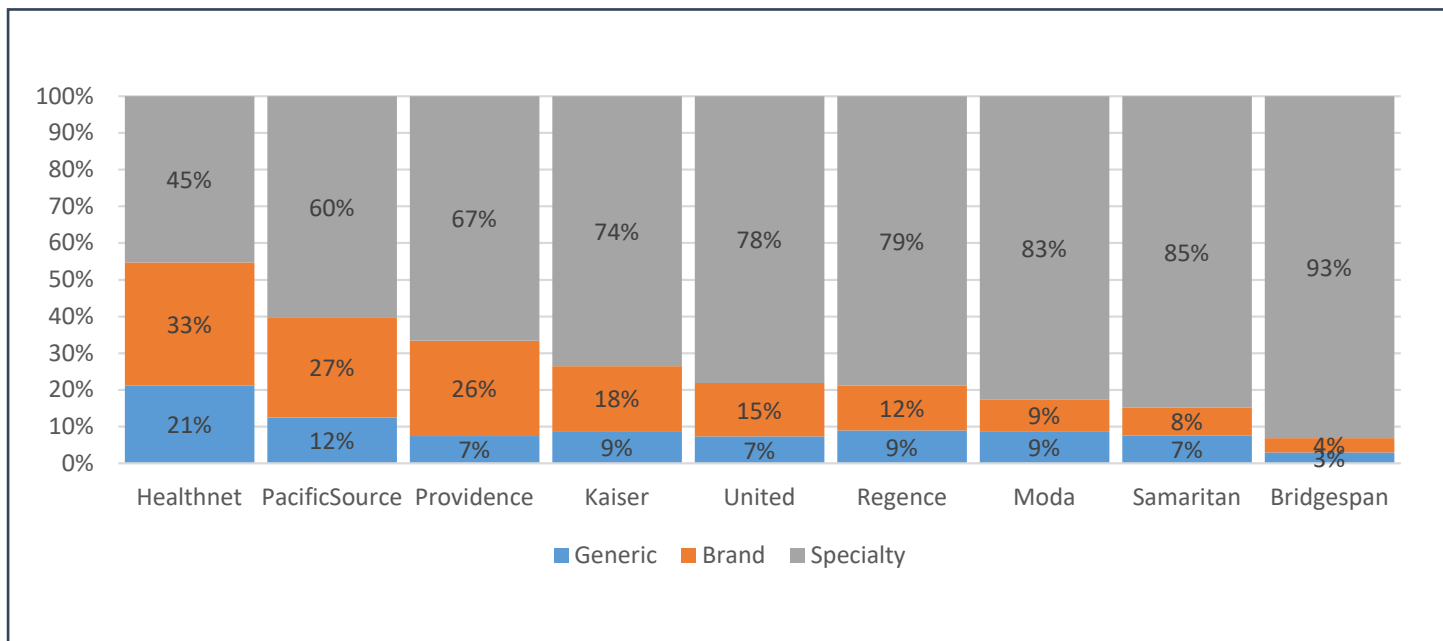
The next chart shows spending on each drug category as a percentage of total spending on prescription drugs. In our insurer data collection, we ask carriers to report data divided into three drug categories: (1) generic drugs, excluding specialty; (2) brand name drugs, excluding specialty; and (3) specialty drugs. For our purposes, consistent with program rules, 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 carriers 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.

Again, BridgeSpan stands out with 93 percent of prescription spending in the specialty category. This is due to a small population prescribed a specialty medication that was the driver of BridgeSpan's high overall pharmaceutical spending. On the other end of the spectrum, Health Net reported

Figure 16: Plan spending on prescription drugs by category (brand, generic, and specialty)



³² "Where Does Your Health Care Dollar Go?" America's Health Insurance Plans, August 2022. https://www.ahip.org/documents/202208-AHIP_HealthCareDollar-v02.pdf. Accessed Nov. 9, 2022.

the lowest proportion of pharmaceutical spending allocated to drugs in the specialty category, at 45 percent. Health Net’s low spending on specialty drugs correlates with its low overall spending on prescriptions as a percentage of premiums.

As we continue to refine the data we collect from insurers, we will be able to give more meaningful analysis in coming years. However, as this is the first year we have presented this data at a carrier-by-carrier level, it is difficult to draw conclusions about what may be driving differences between carriers.

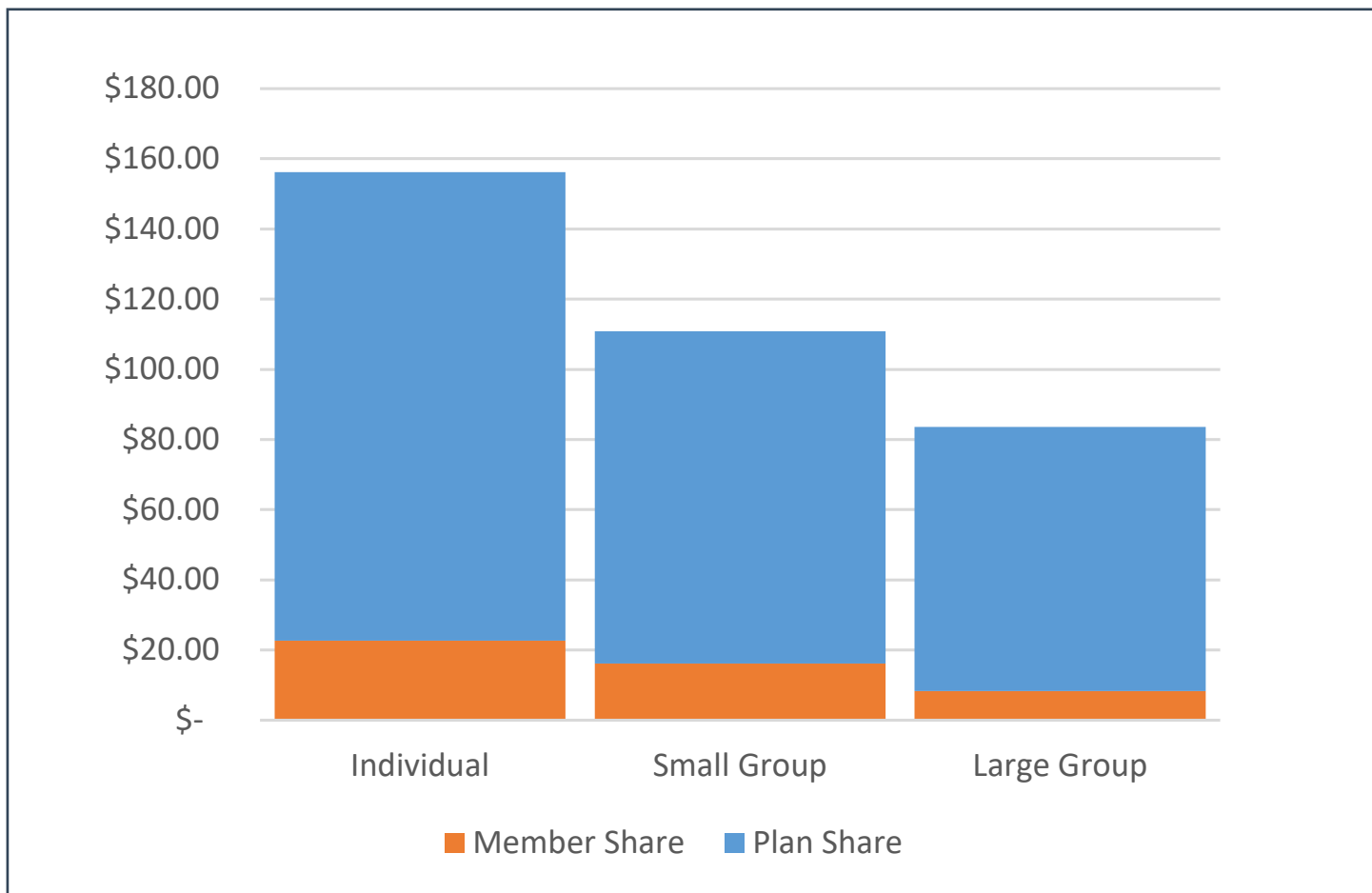
That said, there is at least one significant conclusion we can draw from this data: High-cost specialty drugs present a significant financial risk for insurance companies with small enrollment. The two companies at the extremes of the specialty drug spending chart, BridgeSpan and Health Net,

are two of the smallest companies in Oregon’s insurance market. The difference in spending between these two plans is driven by a very small number of patients and could easily have been reversed if consumers chose to enroll in different plans.

Consumer cost sharing

New data we have collected on consumer cost sharing allows us to present new analysis regarding insured consumer’s cost burden for prescription drugs. The graph below shows dollars spent on a per-member, per-month basis for individual, small group, and large group insurance plans. 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).

Figure 17: Amount spent on prescription drugs per member per month

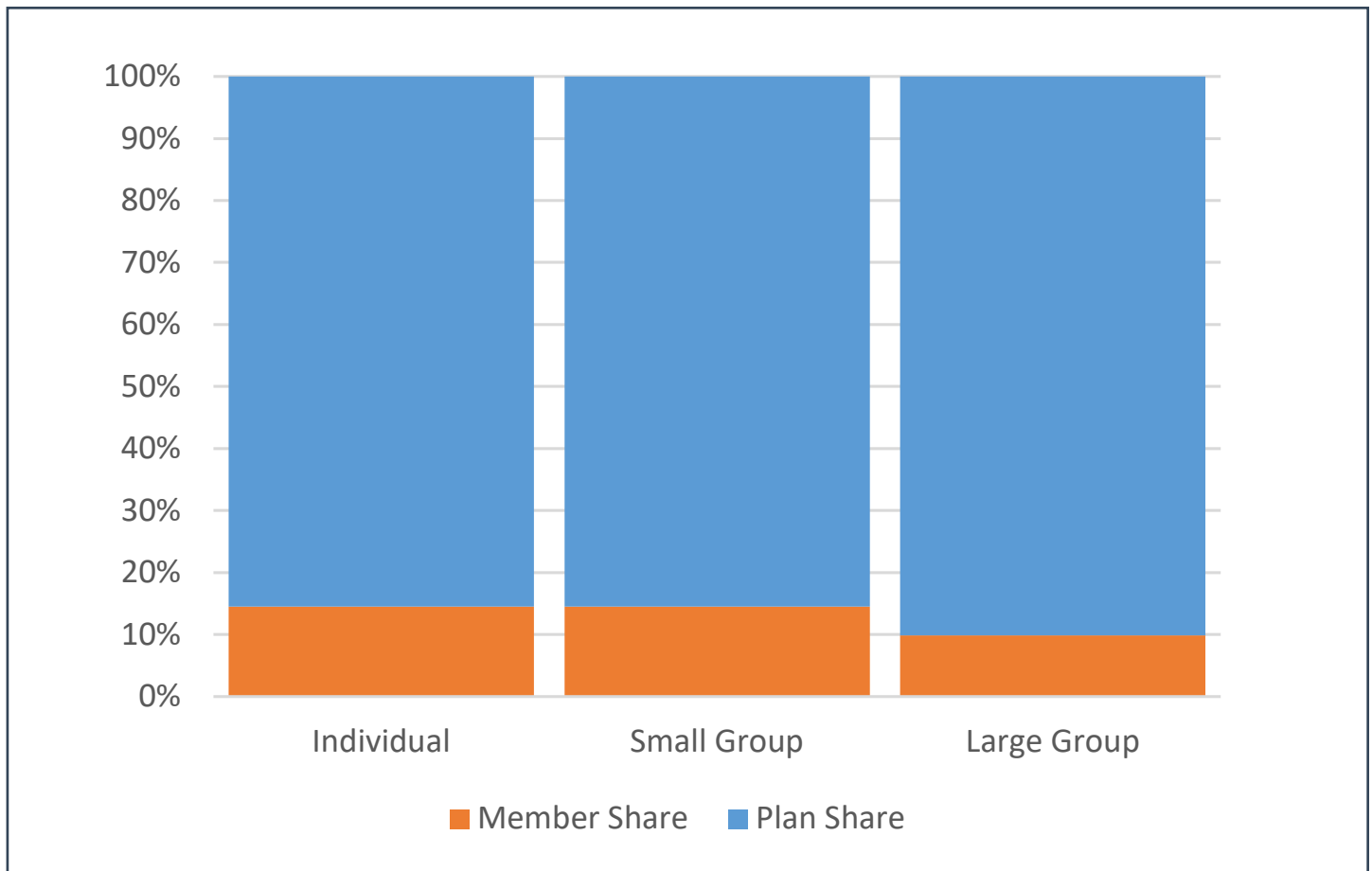


Overall, individual market plans spent the most per-member, per-month on prescriptions, averaging \$156 in total monthly spending. Plan members in the individual market spent an average of \$23 in cost sharing a month, with the plan covering \$134 of the cost of prescriptions. Small group plans spent less overall on prescription drugs, a total of \$111 per-member, per-month with the consumer paying an average of \$16 per month in cost sharing, and the plan covering \$95. Large group plans spent the least on prescription drugs on a monthly basis, an average total of \$84 per member, per month. Large group members paid average monthly cost sharing of \$8, with the plan covering \$75.

Several factors may be contributing to this difference. In general, employer sponsored plans in both 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.³³ Individual plans may also have less market power, and thus have less ability to negotiate lower prices or higher rebates from manufacturers and wholesalers.

The differences are less stark, however, when analyzing consumer cost sharing as a percent of prescription drug spending. The chart below shows member cost sharing versus plan coverage as a percent of spending on prescription drugs.

Figure 18: Percentage of prescription drug spending by member versus plan



³³ Boersma, Peter, Black, Lindsey I, and Ward, Brian W., PhD. "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 Nov. 9, 2022.

On an average basis, consumers in the individual and small group market paid about 15 percent of the cost of their prescriptions. Consumers with large group coverage paid about 10 percent of the cost of their prescriptions. This reflects a more generous prescription drug benefit design in the large group market, while individual and small group coverage (which must align with the Affordable Care Act metal tiers) is less generous.

In combination with the higher total cost paid for prescriptions, however, this places the highest drug cost burden among insured Oregonians on individuals enrolled in either individual or small group coverage.

Rebates

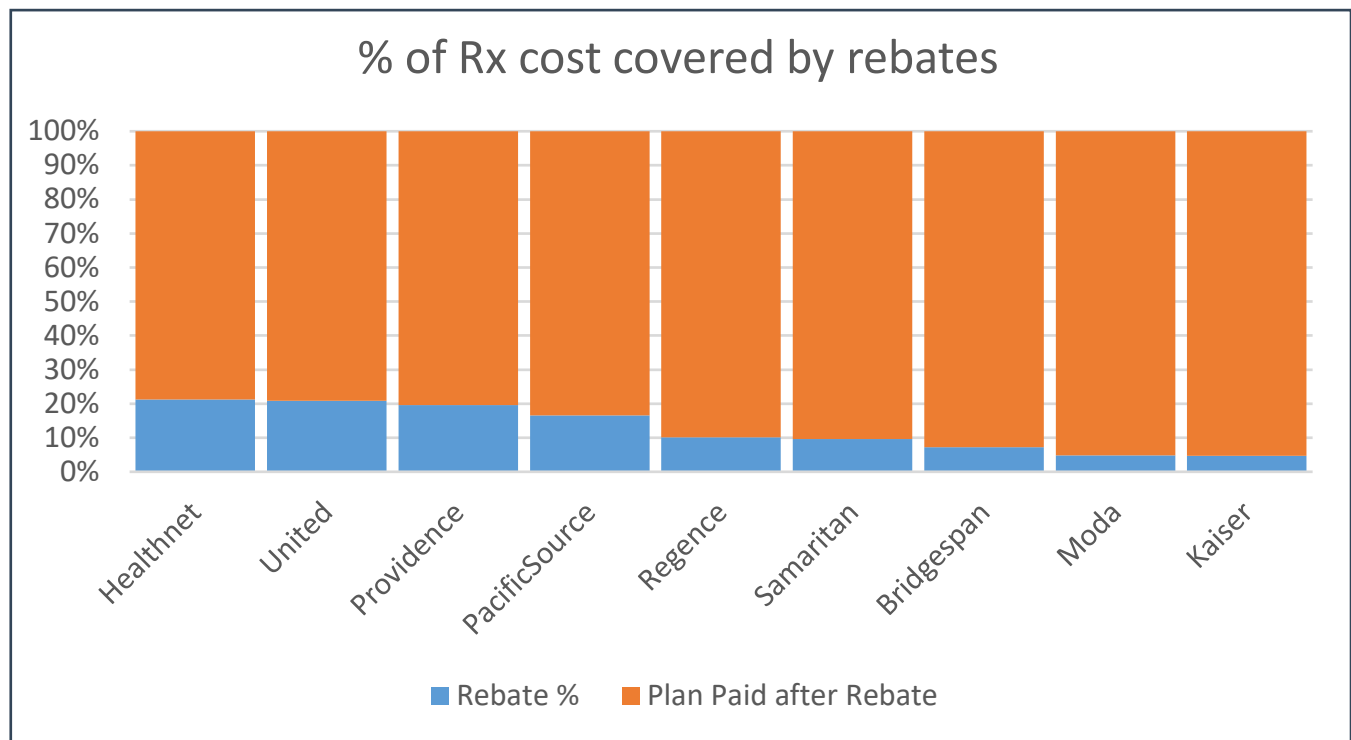
The price of a drug is influenced by many factors, but manufacturer rebates are one of the most significant. Rebates are paid to insurers and negotiated by intermediary companies known as pharmacy benefit managers (PBMs). Typically, a manufacturer will pay a rebate for a portfolio of drugs, rather than 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. This year, for the first time, we have also collected data on the total amount of rebates collected by each insurer as compared to dollars spent on pharmaceuticals. The following chart shows rebate amounts as a percentage of total spending on prescription drugs for data reported on the small group, large group, and individual markets. 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. The bars are ordered from highest to lowest amount of rebates.

Figure 19: Percentage of prescription drug spending covered by rebates versus plan cost



Health Net reported the highest rebates received as a percentage of prescription spending, at 21 percent. We do not have sufficient data to suggest whether there is a correlation between this higher rebate amount, Health Net's low overall drug spending, or Health Net's low spending on specialty tier drugs.

Moda and Kaiser reported the lowest rebates received, both about 5 percent. 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 about 7 percent of total prescription drug spending. Again, we do not have sufficient data to suggest whether this is correlated with BridgeSpan's high spending on specialty drugs, or whether rebates are available for said drugs. All other companies reported total rebates between 10 percent and 20 percent of total pharmaceutical spending.

Most prescribed drugs

The most frequently prescribed class of drugs in 2021 was vaccines, with 768,869 prescriptions

reported, and 537,155 of those prescriptions were for the mRNA COVID-19 vaccines produced by Moderna and Pfizer-BioNTech. This indicates about 65 percent of the individuals covered by this data received a COVID-19 vaccine during plan year 2021. This is unsurprising, given that the primary campaign for the COVID-19 vaccination occurred that spring; however, 231,714 prescriptions reported were for formulations of the flu vaccine, a significant drop from insurer reports for benefit years 2019 (342,608) and 2020 (383,665). We do not have sufficient data to speculate on the reason for this drop, but reduced uptake of flu vaccine in the wake of the COVID-19 pandemic may be an issue worth watching in the future.

The next most prescribed classes of drugs in 2021 were medications for blood pressure (anti-hypertensives, 284,640 prescriptions) and antidepressants (261,867 prescriptions). The cholesterol medication Atorvastatin, sometimes sold under the brand name Lipitor, remained among the most prescribed individual drugs with 194,032 prescriptions reported for 2021.



Figure 20: Top 10 most prescribed drugs

Drug	Class	Prescriptions
COVID-19 (SARS-CoV-2) mRNA Virus Vaccine <i>Moderna and Pfizer-BioNTech</i>	Vaccines	537,155
Influenza Virus Vaccine <i>Includes these brand names: Afluria, Fluarix, Flulaval, Fluzone, Flucelvax, Flublok, Fluad</i>	Vaccines	231,714
Atorvastatin Calcium <i>Includes generics and these brand names: Lipitor</i>	Antihyperlipidemics	194,032
Levothyroxine Sodium <i>Includes generics and these brand names: Euthyrox, Levoxyl, Synthroid, Thyquidity, Tirosint, Unithroid</i>	Thyroid Agents	191,047
Lisinopril	Antihypertensives	172,584
Bupropion HCl <i>Includes generics and these brand names: Wellbutrin</i>	Antidepressants	144,690
Metformin HCl	Antidiabetics	140,073
Amphetamine-Dextroamphetamine <i>Includes generics and these brand names: Adderall, Mydayis</i>	ADHD/Anti-Narcolepsy/ Anti-Obesity/Anorexiant	130,632
Escitalopram Oxalate <i>Includes generics and these brand names: Lexapro</i>	Antidepressants	117,177
Losartan Potassium	Antihypertensives	112,056



biosimilar products for the drug are brought to market. While Humira manufacturer AbbVie's original patent on Humira expired in 2016, the company has successfully used a portfolio of 132 secondary patents to block competitors from entering the market. The first biosimilar for Humira is expected to begin marketing in 2023, and any potential savings would be reflected in our insurer reporting for the 2024 report.

Other notable drugs responsible for high levels of plan spending are Biktarvy, an antiviral used in Pre-

exposure Prophylaxis ("PrEP") treatment for HIV/AIDS, and the COVID-19 mRNA vaccines. Plans reported \$23,245,660 in spending on Biktarvy in 2020. Total reported spending for the COVID-19 vaccines was \$20,679,117, an average of \$38.50 per prescription. It should be noted, that because all doses of COVID-19 vaccine administered in the United States to date were directly purchased by the federal government, these costs are solely associated with the cost of dispensing and delivering the shots to patients, and do not represent the cost of purchasing the drug.

Most costly drugs

Insurer reporting of the most costly drugs reflects the drugs with the highest total payments made on behalf of covered members, including payments made by carriers and member cost sharing, such as co-pays and co-insurance. 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 auto-immune 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 drug for four years running. In 2021, companies reported \$76,966,470 in spending on Humira, a decrease of about 16 million as compared to reported spending in 2020 (\$93,544,597). We do 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 – for example, individuals moving to Medicaid coverage during the pandemic.

However, spending on Humira in coming years should be monitored as the first competitive



Figure 21: Top 10 most costly drugs

Drug	Class	Prescriptions
Adalimumab <i>Brand name: Humira</i>	Analgesics - Anti-Inflammatory	\$76,966,470
Ustekinumab <i>Brand name: Stelara</i>	Dermatologicals	\$35,999,195
Etanercept <i>Brand name: Enbrel</i>	Analgesics - Anti-Inflammatory	\$28,675,010
Bictegravir-Emtricitabine-Tenofovir Alafenamide Fumarate <i>Brand name: Biktarvy</i>	Antivirals	\$23,245,660
COVID-19 (SARS-CoV-2) mRNA Virus Vaccine <i>Moderna and Pfizer-BioNTech</i>	Vaccines	\$20,679,117
Elexacaftor-Tezacaftor-Ivacaftor <i>Brand name: Trikafta</i>	Respiratory Agents	\$17,964,545
Secukinumab <i>Brand name: Cosentyx</i>	Dermatologicals	\$17,770,873
Pembrolizumab <i>Brand name: Keytruda</i>	Antineoplastics and Adjunctive Therapies	\$16,463,259
Vedolizumab <i>Brand name: Entyvio</i>	Gastrointestinal Agents	\$14,872,464
Ocrelizumab <i>Brand name: Ocrevus</i>	Psychotherapeutic and Neurological Agents	\$11,115,070

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.

As with the most prescribed and most costly lists for our data on 2021 claims, the COVID-19 mRNA vaccine stands out as the drug associated with

the largest increase in plan spending from 2020 to 2021. Plans reported a year-over-year increase of \$17,866,475 for the two COVID-19 mRNA vaccines. Note that this is \$2,812,642 less than the spending reported during 2021, indicating around about \$3 million in claims costs occurred during the last months of 2020, when the vaccines first became available.

In previous reports, this list has often been filled with newly released drugs or established drugs with a newly discovered clinical indication. This makes sense, as a year-over-year comparison is an increase from zero. However, this year, with the exception of the aforementioned COVID-19 vaccines, all of the drugs on this list are established products. This indicates that the increases seen here must have been driven either by price increases or

increased utilization. Unfortunately, we do not have sufficient data to indicate which.

It is also possible that there has been a low number of successful new drug releases, in part due to the ongoing COVID-19 pandemic. As we begin to collect data for plan years 2022 onward, we may be able to determine whether any of these trends are associated with the pandemic or reflective of other changes in the market.

Figure 22: Top 10 drugs with the greatest increases in plan spending

Drug	Class	Prescriptions
COVID-19 (SARS-CoV-2) mRNA Virus Vaccine <i>Moderna and Pfizer-BioNTech</i>	Vaccines	\$17,866,475
Ustekinumab <i>Brand name: Stelara</i>	Dermatologicals	\$7,623,454
Elexacaftor-Tezacaftor-Ivacaftor <i>Brand name: Trikafta</i>	Respiratory Agents	\$4,906,302
Semaglutide <i>Includes these brand names: Ozempic, Rybelsus, Wegovy</i>	Antidiabetics	\$3,092,976
Risankizumab-rzaa <i>Brand name: Skyrizi</i>	Dermatologicals	\$3,088,360
Pembrolizumab <i>Brand name: Keytruda</i>	Antineoplastics and Adjunctive Therapies	\$3,072,226
Ocrelizumab <i>Brand name: Ocrevus</i>	Psychotherapeutic and Neurological Agents	\$3,046,577
Emtricitabine-Tenofovir Disoproxil Fumarate <i>Includes generics and these brand names: Truvada</i>	Antivirals	\$2,848,130
Pertuzumab <i>Brand name: Perjeta</i>	Antineoplastics and Adjunctive Therapies	\$2,771,539
Lenalidomide <i>Brand name: Revlimid</i>	Immunomodulators	\$2,628,811

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 most costly 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 impact 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. 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 carriers 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 “co-pay 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.

Accordingly, 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 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 co-pay accumulators in developing future policy.

Health insurer reporting

Recommendation 2: Expand reporting to more insurers

Under the Prescription Drug Price Transparency Act, health insurance companies are required to submit specified information about prescription drug spending and use, including the top 25 most costly drugs and the top 25 most prescribed drugs, as part of the annual rate filing process. Because companies are required to submit rate filings only if they offer individual or small group health benefit plans, some health insurers that do not participate in these markets are not required to submit these reports. This may result in an incomplete picture of health plan spending on drugs in Oregon.

We recommend legislators consider separating the health insurance company reporting requirement from the rate review process and require it as a separate annual report from all health benefit plan issuers in Oregon.

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 working to address prescription drug price transparency. Manufacturers are required

to report to DCBS when price increases or new high-cost drugs occur. Health insurers are subject to regulatory oversight from DCBS including monitoring costs to consumers and reporting of drug information. Other entities in the supply chain, such as PBMs, are required to register with DCBS and follow state laws regarding their interactions with pharmacies. PBMs are also required to report on rebates to the Oregon Health Authority. Reporting requirements also exist for entities such as hospitals and providers as Oregon monitors the cost growth benchmark for rising health care spending.

These policy measures address pieces of transparency across the supply chain; however, there are still gaps in transparency. We recommend the legislature consider transparency across the pharmaceutical supply chain, particularly to entities with no reporting or regulatory oversight, to fully understand what influences and contributes to the price of the drug. This includes aspects of the pharmaceutical supply chain that may impact 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: Continue to consider implementing an “upper payment limit” for certain drugs

During the 2021 session, the legislature authorized creation of the Prescription Drug Affordability Board within DCBS. Working with the data developed by Oregon’s Drug Price Transparency Program, the board is empowered to study drug costs and perform affordability reviews of certain high-cost drugs. However, the board’s ability to act on the findings of an affordability review by setting an upper payment limit for a drug in Oregon was removed from the final bill.

As a concept, an upper payment limit would be a state-level analog to the pharmaceutical rate

setting that exists in some form in most wealthy nations, or the recently created price “negotiation” authority created for Medicare by the federal Inflation Reduction Act of 2022. Several other states have also established drug affordability boards, and two of these state entities have upper payment limit authority. However, no state has attempted to implement or enforce an upper payment limit, and the actual affect of such a decision is untested. Without additional information, it is impossible to assess whether this expanded authority would provide benefit to the people of Oregon.

We recommend that the legislature continue to examine the use of upper payment limits, including the potential for legal challenges and operational difficulties in implementation of the policy.

Recommendation 5: 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 state to create a state operated generic drug manufacturer, CalRx. This new entity is directed to contract with other generic manufacturers and act as a relabeler, with the long-term goal of establishing its own manufacturing capacity. CalRx would provide a supply of 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 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 multi-state purchasing entity. We 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 both 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, we recommend 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, we recommend 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.

Consumer notification reporting

Recommendation 6: Protection of consumer-reported information

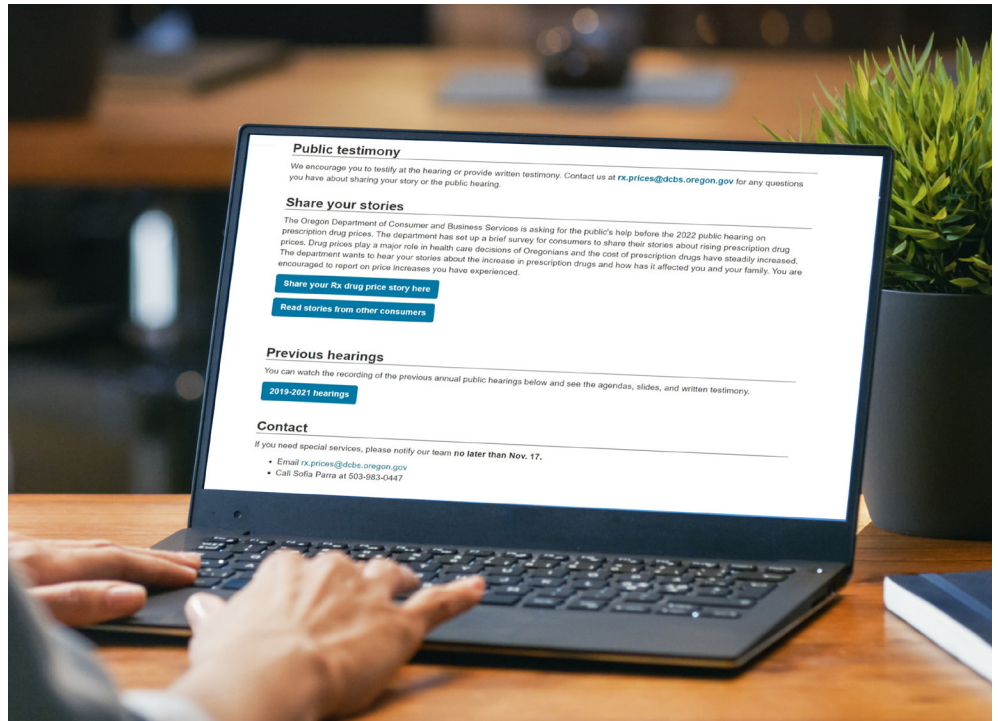
Consumer reports on the price increases of the prescription drugs they take is an essential component to the program. When consumers report to the program, they submit specific information about the drug they are reporting on, which the program uses to compare against the information submitted by drug manufacturers and health insurers. Also, consumers report their ZIP code, health insurance information, and the reasons for the price increase.

This information is important for policymakers and stakeholders to know what is being reported to the department from the consumer perspective; however, collectively, the information could potentially identify a consumer. We recommend clarifying that the personally identifiable information collected will be protected from public disclosure.

Program improvements

Recommendation 7: Data sharing between state agencies working on drug pricing

We have previously recommended that the state consider expanded transparency for more pharmaceutical supply chain entities. Despite



gains in transparency due to the work of this program and others, many aspects of drug pricing remain quite opaque. This is particularly true of manufacturer rebates and pharmacy benefit managers (PBMs). Other than a drug's "list" price, rebates are likely the largest single factor influencing the actual cost of a given drug to the health care system. Drug manufacturer rebates are negotiated by PBMs, and are kept a closely held secret – in many cases, a PBM may keep rebate information secret from their client insurance companies.

As part of its work to support Oregon's Sustainable Health Care Cost Growth Benchmark, OHA has begun to collect information on rebates from PBMs. We recommend that the state agencies that collect drug pricing information, including DCBS and OHA, collaborate to share critical information where it is already being collected by one or the other. This data sharing will reduce compliance and regulatory burden on reporting entities by avoiding duplicative work, and enable better, more informed analysis by both agencies.

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 last few years include:³⁴

- 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, 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, 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 pharmacy benefit managers.

- Coupons and cost sharing: Some states are regulating or prohibiting the use of discounts or coupons by specified pharmaceutical supply chain entities. Many states are limiting cost-sharing on insulin drugs for certain situations.
- Pharmacy benefit managers: Almost all states are regulating or providing additional transparency on the actions of pharmacy benefit managers, such as preventing discrimination against certain protected entities, or preventing pharmacy benefit managers from being able to hold a pharmacy or pharmacist responsible for any fees related to certain processes.

³⁴ “State Drug Pricing Laws: 2017-2022.” National Academy for State Health Policy, Aug. 26, 2022, bullets derived from this list. <https://www.nashp.org/rx-laws/>. Accessed Oct. 10, 2022.

Conclusion

Oregon's Prescription Drug Price Transparency Program has been collecting and analyzing the information received from drug manufacturers, health insurers, and consumers for four 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:

- The majority of insurers spend about 20 percent to 30 percent of all plan spending on prescription drugs, with Kaiser and Health Net reporting the lowest percent spending on prescription drugs, at 13 percent and 17 percent, respectively. BridgeSpan was the exception with a higher percentage spent on prescription drugs above national data.
- Most health insurers reported receiving between 10 percent and 20 percent of total pharmaceutical spending in rebates. Health Net reported the highest rebates received as a percentage of prescription spending at 21 percent. Moda and Kaiser reported the lowest rebates received, both at about 5 percent. The program does not have sufficient data to suggest whether there are any correlations between rebates and spending within the prescription drug data.
- Humira continues to be the most costly drug contributing to more plan spending than any other drug for four years running. In 2021, health insurance companies in Oregon reported \$76,966,470 in spending on Humira.
- Antineoplastics and adjunctive therapies, which are used to treat cancer, were the most frequent category of new high-cost drugs reported to the program. The highest WAC for a brand name drug was \$465,000 for Janssen Biotech's Carvykti, a treatment for multiple myeloma cancer.
- The six largest price increases were for generic drugs. The median price increase reported for generic drugs was 19.9 percent, and the median price increase reported for brand name drugs was 13.4 percent. The largest price increase reported to the program in 2022 was a 2,527 percent increase for a generic of naproxen manufactured by Hikma Pharmaceuticals. The last historical WAC price for this drug was \$34.13 in 2012, and its new WAC, as of Feb. 2, 2021, was \$896.44.
- 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 1,500 reports with more than 9,000 data elements claimed as trade secrets.
- 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.

Resources

For more information about the Drug Price Transparency Program, visit <https://dfr.oregon.gov/drugtransparency/Pages/index.aspx>.

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@dcbsoregon.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-information-consumers/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: 2020 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:

$$\frac{(\$637.37 - \$572.68)}{\$572.68} \times 100 = 11.3\%$$

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:

$$\frac{(\$(\text{average 2021 list price}) - \$(\text{average 2020 list price}))}{\$(\text{average 2020 list price})}$$

Appendix B – Types of plans for insurer reports received in 2022

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