



Prescription Drug Price Transparency
Results and Recommendations – 2020
As required by House Bill 4005 (2018)



About DCBS:

The Department of Consumer and Business Services is Oregon's largest business regulatory and consumer protection agency. For more information, visit <https://www.oregon.gov/dcbs/>.

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The Division of Financial Regulation 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.

This report is based on all data submitted to the program through Oct. 15, 2020.

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Executive summary

Background

More than half of adults in the United States from 18 to 64 years old received a prescription drug in 2017.¹ Prescription use tends to increase with age – nearly 7 in 10 adults ages 40 to 79 used at least one prescription drug in the past 30 days in the United States, and about 1 in 5 used five or more prescription drugs.² Prescription drugs provide therapeutic benefits for many of the diseases and conditions that people face in their lifetime. However, the out-of-pocket costs to people and reimbursement costs to health insurers can be an access barrier for prescription medications.

In 2018, the Oregon Legislature passed the Prescription Drug Price Transparency Act to increase prescription drug transparency as the first step to understanding the pharmaceutical industry and the factors contributing to high prices for prescription drugs.

Program overview

The Prescription Drug Price Transparency Act directed the Oregon Department of Consumer and Business Services to establish a transparency program to collect and publish certain information about the pricing of prescription drugs.

The goal of the act is to provide accountability for prescription drug pricing through the notice and disclosure of specific drug costs and price information. The program collects information from prescription drug manufacturers, health insurance companies, and consumers.

Pharmaceutical manufacturers are required to report information to the department on the following:

- New prescription drugs costing more than \$670 a month upon introduction (or for a shorter course of treatment). This price is the threshold for Medicare Part D's specialty tier, as set by the Centers for Medicare and Medicaid Services.
- Annual price increases for drugs costing more than \$100 a month (or for a shorter course of treatment) that have experienced a 10 percent net increase over the course of the previous calendar year.
- Sixty days in advance of planned price increases. This applies to an increase within a twelve-month period of at least 10 percent or \$10,000 for brand-name drugs; or 25 percent or \$300 for generic drugs. (The requirements stated in this bullet were established by 2019 HB 2658.)

Health insurance companies in Oregon are required through the rate review process to provide information on the top 25 drugs for various categories – most frequently prescribed, most costly, and those causing the greatest increase in insurance spending. Due to our changes in data collection methodology for insurer reports between 2019 and 2020, the data is not directly comparable between the two years of the program, and our analysis is limited to information reported by insurers in 2020.

Consumers may report to the department any price increases they experience when purchasing

¹ Centers for Disease Control and Prevention. *QuickStats: Percentage of Adults Aged ≥ 18 Years Who Were Prescribed Medication in the Past 12 Months, by Sex and Age Group* — *National Health Interview Survey, 2017*. MMWR Morb Mortal Wkly Rep 2019; 68:97. <http://dx.doi.org/10.15585/mmwr.mm6804a6external> icon, visited November 2019.

² Centers for Disease Control and Prevention. *Prescription Drug Use Among Adults Aged 40-79 in the United States and Canada* – NCHS Data Brief No. 347, August 2019. Retrieved at: <https://www.cdc.gov/nchs/products/databriefs/db347.htm>, on December 2, 2020.



prescription drugs, and are encouraged to share personal stories and questions about drug pricing to the department.

Results

Oregon's Prescription Drug Price Transparency Program is one of the first in the nation to be fully implemented and has been collecting data for nearly two years. By analyzing the information received from drug manufacturers, health insurers, and consumers, 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 during the first two years of program implementation, the program has made the following key findings in its 2020 report:

- Most of the new, high-cost drugs reported to the program are generics, but all of the most expensive drugs reported are brand names. Cancer drugs were consistently the most expensive drugs in Oregon on both a list price and per-patient basis, and the highest-cost drug reported in 2020 was Tecartus, a cancer drug with a price of \$373,000 for each dose.
- High prices for new drugs appear to be driven, in part, by the relative cost of established drugs that treat the same condition. This includes treatments for cancer, multiple sclerosis, and rheumatoid arthritis. A similar trend was found in a generic version of the drug Daraprim, which gained notoriety after Martin Shkreli's Turing Pharmaceuticals raised its price more than 5,000 percent in 2015.
- Prescription drug manufacturers submitted 70 percent fewer price increase reports to the state in 2020, compared to 2019. The reasons for this trend are unclear, but do not seem to be related to reduced compliance with reporting requirements. One explanation suggested by the data is that manufacturers are spreading price increases more widely across their portfolio of drugs to avoid triggering transparency requirements.
- Most drugs with price increases were profitable during 2019, with an average profit margin of 19 percent. For the filings we analyzed, half had profit margins of 37 percent or more, with six reporting a profit margin of more than 80 percent, meaning they make 80 cents of pure profit for every dollar of revenue from the drug.
- Humira and Enbrel, both treatments for autoimmune diseases, including rheumatoid arthritis, were the two most costly drugs for Oregon insurers in 2019, with a combined \$114,280,202 in claims paid in 2019. The most expensive drug in 2019 on a per-prescription basis was the cancer drug Yervoy, with \$43,525 spent on average per prescription.

Recommendations

The Prescription Drug Price Transparency Act directs the department to provide the legislature with recommendations for legislative changes to contain the cost of prescription drugs and reduce the effect of price increases. Several of the recommendations offered are suggested improvements for the program to receive better quality data and help inform future policy recommendations. Note: Not all recommendations require legislation.

General program recommendations

- 1. Provide statutory access to the All Payer All Claims (APAC) Database** – Currently, DCBS does not have direct access to the database, but works closely with the Oregon Health Authority when this data is needed. We recommend the legislature include DCBS within the APAC statutes³ to provide direct access to the data to further improve program analyses.
- 2. Evaluate the program's expenditure limitation** – Several unanticipated factors underscore the need for the legislature to evaluate the current expenditure limitation for the Prescription Drug Price Transparency Program. We recommend the legislature work with the department to evaluate the program's expenditure limitation and determine how to properly adjust this based on the unanticipated factors contributing to higher expenses by spring 2021.
- 3. Ongoing program evaluation** – We will continue to evaluate the program. This may result in recommendations to the legislature or changes the department can make to improve the overall program. Improvements may include changes to help manufacturers efficiently submit reports, internal changes to better administer the program and its deadlines, and any other changes that improve the program for the agency and its stakeholders.

Manufacturer reporting recommendations

- 4. Simplify the threshold for annual price increase reports** – House Bill 2658 (2019), which created the 60-day advance notice requirement, contains different threshold price reporting terms than those in the Prescription Drug Price Transparency Act. We recommend changing the Prescription Drug Price Transparency Act statutory language regarding the threshold for annual price increase reports to conform to House Bill 2658 terms.
- 5. Patient assistance reporting for new drug reports** – New drug reports currently do not include any patient assistance information to the program, despite several new drugs coming to market with patient assistance. We recommend the legislature consider including patient assistance reporting for new high-cost drugs reported to the program to improve understanding on these programs.

Health insurer recommendations

- 6. Expand reporting to additional insurers** – Health insurance carriers are required to submit rate filings only if they offer individual or small group health benefit plans. Therefore, health insurers that do not participate in these markets are not required to submit these reports. 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.

Consumer notification recommendation

- 7. Protection of consumer reported information** – When consumers submit reports 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. Additionally, consumers report their ZIP code, health insurance

³ Oregon Revised Statutes 442.373



information, and the reasons for the price increase. We recommend clarifying that the personally identifiable information collected will be protected from public disclosure.

Other recommendations

8. Transparency across the pharmaceutical supply chain – The price of a prescription drug is influenced by several factors. This includes the interactions and financial negotiations between pharmaceutical supply chain entities. Several of these entities can influence the price of the drug to the consumer at the pharmacy counter, through their health insurance premium, or how drug costs contribute to overall health care system costs. We recommend the legislature consider transparency across the pharmaceutical supply chain entities to fully understand what influences and contributes to the price of the drug.

9. Program structure for current and future transparency requirements – In 2019, the legislature passed House Bill 2658, which requires the department to receive advance notices for certain drug price increases. This new statute, while similar to the Prescription Drug Price Transparency Act, is completely separate. As the legislature considers more prescription drug transparency requirements, we recommend integrating current and future transparency requirements to standardize the infrastructure and resources such as funding, rulemaking, and enforcement authorities.

The program will continue to build upon the information received in its first two years to continue improving the program and to expand our understanding of prescription drug pricing and the effects of high-cost prescription drugs. As more information is received, the program will engage in analyses to further inform policies to reduce the cost of prescription drugs to Oregonians.

Background

More than half of adults in the United States from 18 to 64 years old received a prescription drug in 2017.⁴ Prescription use tends to increase with age – nearly 7 in 10 adults ages 40 to 79 used at least one prescription drug in the past 30 days in the United States, and about 1 in 5 used five or more prescription drugs.⁵ Prescription drugs provide therapeutic benefits for many of the diseases and conditions people face in their lifetime. However, the out-of-pocket costs to people and reimbursement costs to health insurers can be an access barrier for prescription medications.

A recent poll by the Kaiser Family Foundation found that 1 in 4 adults and seniors say it is difficult to afford their prescription drugs, including about 1 in 10 who say it is “very difficult.”⁶ While a majority of Americans (56 percent) believe that prescription drugs developed in the past 20 years have made the lives of people in the United States better, nearly 8 in 10 (79 percent) said that the cost of prescription

drugs is “unreasonable.”⁷ Around 30 percent of Americans reported not taking their medications as prescribed because of the cost, and about 1 in 3 who did so reported that their health worsened as a result of doing so.⁸

The poll also asked participants about the reasons behind rising prescription prices. About 80 percent of Americans view drug manufacturer profits as a “major factor” contributing to the cost of prescription drugs, but a majority (63 percent) also point to the profits made by pharmacy benefit managers.⁹

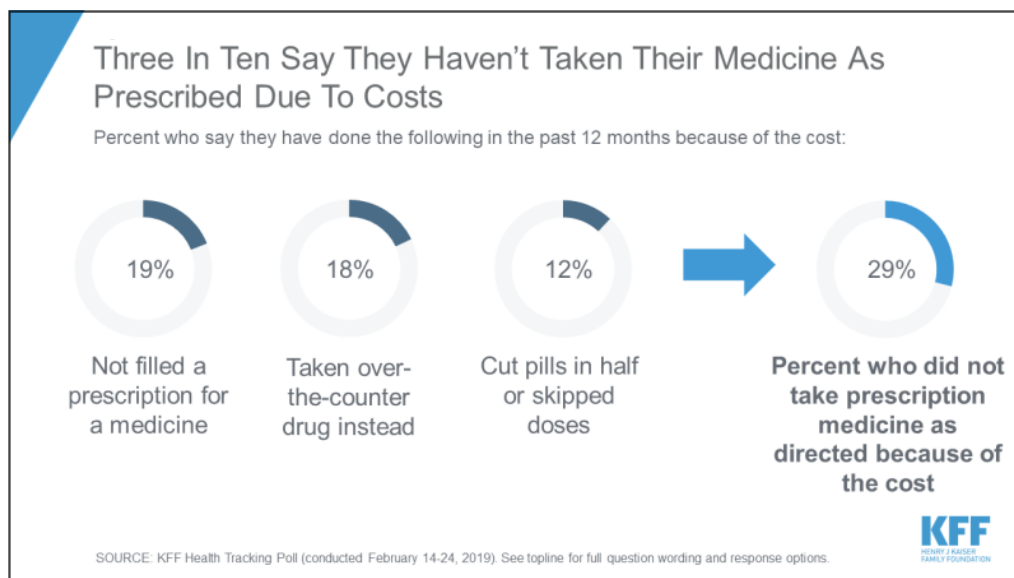


Figure 1: Strategies consumers use to reduce the cost of their prescriptions

⁴ Centers for Disease Control and Prevention. *QuickStats: Percentage of Adults Aged ≥ 18 Years Who Were Prescribed Medication in the Past 12 Months, by Sex and Age Group — National Health Interview Survey, 2017*. MMWR Morb Mortal Wkly Rep 2019; 68:97. <<http://dx.doi.org/10.15585/mmwr.mm6804a6external icon>>, visited November 2019.

⁵ Centers for Disease Control and Prevention. *Prescription Drug Use Among Adults Aged 40-79 in the United States and Canada – NCHS Data Brief No. 347*, August 2019. Retrieved at: <https://www.cdc.gov/nchs/products/databriefs/db347.htm> on December 3, 2020.

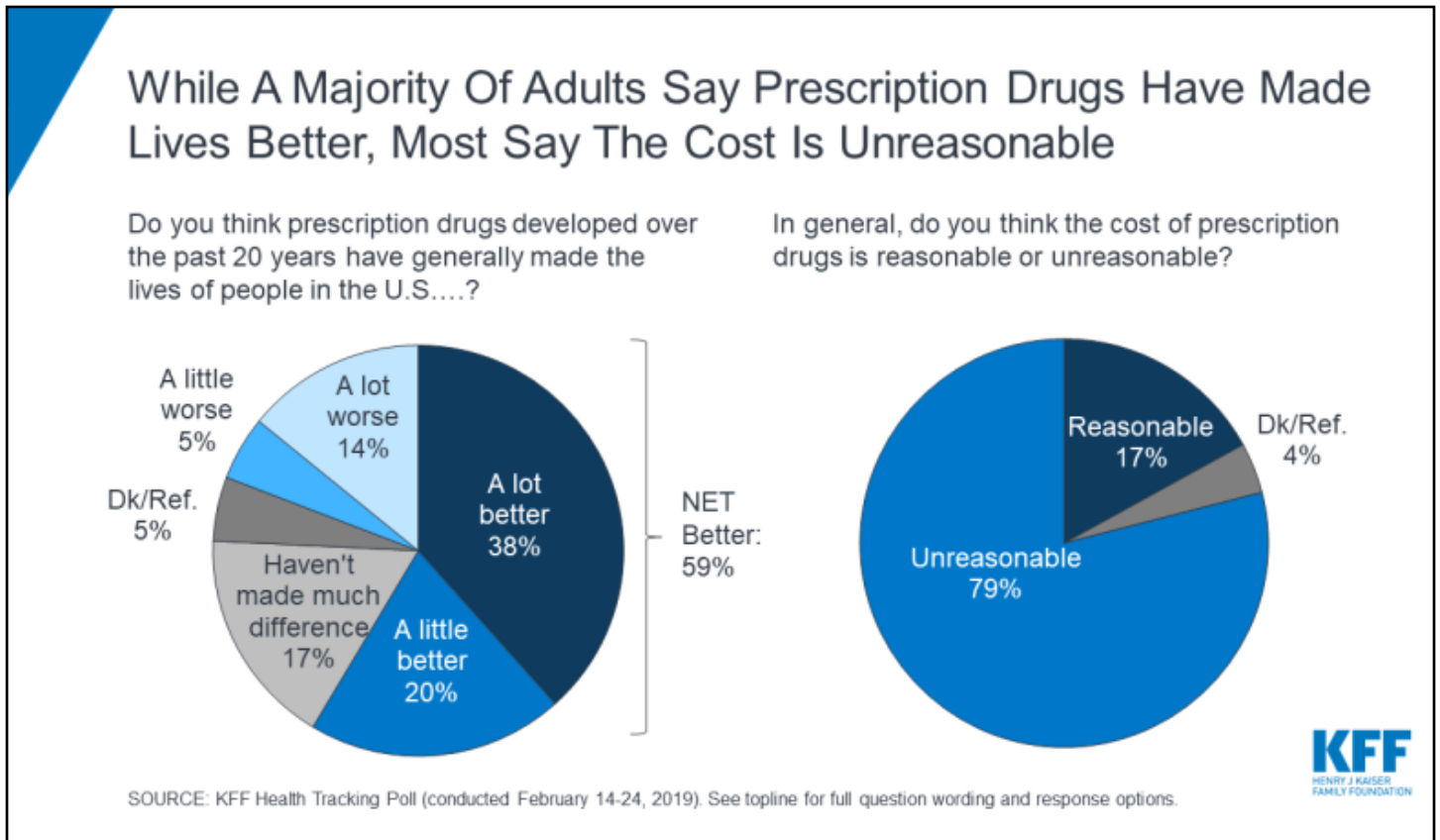
⁶ Ashley Kirzinger, et al, *KFF Health Tracking Poll – February 2019: Prescription Drugs*, March 1, 2019. Retrieved at: <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/> on December 3, 2020.

⁷ Id.

⁸ Id.

⁹ Id.

Figure 2: Consumer attitudes around the cost and benefits of prescription drugs



Given the public pressure for action on drug prices, both state and federal legislators have tried to pass reforms to control the price of prescription drugs. While a number of drug price bills were introduced in Congress in 2019, none ultimately passed.¹⁰

However, the COVID-19 (Coronavirus disease 2019) pandemic has placed renewed focus on prescription drug pricing as pharmaceutical companies work to develop vaccines and therapeutics for the novel coronavirus (SARS-CoV-2). A number of pharmaceutical interventions are in development or undergoing clinical trials for the treatment and prevention of COVID-19, but only one, Gilead's Veklury (Remdesivir) has received full approval from the U.S. Food and Drug Administration as of this report.

This report focuses on analysis of the data the Oregon Department of Consumer and Business Services received from prescription drug manufacturers, health insurance companies, and consumers of prescription drugs. This includes an overview of prescription drugs and spending on prescriptions in the U.S. and Oregon, a brief overview of the Oregon Prescription Drug Price Transparency Program, data collected by the program in 2019 and 2020, a conclusion with policy recommendations to the legislature based on program implementation and the information collected, and a summary of recent legislation on drug prices considered by other states.

¹⁰ Rachel Sachs, "Prescription Drug Legislation in Congress: An Update," *Health Affairs*, December 12, 2019. Retrieved at: <https://www.healthaffairs.org/doi/10.1377/hblog20191211.802562/full/> on December 3, 2020.

Overview of prescription drugs

Prescription drugs are substances used to provide a therapeutic benefit to people with specific diseases or conditions and are required to have a health care practitioner's approval for someone to purchase them.¹¹ Prescription drugs can be either a brand-name drug or generic drug. Brand-name prescription drugs are protected 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 is considered to be the same as a brand-name drug and competes with the brand-name drug once the patent has expired.¹² Generic drugs typically cost less than brand-name drugs and are used more frequently due to the reduced cost when they are available.

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.¹³ Many high-cost new prescription drugs and new innovative therapies, including technologies such as "CAR-T" and monoclonal antibodies, are considered biologics. However, even some well-established prescription compounds such as insulin and human growth hormone would technically be considered biologics under current law if they were developed today.¹⁴

All prescription drugs are initially priced by the drug manufacturer with a wholesale acquisition cost (WAC). WAC is sometimes referred to as the list price for a prescription drug and is the starting point for the drug price, which 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, which 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.



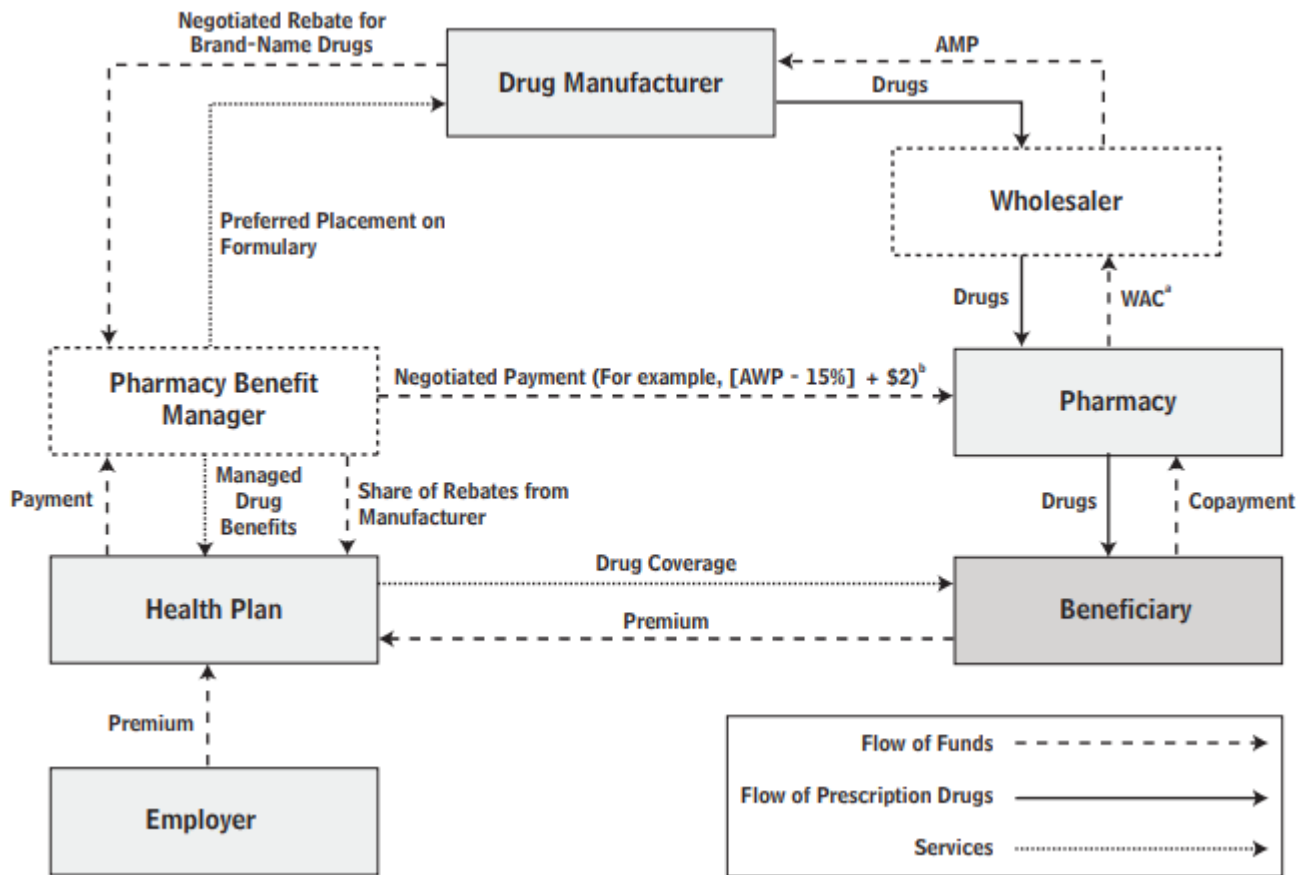
¹¹ U.S. Food & Drug Administration. *Prescription Drugs and Over-the-Counter (OTC) Drugs: Questions and Answers*. <<https://www.fda.gov/drugs/questions-answers/prescription-drugs-and-over-counter-otc-drugs-questions-and-answers>>, visited November 2019.

¹² U.S. Food & Drug Administration. *Questions, Answers, and Facts About Generic Drugs*. <<https://www.fda.gov/drugs/resources-you-drugs/questions-answers-and-facts-about-generic-drugs>>, visited November 2019.

¹³ Thomas Morrow, MD, Linda Hull Felcone, "Defining the difference: What Makes Biologics Unique," *Biotechnology Healthcare*, September 2004, retrieved at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564302/> on December 3,

¹⁴ Id.

Figure 3: Pharmaceutical supply chain for brand-name drug at retail pharmacy with employer health insurance plan



Source: Congressional Budget Office ¹⁵

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. 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. Placement on a higher tier typically results in a higher cost 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 \$5 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.

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

¹⁵ Congressional Budget Office. [Prescription Drug Pricing in the Private Sector](#), 2007, visited November 2019.

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 2018, U.S. health care spending reached \$3.6 trillion, which is approximately \$11,000 per person.¹⁶ It is estimated that prescription drug spending accounts for approximately 13 percent of health care spending – 9 percent retail and an estimated 4 percent nonretail.¹⁷ 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.

News reports describe the effect of prescription drug costs, highlighting instances in which people have not taken the drugs they depend on to live, resulting in serious harm or death.^{18,19} These reports have increased the attention on the effect prescription drug costs have on U.S. households.

Oregon prescription drug spending

Prescription drug spending and the effect of costs on Oregonians has been a growing interest for policymakers, health care providers, and the public in recent years. In Oregon, retail prescription drug spending accounts for approximately 11 percent of total health expenditures and has increased an average of 7.2 percent annually from 1991 to 2014.^{20,21}



¹⁶ Centers for Medicare and Medicaid Services. *National Health Expenditure 2018 Highlights*. <<https://www.cms.gov/files/document/highlights-2>>, visited December 2019.

¹⁷ Altarum Institute. *Projections of the Prescription Drug Share of National Health Expenditures Including Non-Retail*. June 2019. <<https://altarum.org/publications/projections-prescription-drug-share-national-health-expenditures-including-non-retail-0>>, visited November 2019.

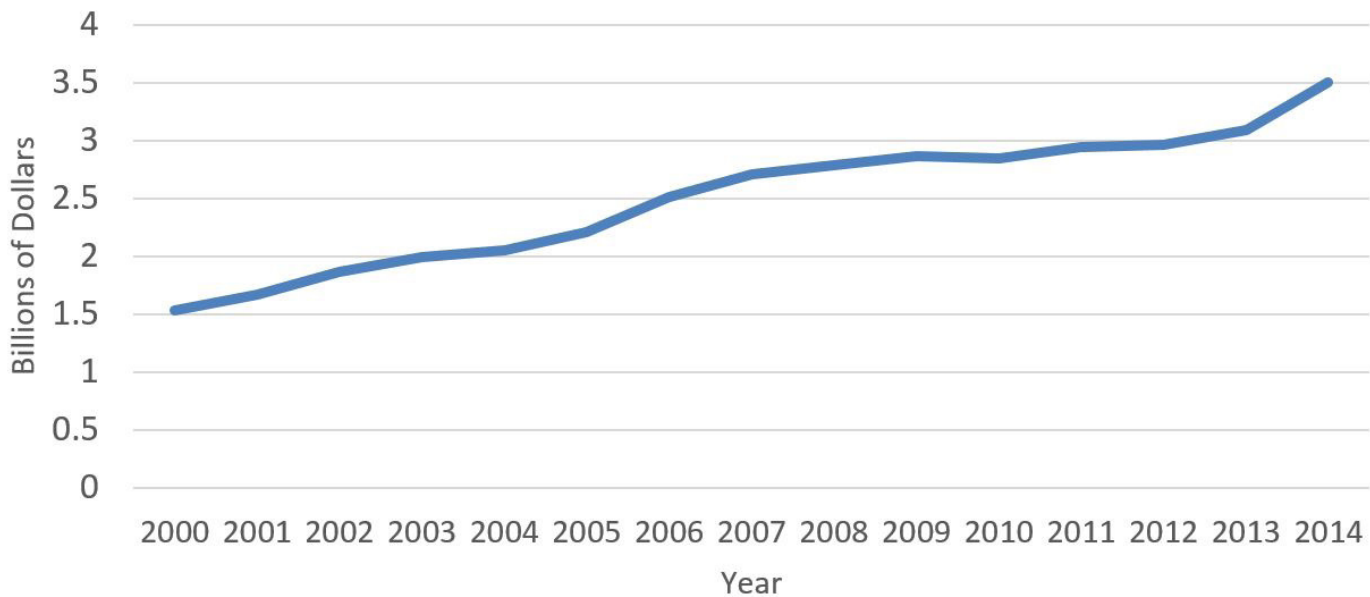
¹⁸ Sable-Smith, Bram. "Insulin's Steep Price Leads to Deadly Rationing". *Kaiser Health News*, Sept. 2018. <<https://khn.org/news/insulins-high-cost-leads-to-deadly-rationing/>>, visited November 2019.

¹⁹ Carroll, Linda. "U.S. heart patients cut back on life-saving drugs due to cost." *Reuters*, Nov. 2019. <<https://www.reuters.com/article/us-health-heart-expenses/us-heart-patients-cut-back-on-life-saving-drugs-due-to-cost-idUSKBN1XZ2HM>>, visited November 2019.

²⁰ Kaiser Family Foundation. *Distribution of Health Care Expenditures by Service by State of Residence in Millions*. <<https://www.kff.org/other/state-indicator/distribution-of-health-care-expenditures-by-service-by-state-of-residence-in-millions/?currentTimeframe=0&selectedRows=%7B%22states%22:%7B%22oregon%22:%7B%7D%7D%7D&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>>, visited November 2019.

²¹ Centers for Medicare & Medicaid Services. *National Health Expenditures by State of Residence, 1991-2014*. <<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsStateHealthAccountsResidence>>, visited November 2019.

Graph 4: Estimated expenditure on retail prescription drugs in Oregon (1991 to 2014)



Source: Department of Consumer and Business Services, 2019.
Data: CMS National Health Expenditure Data – Accessed November 2019.

The state is a major purchaser of prescription drugs through the administration of health benefit plans for Oregonians. From 2013 to 2015, it was estimated the Oregon Health Authority (OHA) would spend \$1.2 billion on prescription drugs through the programs it administers, such as the Oregon Health Plan, Oregon Prescription Drug Program, Oregon Educators Benefit Board, Public Employees Benefit Board, and the Oregon AIDS Drug Assistance Program.²² The Oregon Health Plan, which provides Medicaid insurance coverage to Oregonians, accounted for approximately 62.5 percent of OHA’s estimated spending on prescription drugs. The Oregon Youth Authority, Oregon Department of Corrections, and Oregon State Hospital also purchase prescription drugs for the people in their care.

COVID-19 therapeutics and vaccine candidates

2020 has been largely defined by the novel coronavirus pandemic. The race to develop or

identify treatments for COVID-19 has put renewed attention on how prices are set for new prescription drugs. Gilead Sciences’ Veklury (remdesivir), attracted particular attention as the first new compound to win full FDA approval as a treatment for COVID-19. The company filed a new drug report for Veklury in late November 2020, since the drug meets Oregon’s reporting threshold at a cost up to \$3,120 for a typical five-day course of treatment. Additional discussion of remdesivir can be found in the “New high-cost drug” section of this report.

COVID-19 also disrupted the market for established prescription drugs due to demand for these drugs as COVID -19 cases increased. Many COVID-19 patients with severe illness require mechanical ventilation, leading to concerns of shortages in multiple drugs used to support the process, such as paralytics, analgesics (painkillers), and sedatives. The promotion of

²² Legislative Policy and Research Office. *Background Brief on Prescription Drugs*. 2014. <<https://www.oregonlegislature.gov/lpro/Publications/BB2014PrescriptionDrugs.pdf>>, visited November 2019.

Hydroxychloroquine, an anti-malarial, as a potential COVID-19 treatment led to shortages in the spring of 2020, despite little clinical evidence of benefits from its use.²³ In the United States and Europe, 29 of 40 drugs commonly used to treat the novel coronavirus have been in short supply this fall.²⁴ Shortages like these, whether due to supply disruptions, unexpected demand, or both, can be a contributing factor to rising drug prices.

COVID-19 vaccinations

Currently, there are at least 87 pre-clinical vaccine candidates under investigation in animals, and 57 vaccines are undergoing clinical trials in humans.²⁵ One vaccine in final clinical trial stages is being evaluated for emergency-use authorization, and a second, manufactured by Pfizer, in partnership with BioNTech, began national distribution this week following emergency approval from the FDA.

The Centers for Medicare and Medicaid Services has released regulations related to the out-of-pocket cost to people who receive a COVID-19 vaccine. Under

these rules, vaccinations should be free to all Americans, though there may be some fees related to delivery.²⁶ Under the federal government's "Operation Warp Speed" program, a number of manufacturers have already been contracted to provide millions of doses of vaccines to the states once the vaccine is available.²⁷ The general manufacturer price for a COVID-19 vaccination initially will be between \$15 and \$40 per dose (\$30 to \$80 per patient, for two doses) based on the government contracts.²⁸

Dexamethasone

The only drug currently on the market with clinical evidence showing a reduction in mortality for severe COVID-19 cases is the generic steroid Dexamethasone.²⁹ A commonly available generic steroid drug, Dexamethasone is sold under over 250 NDCs manufactured by over 70 different companies, though the bulk of the supply comes from a single company, Fresenius Kabi.³⁰ 2020

²³ Elaine MacKenzie, Meredith Goodwin, "This is how the Hydroxychloroquine shortage is hurting people with rheumatoid arthritis," Healthline, June 26, 2020. Retrieved at: <https://www.healthline.com/health/rheumatoid-arthritis/hydroxychloroquine-shortage-rheumatoid-arthritis-covid-19>, on December 9, 2020.

²⁴ Ed Silverman, "As Covid-19 intensifies, shortages of staple drugs may grow worse," STAT, October 21, 2020. <https://www.statnews.com/pharmalot/2020/10/21/covid19-coronavirus-pandemic-shortages/> visited on December 9, 2020.

²⁵ Carl Zimmer, Jonathan Corum, Sui-Lee Wee, "Coronavirus Vaccine Tracker", *The New York Times*, visited on December 1, 2020.

²⁶ Karyn Schwartz, et al, *Vaccine Coverage, Pricing, and Reimbursement in the US*, Kaiser Family Foundation, retrieved at: <https://www.kff.org/coronavirus-covid-19/issue-brief/vaccine-coverage-pricing-and-reimbursement-in-the-u-s/> on December 3, 2020.

²⁷ Health and Human Services, *Fact Sheet: Explaining Operation Warp Speed*, retrieved at: <https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html> on December 3, 2020.

²⁸ Katie Jennings, "How Much Will a Covid-19 Vaccine Cost?" Forbes, November 17, 2020. Retrieved at <https://www.forbes.com/sites/katiejennings/2020/11/17/how-much-will-a-covid-19-vaccine-cost/?sh=61333cd576de> on December 3, 2020

²⁹ Michael A Matthay, B Taylor Thompson, "Dexamethasone in hospitalized patients with COVID-19: addressing uncertainties," *The Lancet*, October 16, 2020, retrieved at: [https://doi.org/10.1016/S2213-2600\(20\)30452-5/](https://doi.org/10.1016/S2213-2600(20)30452-5/) on December 1, 2020.

³⁰ Maia Anderson, "Dexamethasone price has increased 137% in recent months," *Becker's Hospital Review*, October 7, 2020. Retrieved at: <https://www.beckershospitalreview.com/pharmacy/dexamethasone-price-has-increased-137-in-recent-months.html> on December 2, 2020. NDC & manufacturer count based on information from Medi-Span.

Dexamethasone typically costs less than \$1.00 per dose, but some observers have found a price increase of 137 percent in recent months, and the drug is listed as in shortage by both the FDA and the American Society of Health-System Pharmacists.³¹ The program is actively monitoring the WAC price of Dexamethasone on price lists, but has not seen any unusual price changes for the steroid so far – however, this may be simply due to lag in our data sources.

Monoclonal antibodies

One other category of therapeutic for COVID-19 has drawn significant attention: monoclonal antibodies, a technology that uses engineered human cells to generate antibody proteins similar to those naturally created by the immune system. Many of the innovative therapies developed by pharmaceutical companies over the past 20 years, including many treatments for cancers, are monoclonal antibody therapies.

There are at least two efforts to develop a monoclonal antibody-based treatment for COVID-19, both of which have received emergency-use authorization from the FDA. Clinical data has indicated that these treatments may be effective in preventing severe complications from COVID-19-related illness, making them the only effective known treatment for the early stages of COVID-19 infection.³²

It is unclear how much antibody treatments will cost. Historically, monoclonal antibodies tend to be expensive drugs, with an average price around \$100,000 per patient per year.³³ However, they are also fairly inexpensive to actually manufacture, with an estimated production cost around \$20 to \$100 per gram,³⁴ about 1 percent to 5 percent of the typical sales price per gram. The high price typically assigned to these drugs is instead attributable to factors including (1) the highly targeted nature of many antibody therapies, which typically treat conditions with very small patient populations; (2) the recency of the technology's development; (3) higher than average research and development costs; and (4) the high prices of existing compounds in this class.

As the COVID-19 pandemic continues, the program is monitoring the prices of approved drugs and new drugs that come to market. Given that drug shortages have been identified by manufacturers who report to Oregon as one reason for price increases on generic drugs, we have been monitoring publicly available pricing information for dexamethasone NDCs and other NDCs associated with COVID-19 treatments. However, no sign of unusual price increases have been identified at the WAC price level so far.

³¹ Maia Anderson, "Dexamethasone price has increased 137% in recent months," *Becker's Hospital Review*, October 7, 2020. Retrieved at: <https://www.beckershospitalreview.com/pharmacy/dexamethasone-price-has-increased-137-in-recent-months.html>, 2020. NDC & manufacturer count based on information from Medi-Span.

³² U.S. Food & Drug Administration, "Coronavirus (COVID-19) Update: FDA Authorizes Monoclonal Antibody for Treatment of COVID-19", November 9, 2020. Retrieved at: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibody-treatment-covid-19> on December 3, 2020.

³³ Inmaculada Hernandez, et al, "Pricing of Monoclonal Antibody Therapies: Higher if Used for Cancer?," *The American Journal of Managed Care*, Vol 24, No. 2, February, 2018. <https://www.ajmc.com/view/pricing-of-monoclonal-antibody-therapies-higher-if-used-for-cancer>, visited December 9, 2020.

³⁴ Brian Kelley, "Industrialization of mAb production technology: the bioprocessing industry at a crossroads," *mAbs*, September 2009. Retrieved at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2759494/#:~:text=The%20average%20U.S.%20wholesale%20prices,is%20approximately%20%248%2C000%20per%20gram> on December 9, 2020.

Oregon Prescription Drug Price Transparency Program



Statutory authority

In 2018, the Oregon Legislature passed Oregon’s Prescription Drug Price Transparency Act to increase prescription drug price transparency, creating the Oregon Prescription Drug Price Transparency Program.³⁵ The goal of the Prescription Drug Price Transparency Program is to provide accountability for prescription drug pricing through transparency of specific drug cost and price information from pharmaceutical manufacturers, health insurers, and consumers.

Legislators have called Prescription Drug Price Transparency Act the first step to understanding prescription drug cost and pricing through increased transparency.

In 2019, the legislature expanded the reporting requirements on manufacturers through passage of House Bill 2658, or the “60-day notice” bill. This law requires manufacturers to provide notice to the state 60 days in advance of the date a planned

price increase will go into effect. This requirement applies, regardless of whether or not the price increase ultimately goes into effect. The reporting thresholds for the 60-day notice requirement are different, depending on whether a drug is generic or brand name, and also differ slightly from the Prescription Drug Price Transparency Act’s annual price increase report requirements. A report is required:

- For generic drugs: With a cumulative increase of either (a) 25 percent or more, or (b) \$300 or more across the previous 12 months.
- For brand-name drugs: With a cumulative increase of either (a) 10 percent or more, or (b) \$10,000 or more across the previous 12 months.

Program implementation

In 2018, the department convened a rulemaking advisory committee consisting of biologic drug manufacturers, consumer advocates, generic drug manufacturers, health care providers, insurance companies, pharmacy benefit managers, pharmacies, brand-name prescription drug manufacturers, and wholesale drug distributors to provide input on program regulations and its estimated fiscal and economic impacts.³⁶

In 2019, the program had fully implemented all of the components required by the Prescription Drug Price Transparency Act, and started collecting information from drug companies, insurance companies, and Oregon consumers about drug pricing. The program also held its first hearing in November 2019, and released its first report to the legislature in December 2019.

³⁵ House Bill 4005 (2018), <https://olis.leg.state.or.us/liz/2018R1/Measures/Overview/HB4005>.

³⁶ Division of Financial Regulation. *Prescription Drug Price Transparency Rulemaking Advisory Committee (HB 4005)*. < <https://dfr.oregon.gov/help/committees-workgroups/Pages/prescription-price-transparency-rac.aspx>>. Visited December 2019.

This year, the program has fully implemented the requirements of the 60-day notice bill and continued working on implementation of the Prescription Drug Price Transparency Act.

The following sections summarize the findings from all data collected from the program's inception through November 2020. 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 trade secret is not disclosed.

Consumer notifications and stories

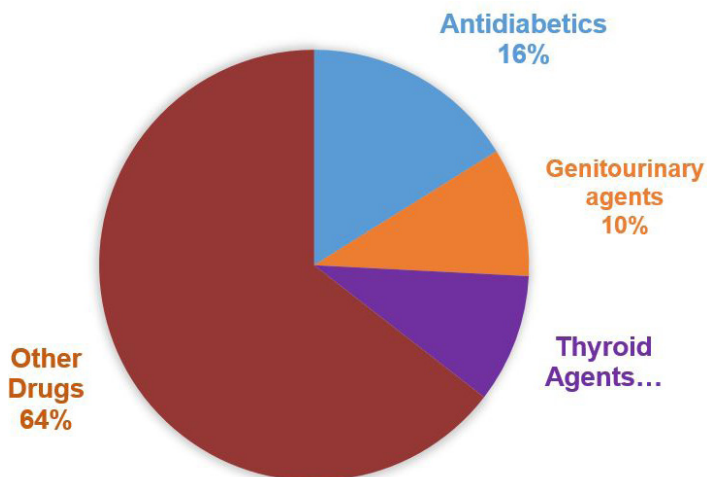
There are three ways consumers can contact the department: by phone, email, or online submission form. The department has conducted outreach to provide Oregonians with information about the option to report a price increase. Outreach in 2020 has been limited due to the COVID-19 pandemic and adhering to physical distancing guidelines. Early in the year, the program reached out to agency directors and staff members working with aging adults and people with disabilities to provide information to these communities. Also, the program connected with pharmacy directors at Oregon's coordinated care organizations through virtual presentation.

The program will continue outreach to Oregonians in 2021, using a variety of strategies, including virtual opportunities for people to connect with the program. Program materials are currently available in English, Spanish, and Vietnamese.

Price increase notices

Anyone from the public can provide notification of an increase in the cost of prescription drugs to the Prescription Drug Price Transparency Program. Each notification includes information about the consumer's insurance coverage, the drug that increased in price, and when and where the consumer experienced the price increase.

Figure 5: Consumer reports by therapeutic class

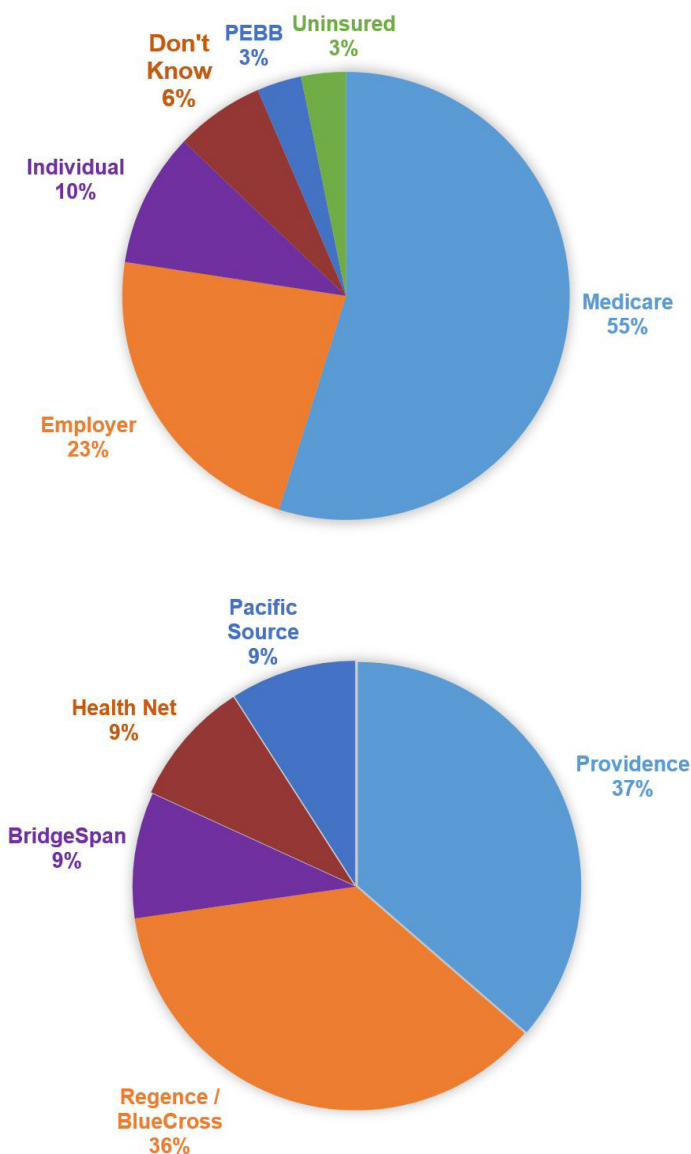


Source: Oregon Prescription Drug Price Transparency Program

Consumers submitted a total of 31 notifications for 31 national drug codes (NDCs) since the start of the program. The most-reported drug categories were insulins (antidiabetic drugs, five notifications), prostrate drugs (genitourinary agents, three notifications), and thyroid agents (three notifications).



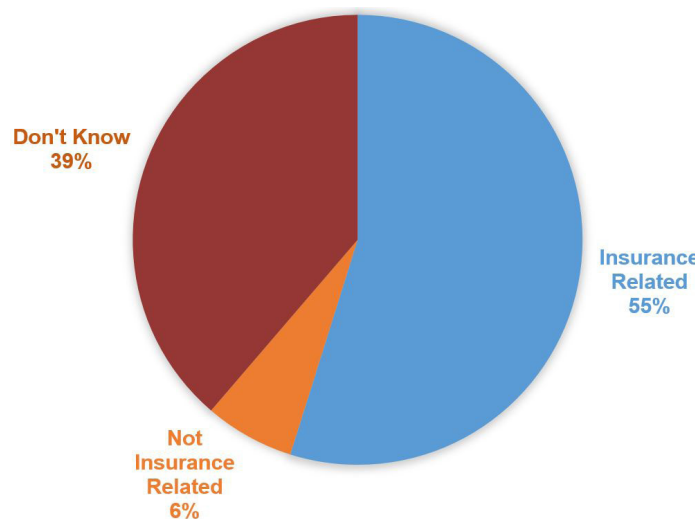
Figure 6: Consumer reports by therapeutic class



Source: Oregon Prescription Drug Price Transparency Program

The program also collects data from consumers who report price increases about what type of insurance they have. Slightly more than half of the reports we received (17) came from patients insured through Medicare, followed by seven reports (23 percent) that were received from consumers with employer-sponsored health insurance. Consumers with health insurance through their employer, with health

Figure 7: Consumer reports by therapeutic class



Source: Oregon Prescription Drug Price Transparency Program

insurance through Public Employees Benefit Board (PEBB), or with direct individual health insurance were also asked to identify their insurance company.

Consumers are asked to provide the reason for the price increase. More than one-third of consumers (12 notifications) did not know the reason for the price increase. Of the remaining 19 notifications, 17 were insurance-related cost increases and two were not insurance related.

Prescription drug manufacturers

Under the Prescription Drug Price Transparency Act, drug manufacturers are required to submit two types of reports to the program.

First, manufacturers are required to submit a new drug report within 30 days of introducing a new drug with a list price of \$670 or more for a 30-day supply or for a course of treatment shorter than one month. Second, 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 for a course of treatment

shorter than one month that experiences a net price increase of 10 percent or more from the previous year.

Under both types of reports, 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.

Also, in many parts of this report, we will 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 for individual NDCs. As program staff members reviewed submissions from manufacturers, we found that several manufacturers indicated in their reports that they do not track costs, revenues, or profits for individual NDCs. Instead, they aggregate and track this information by "product family." Consequently, they entered identical numbers in the costs, revenue, and profit fields in all reports they submitted for NDCs in the same product family.

After further investigation, we discovered that several other manufacturers apparently did the same, entering identical numbers in multiple reports for related NDCs, but they did not include a statement to confirm it. We observed that when manufacturers submitted reports with identical revenue and profit numbers, the numbers would match in all reports with the same trade name. So, when we say "drug product family," we are referring to a set of NDCs from a specific 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.

This report is based on all data submitted to the program through Oct. 15, 2020. 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 trade secret is not disclosed.

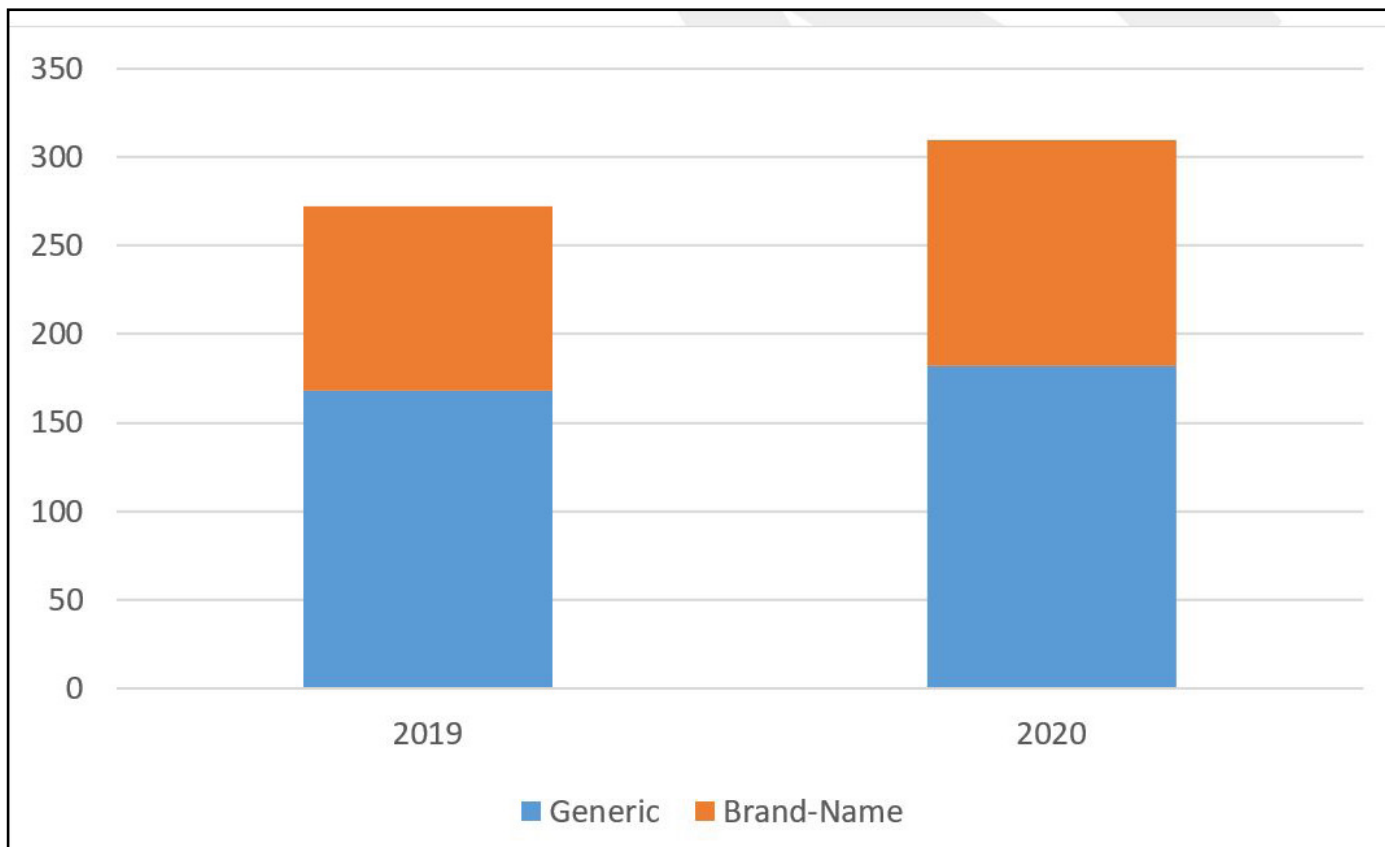
New high-cost drug reports

New high-cost drugs are reported to the program when they are priced at \$670 or more. This is the financial threshold set by the federal government to categorize a drug as a specialty drug under Medicare Part D. Reports for new drugs come in continuously, and there is a lot of variation in the volume of reports the program receives (anywhere from 10 to 60 reports per month). Most of the reports we receive are for generic drugs, though we do also receive a large number of reports for brand-name drugs. Overall, the split between generics and brands is around 60 percent to 40 percent. When a brand-name drug loses patent protection, multiple manufacturers may launch generic versions around the same time, which may be one reason why we receive more reports for generic drugs overall.

Overview of reports received

In 2019, the program received new drug reports for 272 NDCs, 168 generic (62 percent) and 104 name brand (38 percent). During the first three quarters of 2020, the program has received new drug reports for 310 NDCs, a 15 percent increase for a comparable time period (the program began accepting reports in April 2019, so the 2019 data also represents a three-quarter time period). The split between generics and brand names remained roughly the same, with 182 generic reports (59 percent) and 128 name-brand reports (41 percent).

Figure 8: New generic and brand-name drug reports received, 2019-2020



Source: Oregon Prescription Drug Price Transparency Program

Veklury (remdesivir) and pricing for novel COVID-19 therapeutics

Gilead Sciences, Inc.'s Veklury, more commonly known by its generic name remdesivir, is the first new drug to receive FDA approval as a treatment for COVID-19 patients. To date, while several emergency-use authorizations have been issued for other therapies, remdesivir is the only drug with full FDA approval for a COVID-19-related indication.

Gilead submitted a report regarding the launch of remdesivir to the program on Nov. 20, 2020. Much of the information Gilead provided in its submission was claimed as a trade secret. Since this filing was only recently received, and remains under

review for sufficiency and trade secret claims, the analysis in this section of the report is based solely on previous public disclosures made by Gilead.

Institute for Clinical and Economic Review (ICER) analysis of remdesivir

ICER is an independent, nonpartisan research organization that objectively evaluates the economic and clinical benefits of health care innovations, including prescription drugs.³⁷ The group has conducted an analysis of the clinical and economic evidence of remdesivir's effects and potential benefits to recommend a value-based price for the drug.

³⁷ ICER, "About," visited on December 2, 2020 at <<https://icer-review.org/about/>>

In late June, ICER recommended a price for remdesivir between \$1,010 and \$5,080 for a course of treatment.³⁸ However, this recommendation included two significant caveats: (1) if patients are also treated with the steroid Dexamethasone as part of the standard of care, the price for remdesivir should only be around \$2,800; and (2) if remdesivir does not have a mortality benefit, the price should only be \$310.³⁹

Treatment with Veklury does have economic value, even in the absence of a mortality benefit, since one day of intensive care unit (ICU) treatment can cost more than \$4,000, and Veklury can potentially reduce hospitalization time for COVID-19 patients by four to five days.⁴⁰ However, despite extensive studies, no statistically significant evidence has been covered for a mortality benefit has been found. ICER's suggested price of \$310 without a mortality benefit is less than 1/10th of the price set by Gilead.

Gilead's pricing of remdesivir

On June 29, 2020, Gilead announced its pricing for remdesivir: \$390 per vial for government payers in developed countries and \$520 per vial for private payers in the United States.⁴¹ For a typical, five-day, six-vial course of treatment, this represents a cost of \$2,340 for government payers and \$3,120 for private payers in the United States.⁴² This is roughly comparable to ICER's suggested price range for remdesivir of \$2,800 to \$5,080 if the compound has a mortality benefit.

In announcing its pricing for remdesivir, Gilead offered the following explanation for its pricing decision⁴³ (This information is sourced solely from publicly available information released by Gilead, and does not rely on any submissions claimed as trade secret by Gilead):

³⁸ Melanie D. Whittington, PhD, Jonathan D. Campbell, PhD, *Alternative Pricing Models for Remdesivir and Other Potential Treatments for COVID-19*, ICER, June 24, 2020. The lower bound price of \$1,010 is the estimated price per vial for Gilead to recover its investment in manufacturing remdesivir and performing clinical trials. The upper bound price of \$2,800 assumes a mortality benefit from remdesivir in COVID-19 patients treated with a standard-of-care which also includes Dexamethasone. https://icer.org/news-insights/press-releases/updated_icer-covid_models_june_24/ visited on December 9, 2020.

³⁹ Id.

⁴⁰ Jyoti Aggarwal, et al, "Cost-Minimization of Dexmedetomidine Compared to Other Sedatives for Short-Term Sedation During Mechanical Ventilation in the United States," *Clinico Economics and Outcomes Research*, July 2020. Estimated cost per day for ICU hospitalization in the US of \$10,794 (ventilated) and \$6,667 (not ventilated) for first day, \$3,968 (ventilated) and \$3,184 (not ventilated) after second day of ICU admission. <https://www.dovepress.com/cost-minimization-analysis-of-dexmedetomidine-compared-to-other-sedati-peer-reviewed-article-CEOR#:~:text=Conclusion%3A%20Dexmedetomidine%20was%20associated%20with,on%20overall%20cost%20per%20episode.> Visited December 9, 2020.

⁴¹ Daniel O'Day, "An Open Letter from Daniel O'Day, Chairman & CEO, Gilead Sciences," <https://www.gilead.com/news-and-press/press-room/press-releases/2020/6/an-open-letter-from-daniel-oday-chairman--ceo-gilead-sciences> visited December 9, 2020.

⁴² Note that there is some debate over whether a five-day or 10-day course of treatment with Remdesivir is appropriate, trials have indicated that a five-day course of treatment is just as effective. Jason D. Goldman, M.D., M.P.H, et al, "Remdesivir for 5 or 10 Days in Patients with Severe Covid-19," *New England Journal of Medicine*, May 27, 2020. Retrieved at: <<https://www.nejm.org/doi/full/10.1056/NEJMoa2015301>> on December 2, 2020.

⁴³ This information is sourced solely from publicly available information released by Gilead, and does not rely on any submissions to the program claimed as trade secret by Gilead.



"In normal circumstances, we would price a medicine according to the value it provides. The first results from the NIAID study in hospitalized patients with COVID-19 showed that remdesivir shortened time to recovery by an average of four days. Taking the example of the United States, earlier hospital discharge would result in hospital savings of approximately \$12,000 per patient. Even just considering these immediate savings to the healthcare system alone, we can see the potential value that remdesivir provides . . .

"We have decided to price remdesivir well below this value . . . At the current price of \$390 per vial, remdesivir is positioned to achieve the aim of providing immediate net savings for healthcare systems. In the U.S., the same government price of \$390 per vial will apply. Because of the way the U.S. system is set up and the discounts that government healthcare programs expect, the price for U.S. private insurance companies, will be \$520 per vial. At the level we have priced remdesivir and with government programs in place, along with additional Gilead assistance as needed, we believe all patients will have access."⁴⁴

This explanation relies on the expected savings from reduced hospitalization time, which Gilead estimated at \$12,000 (\$4,000 per day for four days). With a course of treatment cost of \$2,340 to \$3,120,

this represents potential health system savings of \$8,880 to \$9,660. However, it is also 86 percent to 90 percent higher than ICER's recommended value based price if remdesivir does not provide a mortality benefit – which was suggested in early studies, but has not been shown in extensive subsequent studies.

Highest reported WAC prices

The program received reports for new drugs with Wholesale acquisition costs (WACs) ranging from \$2.00 to \$373,000. 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 and requires two doses in one month, would still cost \$670 for a course of treatment and a report would be required. However, it is likely that many of the lower cost reports we received are for lower cost drugs that may have been submitted in error.

The chart below shows the 20 highest WAC prices for new drugs reported to the program in 2020. It's important to note that 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.

⁴⁴ Daniel O'Day, "An Open Letter from Daniel O'Day, Chairman & CEO, Gilead Sciences," June 29, 2020. <https://www.gilead.com/news-and-press/press-room/press-releases/2020/6/an-open-letter-from-daniel-oday-chairman--ceo-gilead-sciences> visited December 9, 2020.

Figure 9: New generic and brand-name drug reports received, 2019-2020

Drug	WAC	Therapeutic class	Manufacturer
Tecartus	\$373,000	Antineoplastics and Adjunctive Therapies	Kite Pharma
Uplizna	\$131,000	Immunosuppressive Agents	Viela Bio
Procysbi	\$6,079 - \$48,634	Genitourinary Agents	Horizon Therapeutics
Givlaari	\$39,000	Hematological Agents	Alnylam Pharmaceuticals
Metyrosine	\$35,005	Antihypertensives	Amneal Pharmaceuticals
Ayvakit	\$32,000	Antineoplastics and Adjunctive Therapies	Blueprint Medicines
Qinlock	\$32,000	Antineoplastics and Adjunctive Therapies	Deciphera Pharmaceuticals
Harvoni	\$31,500	Antivirals	Gilead Sciences
Pyrimethamine	\$29,250	Antimalarials	Dr. Reddy's Laboratories
Sovaldi	\$28,000	Antivirals	Gilead Sciences
Miglustat	\$24,111	Hematopoietic Agents	Ani Pharmaceuticals
Asparlas	\$24,000	Antineoplastics and Adjunctive Therapies	Servier Pharmaceuticals
Trikafta	\$23,896	Respiratory Agents	Vertex Pharmaceuticals
Fensolvi	\$22,578	Endocrine and Metabolic Agents	Tolmar Pharmaceuticals
Xpovio	\$22,000	Antineoplastics and Adjunctive Therapies	Karyopharm Therapeutics
Nitisinone	\$4,360 - \$21,797	Endocrine and Metabolic Agents	Par Pharmaceutical
Jelmyto	\$21,376	Antineoplastics and Adjunctive Therapies	Urogen Pharma
Onureg	\$21,158	Antineoplastics and Adjunctive Therapies	Bristol-Myers Squibb
Penicillamine	\$20,951	Chelating Agents	Ani Pharmaceuticals
Penicillamine	\$20,951	Chelating Agents	Apotex Corp

Source: Oregon Prescription Drug Price Transparency Program

The highest WAC reported in 2020 was for Tecartus, with a per-dose price of \$373,000. Tecartus belongs to a class of treatments called chimeric antigen receptor T-cell therapy (“CAR-T”), 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.⁴⁵ Tecartus is a CAR-T treatment for mantle cell lymphoma, a cancer of the immune system.⁴⁶

While CAR-T therapies have shown exceptional promise as cancer therapeutics, they have also drawn criticism given their extremely high price. The CAR-T therapies with current FDA approval have WACs ranging from \$373,000 to \$500,839, meaning a course of treatment can cost more than \$1 million.⁴⁷

This is likely because of the unusually high prices for existing cancer treatments relative to treatments for other diseases. In the two years the program has been collecting data, cancer drugs have consistently been the most expensive per patient (more discussion can be found in this report’s section on “Insurer reports”). In fact, a study of pricing for another class of innovative therapy, monoclonal antibodies, found that monoclonal antibodies used in cancer treatment were priced

about \$100,000 more than monoclonal antibodies used to treat other disease states.⁴⁸

Another notable drug on this list is pyrimethamine, submitted by Dr. Reddy’s Laboratories at a WAC price of \$29,250. Pyrimethamine, originally developed as a treatment for malaria, is currently used for the treatment of the parasitic disease toxoplasmosis and as a second-line treatment for certain pneumonias in HIV-positive patients.⁴⁹ This drug is the generic form of brand-name Daraprim, which gained notoriety in 2015 after its production rights were acquired by Turing Pharmaceuticals, which subsequently raised the price more than 5,000 percent from \$13.50 to \$750 per tablet.⁵⁰

Five years later, the first generic versions of Pyrimethamine have begun to come to market, including the listed drug manufactured by Dr. Reddy’s. The list price of \$29,250 is associated with an NDC for a 100-pill bottle, representing a price per pill of \$292.50. While this is less than half the price set by Turing at its peak, it is still more than 2,000 percent higher than the price of Daraprim before its acquisition in 2015.

⁴⁵ American Cancer Society, “CAR T-cell Therapy and Its Side Effects,” retrieved at: <<https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/immunotherapy/car-t-cell1.html>> on December 2, 2020.

⁴⁶ Kite Pharma, Tecartus Patient Website, retrieved at: <https://www.tecartus.com/> on December 2, 2020; Leukemia & Lymphoma Society, “Mantle Cell Lymphoma Facts,” retrieved at: https://www.lls.org/sites/default/files/file_assets/mantlecelllymphoma.pdf on December 2, 2020.

⁴⁷ Samantha Hitchcock, “Does the Cost Outweigh the Benefit for CART-Cell Therapy?” *Targeted Oncology*, January 9, 2019. <https://www.targetedonc.com/view/does-the-cost-outweigh-the-benefit-for-car-t-cell-therapy>, visited December 9, 2020.

⁴⁸ Inmaculada Hernandez, et al, “Pricing of Monoclonal Antibody Therapies: Higher if Used for Cancer?,” *The American Journal of Managed Care*, Vol 24, No. 2, February 2018. <https://www.ajmc.com/view/pricing-of-monoclonal-antibody-therapies-higher-if-used-for-cancer>, visited December 9, 2020.

⁴⁹ Drugs.com, “Pyrimethamine,” retrieved at <https://www.drugs.com/monograph/pyrimethamine.html> on December 2, 2020.

⁵⁰ Andrew Pollack, “Drug Goes From \$13.50 a Tablet to \$750, Overnight,” *The New York Times*, September 20, 2015. <https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html#:~:text=The%20drug%2C%20called%20Daraprim%2C%20was,hundreds%20of%20thousands%20of%20dollars>. Visited December 9, 2020.

The common factor between Daraprim (Pyrimethamine) and Tecartus is that the high price is driven by the high price for existing drugs in the same therapeutic class, which is frequently cited by manufacturers as a consideration in their pricing decisions. In the case of Tecartus, the high price for comparators is due to the typical cost of cancer treatments, while Pyrimethamine is expensive largely due to the opportunistic pricing of Turing five years ago. While generic competition from companies like Dr. Reddy's is likely to lead to a somewhat lower price than was set by Turing's monopoly, a higher overall price point remains in place due to that decision.

Distribution of new high-cost drugs across therapeutic classes

In order to determine what disease states are most associated with the introduction of new, high-cost drugs, the program analyzed the number of reports we received by disease treated. To do so, we used

data from a publicly accessible database to identify the therapeutic class of every NDC with a new drug filing in 2020.⁵¹ The table below shows the 10 therapeutic classes with the most new drug reports filed this year.

More new drug reports were filed for cancer drugs (Antineoplastics and Adjunctive Therapies) than any other therapeutic class, with 100 NDCs reported across 40 manufacturers. This is 81 more NDCs than the next most reported therapeutic class, Endocrine and Metabolic agents. Notably, cancer drugs also represent seven out of 20 (35 percent) of the drugs that appeared on the preceding list of the most expensive individual drugs reported in 2020.

The next table shows 10 therapeutic classes with the highest median reported WAC. Where multiple WACs were reported in a single therapeutic class, we also show the lowest and highest reported WACs. The only therapeutic class that appears on both the most-reported and the highest median price lists is, again, cancer drugs.

Figure 10: Most reported therapeutic classes of new drugs

Source: Oregon Prescription Drug Price Transparency Program

Therapeutic class	NDCs	Manufacturers
Antineoplastics and Adjunctive Therapies	100	40
Endocrine and Metabolic Agents	19	10
Antidotes and Specific Antagonists	17	7
Antipsychotics/Antimanic Agents	13	7
Cardiovascular Agents	13	4
ADHD/Anti-Narcolepsy/Anti-Obesity/Anorexiant	13	3
Allergenic Extracts	13	1
Psychotherapeutic and Neurological Agents	12	7
Anticonvulsants	12	4
Dermatologicals	11	7

⁵¹ In general, the term “therapeutic class” refers to what type of disease is treated by a particular drug.

Figure 11: Therapeutic classes with the highest median WAC prices

Source: Oregon Prescription Drug Price Transparency Program

Therapeutic class	Median WAC	WAC range	NDCs
Antihypertensives	\$35,005	-	1
Antimalarials	\$29,250	-	1
Antivirals	\$28,000	\$800 - \$31,500	7
Respiratory Agents	\$23,896	-	1
Genitourinary Agents	\$18,238	\$6,079 - \$48,634	4
Chelating Agents	\$12,130	\$4,653 - \$20,951	10
Antineoplastics and Adjunctive Therapies	\$6,433	\$100 - \$373,000	100
Psychotherapeutic and Neurological Agents	\$6,089	\$899 - \$8,718	12
Antimyasthenic/Cholinergic Agents	\$4,536	\$1,072 - \$8,000	2
Hematopoietic Agents	\$4,019	\$2,357 - \$24,111	7

Cancer drugs have the seventh highest median WAC (\$6,433) of therapeutic categories reported in 2020, although Tecartus, with the highest WAC reported in 2020 (\$373,000), belongs to this category. Chelating agents, with an average price of \$12,130 for reported drugs, are sixth. In the pharmaceutical context, they are used as imaging contrast agents for MRI and PET scans.

Three of the drugs that appear on this list are due to a single NDC. Antimalarials appear on the list due to Pyrimethamine (generic Daraprim, discussed above) at \$29,250 for 100 pills. Antihypertensives appear on the list due to Amneal’s report for Metyrosine (generic Desmer at \$35,005), and Respiratory Agents appear due to Vertex Pharmaceuticals Trikafta (\$23,896), a treatment for cystic fibrosis. While Metyrosine is listed as an antihypertensive, it is currently indicated only for hypertension symptoms caused by a specific, rare form of cancer in the adrenal gland – meaning its price is more comparable to other cancer therapies.

Also notable on this list is the category of antivirals, with a median WAC of \$28,000 for seven NDCs

reported to the program in 2020. The median WAC for this category was as high as it is due only to four reports submitted by Gilead, which is also the manufacturer of the COVID-19 antiviral Veklury (remdesivir). Gilead submitted reports for four hepatitis C drugs - two NDCs associated with Sovaldi (at \$28,000), and two NDCs associated with Harvoni (\$31,500).

Marketing description

Manufacturers are required to submit a description of their planned marketing for a new prescription drug as part of any new drug reports submitted. This includes the amount the company expects to spend on marketing directly to consumers, as well as on marketing to health care providers. It also requires a narrative description of what marketing activities a company plans to engage in, including, but not limited to, advertising on television and in magazines, using peer-to-peer communications such as sponsored speakers at medical seminars, and employing sales representatives.

Here is an example of a typical submission for the marketing description data element, submitted by Karyopharm Therapeutics for its cancer drug XPOVIO, and not claimed as a trade secret:

“XPOVIO® was approved by the FDA in July 2019 for the treatment of adult patients with relapsed or refractory multiple myeloma. On June 22, 2020, FDA approved XPOVIO® for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma. To market this new indication, Karyopharm designed activities to increase awareness and understanding with healthcare providers about the change to the FDA approved label. Marketing activities are planned to include education and training provided by our existing sales force and by contracted speakers to health care providers (HCPs), an updated XPOVIO® website, and other digital and print advertising for HCPs. Patient educational materials will also be provided to HCPs but, with the exception of the XPOVIO® website, no further direct-to-consumer advertising is planned. Karyopharm will offer a patient assistance program to qualifying patients.”

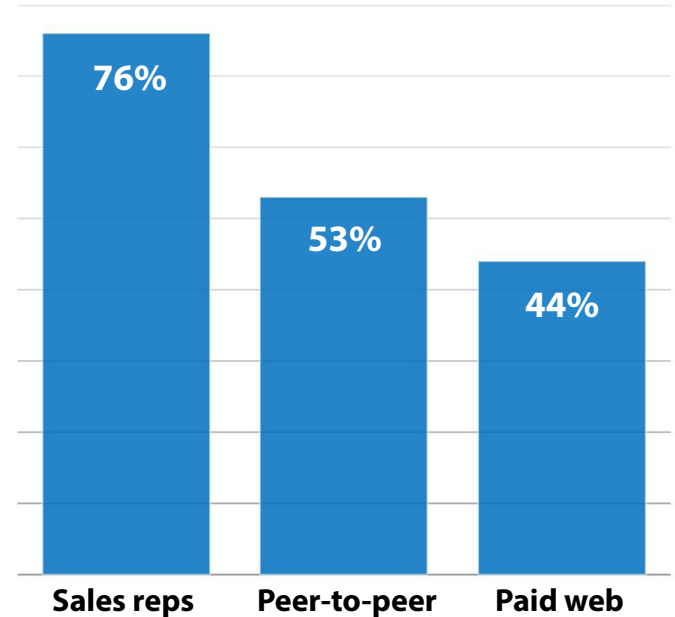
While the program collects this information for all new drug reports, both generic and brand name, we have found that most companies do not engage in any marketing for generic drugs. The scope of promotion for generics is typically limited to listing the drug in wholesaler catalogs. However, biosimilars,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

The quality of information submitted by manufacturers was extremely variable, ranging from blanket refusals to provide any information to detailed descriptions of a company’s plans for a drug’s lifecycle. While the program frequently sends requests for more information or clarification to companies with insufficient filings, staff members are still working through the process of integrating responses to these questions with previous submissions.

From the reports we received in 2020, we identified 35 brand-name product families

whose submission contained sufficient detail on marketing in their initial filing to analyze. Most of these product families represent multiple NDCs, and Information covering multiple drugs has been de-identified and aggregated so that information claimed to be trade secret is not disclosed.

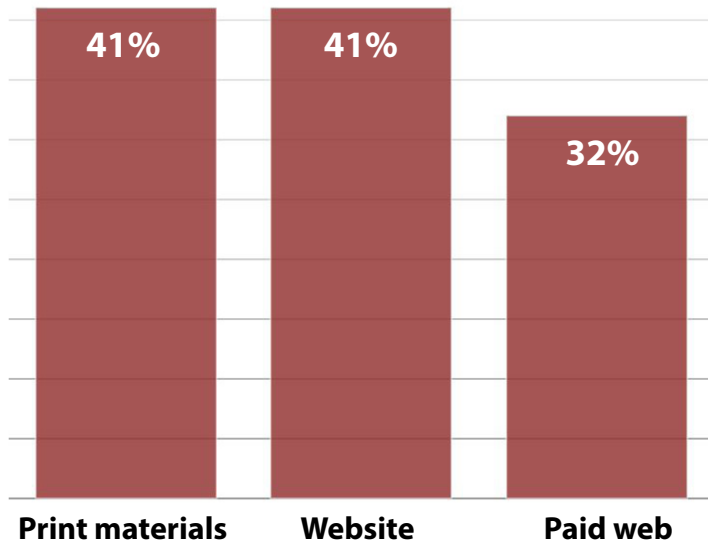
Figure 12: Marketing strategies targeting health care professionals



Source: Oregon Prescription Drug Price Transparency Program

The chart above shows the three most frequently referenced marketing strategies targeting health care professionals for the 35 drug families we analyzed. Seventy-six percent of the reports referenced the use of sales representatives, and 44 percent mentioned the use of paid web advertising such as banner ads, social media ads, or paid search ads directed to prescribing health care professionals. Fifty-three percent of the drug families referenced the use of peer-to-peer communications in the promotion of the drug. This included the use of sponsored speakers, sponsored continuing education events, webinars, and podcasts.

Figure 13: Direct-to-consumer marketing strategies



Source: Oregon Prescription Drug Price Transparency Program

The program has also analyzed the direct-to-consumer marketing strategies referenced by manufacturers of new, high-cost drugs. The graph above shows the three most frequently referenced direct-to-consumer marketing strategies for the 35 drug families we analyzed. Print materials and websites targeted to a consumer audience were both mentioned by 41 percent of manufacturers. Paid web advertising such as banner ads, social media ads, or paid search ads directed to consumers was mentioned by 32 percent of the drug families we analyzed.

None of the 35 drug families referenced direct-to-consumer ads on television in their 2020 reports, although several expressly stated that they would not engage in advertising on television and the radio for that drug.

The program will continue to work with manufacturers to ensure improved data quality of a larger proportion of submissions by integrating information received through follow-up requests and outreach and education to manufacturer representatives. We expect our 2021 report to contain analysis of marketing strategies based on a more comprehensive set of collected data.

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 usually 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.

Here is an example of a typical submission for the pricing methodology data element, submitted by Bristol Meyers Squibb for its drug ONUREG, used as a treatment for acute myeloid leukemia after chemotherapy. This information was not claimed as a trade secret by Bristol Meyers Squibb in its submission.

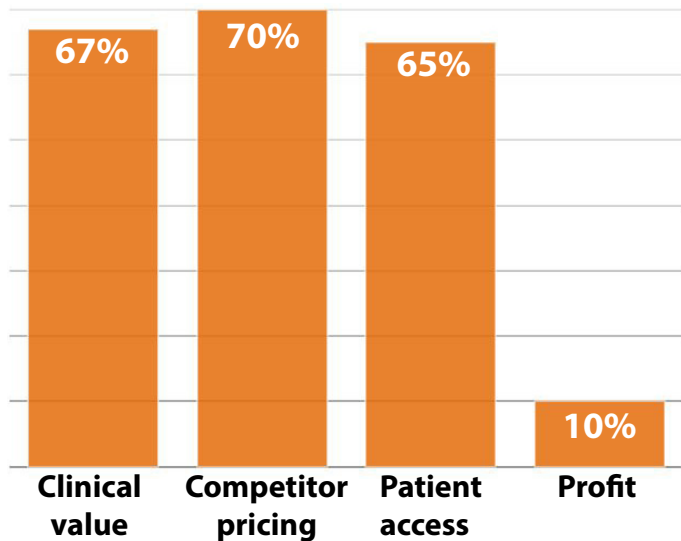
"We consider multiple factors when setting a list price for a medicine, including:

- The benefits the medicine brings to patients, healthcare systems and society - in terms of clinical outcomes and quality of life, longevity of life, and savings generated for other parts of the healthcare system such as reduced hospitalization and treatment costs.
- Market and business considerations, including:
 - Ongoing research-investment costs; BMS invests more than 35 percent of its annual revenues in R&D, among the highest of any large company in any industry in the world;
 - Medical- and patient-service costs; this includes funding growing patient assistance programs;
 - Inflationary and capital-investment costs associated with manufacturing, storage and supply."

As with the information submitted for marketing plans, the quality of information we received for pricing methodology was extremely varied,

and much of it was unusable for detailed analysis. From the reports we received in 2020, we identified 43 brand-name product families whose submission contained in their initial filing had sufficient detail to analyze on pricing methodology. Most of these product families represent multiple NDCs, and information covering multiple drugs has been de-identified and aggregated so that information claimed to be trade secret is not disclosed.

Figure 14: Factors considered in setting initial price



Source: Oregon Prescription Drug Price Transparency Program

The chart above shows the three most frequently referenced pricing factors across the 43 drug families we analyzed, plus the frequency that profit targets was mentioned as a pricing factor. The most frequently referenced pricing factor, as discussed above in our discussion of therapeutic classes, was the price of established competitors in the same therapeutic category, mentioned by 70 percent of these product families. Sixty-seven percent mentioned the clinical value of the drug’s benefits, and 65 percent mentioned ensuring patient access as a factor in their pricing decision.

Less than 10 percent of manufacturers mentioned profit targets for the drug family as a consideration in their price setting decision.

The program plans to continue working with manufacturers to ensure improved data quality of a larger proportion of submissions by integrating information received through follow-up requests and outreach and education to manufacturer representatives. We expect our 2021 report to contain analysis of marketing strategies based on a more comprehensive set of collected data.

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 for a course of treatment shorter than one month that experience a net price increase of 10 percent or more from the previous year.⁵² The first annual price increase reports were due July 1, 2019, while in 2020 and subsequent years, the reports have been due on March 15. Reports are filed for price increases that occurred over the preceding calendar year, so reports received in 2020 apply to increases that occurred between Jan. 1, 2019, and Dec. 31, 2019.

In 2019, the program received a total of 551 reports, of which the vast majority (515 or 93 percent) were for brand-name drugs. In 2020, the program received only 160 reports, a 70 percent decrease from 2019 and about two-thirds (90, or 66 percent) of which were for generic drugs.

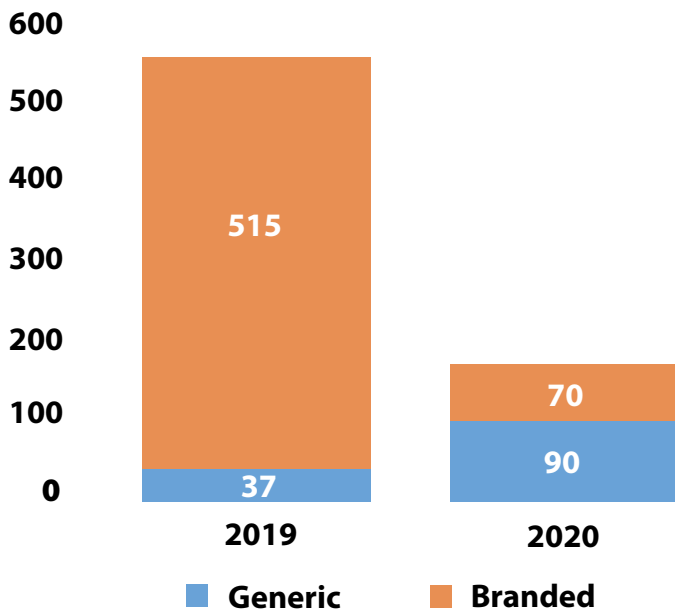
In 2019, generic drugs had an average price increase of 33 percent across the 37 reports we received, ranging from the reporting cutoff of 10 percent up to 219 percent. In 2020, we received 90 reports for generic NDCs, double the number we received in 2019. The average reported increase for generics also more than doubled, to 75 percent, with a range from 10 percent to 520

⁵² See the appendix “Calculating a Net Increase Percentage” for details on how a net price increase percent is calculated.

percent. The 520 percent figure was reported for two separate NDCs for Desmopressin acetate, a treatment for diabetes insipidus, manufactured by Teva Pharmaceuticals. However, a number of NDCs reported price increases during 2019 between 300 percent and 500 percent.

The average price increase reported for brand-name drugs in 2019 was 15 percent, across the 551 NDCs, with a range from 10 percent to 219 percent. The average price increase reported for brand names, like generics, also increased in 2020 to 24 percent, though the 70 reports we received is less than one-fifth of the 515 filed in 2019.

Figure 15: Price increase reports filed for brand names and generics by year



Source: Oregon Prescription Drug Price Transparency Program

The reason for the decline in price increase filings is unclear, and will require more years of data to analyze. We do not believe this is the result of a lower compliance with the program in 2020, which is discussed below in the “Compliance” section of this report.

However, the increasing number of generic price increases reported, and the size of those price increases, may offer one potential explanation. A number of prominent drug manufacturers, including AbbVie, Allergan, Novo Nordisk, and Valeant, have pledged to keep price increases below 10 percent annually.⁵³ Assuming that these and other companies have been restricting price increases by not raising prices more than 9.9 percent annually, they can continue to raise prices while avoiding scrutiny from state and federal transparency efforts, such as this program.

At the same time, companies that manufacture both generic and brand-name drugs may be distributing their price increases across their generic portfolio – avoiding high scrutiny price hikes on expensive brand-name drugs, while making larger price increases on larger numbers of lower cost generic drugs. Program staff members will continue to monitor public information around drug pricing, and reports in coming years, to see if this pattern continues, and to identify other trends in drug pricing.

Reasons given for price increases in 2019

Manufacturers are required to provide a narrative explanation of the factors that lead to a reported price increase, including an explanation of all major financial and nonfinancial factors that influenced the decision to increase the WAC of the drug and to decide the amount of the increase. As with all narrative submissions we receive, the quality of the data is extremely varied across manufacturers.

Here is a typical example of a narrative submission explaining a price increase, submitted by Cosette Pharmaceuticals for its drug Migerot,

⁵³ Jeroen Van Meijgaard, PhD, “Drug Makers Keep Promises to Limit Price Increases to 10% - But Barely,” GoodRx Blog, accessed at: <https://www.goodrx.com/blog/drug-manufacturers-keep-price-increase-pledge-ten-percent-barely/>, on December 2, 2020.

a migraine treatment. This information was not claimed as a trade secret:

“Cosette Pharmaceuticals acquired this product in June of 2019. When we looked at the pricing of this product, as we do with all of our products, we carefully and holistically evaluated a variety of factors including accessibility and affordability of this treatment option for both patients and payors, the number of patients who take the product, the market conditions, the overall increase in the cost of labor and goods, the required capital investment in manufacturing facilities and systems, and the funding of research and new product development designed to meet the needs of patients and healthcare professionals today and in the future. In this instance, the price had to be adjusted in light of the declining net utilization, increase in cost of labor and goods, and

financial costs and debt incurred with acquiring the product.”

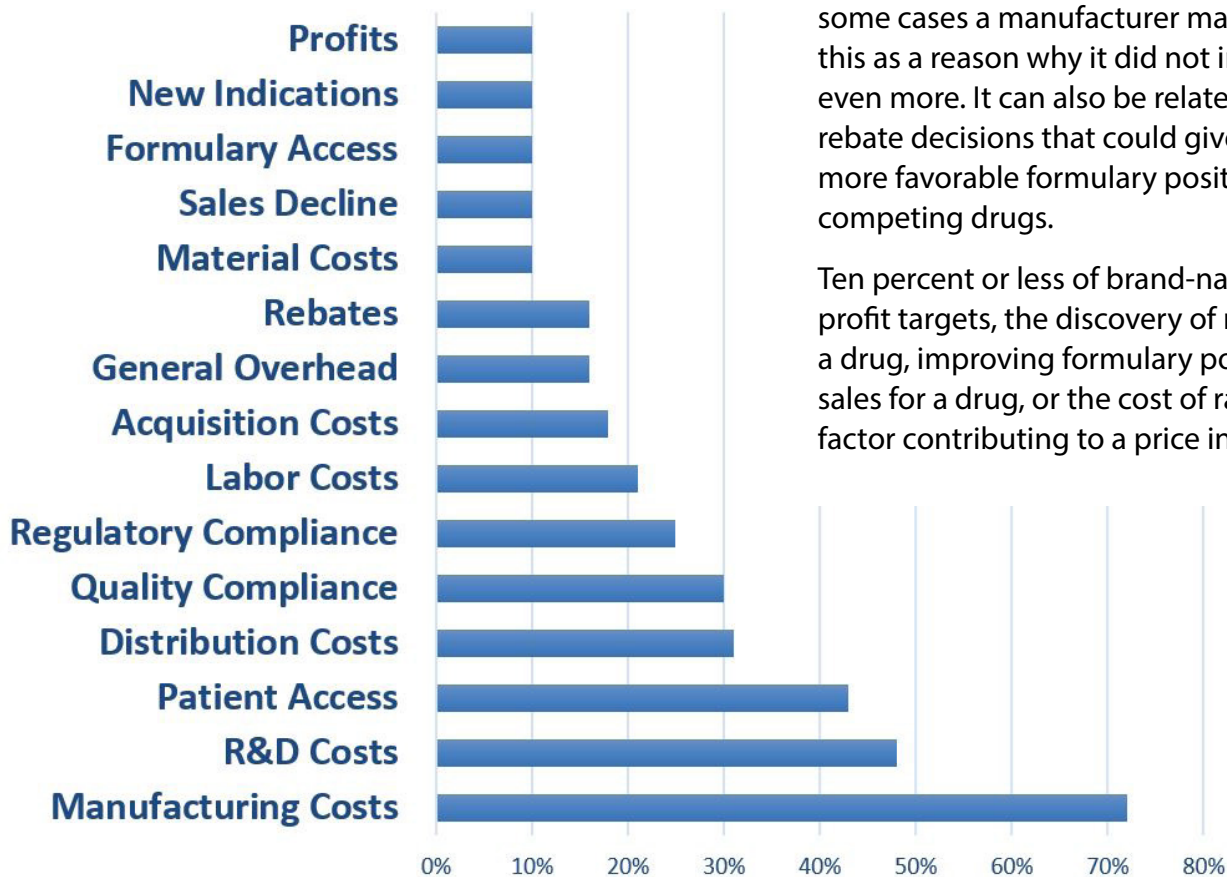
We analyzed narrative price increase submissions for 62 brand-name NDCs. The graph below shows the most cited factors for price increase decisions reported by brand names.

The most frequently cited price increase factor reported for brand names was increasing manufacturing costs, cited by 72 percent of reports analyzed. This was followed by research and development costs, mentioned by 48 percent of reports. While sometimes this referred to clinical studies of secondary indications for the referenced drug, other manufacturers claimed that the need for revenue to support development of other products justified a price increase.

Finally, 43 percent of brand-name reports cited maintaining patient access to the drug as a factor contributing to the pricing decision. This isn’t necessarily as counter-intuitive as it sounds – in some cases a manufacturer may simply be citing this as a reason why it did not increase prices even more. It can also be related to pricing and rebate decisions that could give a manufacturer more favorable formulary position relative to competing drugs.

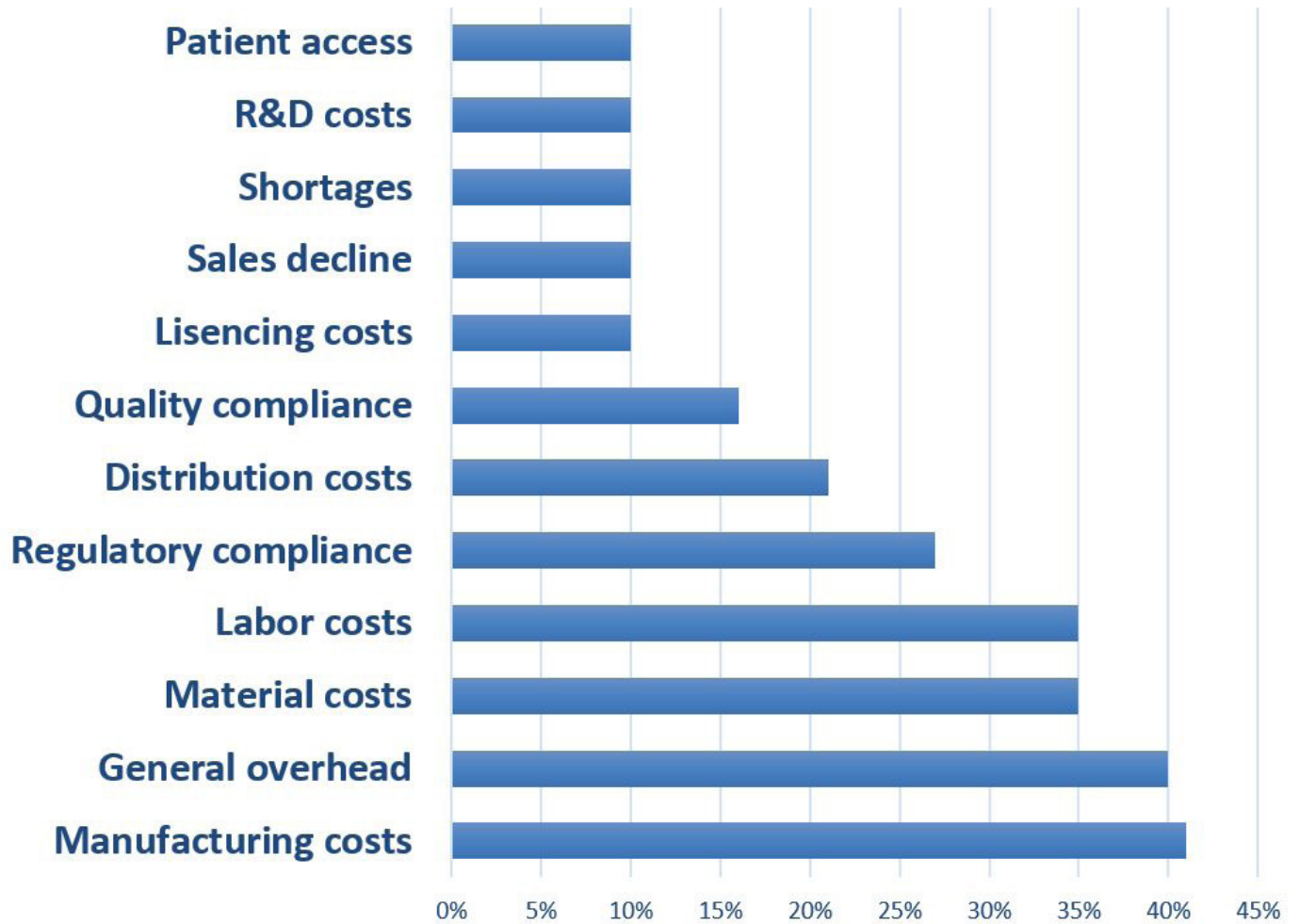
Ten percent or less of brand-name reports cited profit targets, the discovery of new indications for a drug, improving formulary position, declining sales for a drug, or the cost of raw materials as a factor contributing to a price increase decision.

Figure 16: Price increase factors reported for brand-name drugs



Source: Oregon Prescription Drug Price Transparency Program

Figure 17: Price increase factors reported for brand-name drugs



Source: Oregon Prescription Drug Price Transparency Program

We also analyzed the narrative submissions of generic drugs that reported price increases. The chart above show the 12 most cited factors for generic manufacturers across 83 NDCs analyzed.

The most frequently cited reason for a generic price increase was an increase in overhead costs for the product, including manufacturing costs, the cost of raw materials, general overhead costs, labor costs, and regulatory compliance costs. Less than 10 percent cited patient access, research and development costs, declining sales, or an ongoing product shortage.

Profits and revenues

Manufacturers are required to report their profits and revenues in the previous year for each drug for which they file price increase reports. Since this information is often tracked and reported by manufacturers at a product family rather than NDC level, we analyzed the reported profits and revenues across 62 drug product families (comprised of 121 NDCs) from the price increase filings submitted this year. Three quarters of the drug product families reported positive profits. Half of the drugs reported profit margins of 37 percent or higher, and six drugs reported profit margins more than 80 percent.

Figure 18: Distribution of profitability for drugs with price increases in 2019, by product family



Source: Oregon Prescription Drug Price Transparency Program

An 80 percent profit margin means that, for every dollar of revenue brought in by the drug, 80 cents was pure profit. Those drugs made back their costs five times over.

One quarter of the drug product families reported losing money, with revenues that did not cover their costs. The worst performing drug recouped only 31 percent of its cost.

A single manufacturer may have drugs that turn a profit and drugs that lose money, as was the case with several reporting manufacturers. Other manufacturers reported only those drugs that turned a profit, and still others reported only those drugs that lost money. In total, the drugs we analyzed reported \$1.96 billion in revenue and \$374 million in profit. The overall profit margin across all drugs that reported price increases was 19 percent.

Direct costs reported by manufacturers

Pharmaceutical manufacturers are also required to report the direct costs they incurred in the previous calendar year for each drug for which they file a price increase report. They are required to report direct costs across four potential categories:

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

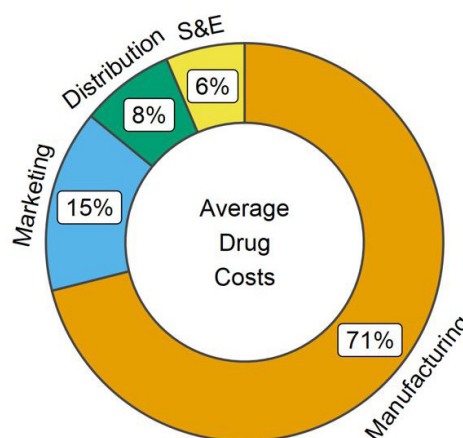
Like profits and revenues, many manufacturers track this information only at the product family

level. We analyzed the reported costs for 81 drug product families (comprised of 143 NDCs) from the price increase filings submitted this year.

Overall, manufacturers tended to spend more on manufacturing than on other costs. Drugs for which manufacturers reported little to no marketing, distribution, and safety and effectiveness research costs tended to be generic drugs. On average, manufacturing accounted for 71 percent of a product family’s costs, marketing accounted for 15 percent, distribution accounted for 8 percent, and safety and effectiveness (S&E) research accounted for 6 percent.

Note: These percentages varied greatly from drug to drug. For example, reports for 13 product families indicated that manufacturing costs accounted for 25 percent or less of each of their cost pies.

Figure 19: Direct costs reported for drugs with price increases in 2019



Source: Oregon Prescription Drug Price Transparency Program

Health insurance companies

The program requires health insurance companies to report on prescription drugs in Oregon. Health insurance companies are required by state law to report the 25 most prescribed drugs, the 25 most costly drugs, and the 25 drugs that caused the biggest increases in yearly health plan spending in the 2019 calendar year.

For 2020, we provided additional instructions to carriers to produce more consistent data across reporting insurers, due to inconsistencies in how reports were filed in 2019. Our analysis of insurer data in 2019 was also supported by information shared from the All-Payer All-Claims (APAC) database maintained by the Oregon Health Authority. For 2020, we directly asked reporting insurers for several more pieces of data for each drug, including the number of prescriptions issued, the number of enrollees affected, and the total amount of plan spending on each drug (net of rebates and other price concessions). With this additional information, we have been able to conduct more comprehensive analysis without relying on APAC data.

While we believe this has led to an overall more accurate set of data, it is also much more limited, since the program currently receives reports only from companies that sell plans on the state's individual and small group insurance marketplaces. These companies are the only ones required to report to the program. Less than 50 percent of the insurance market is represented in this data. It does not include most group health insurance, Medicare, or government sponsored insurance. For 2020, lists were received from all 10 health insurance companies required to file:

- BridgeSpan Health Company
- Health Net Health Plan of Oregon
- Kaiser Foundation Health Plan of the Northwest
- Moda Health Plan

- PacificSource Health Plans
- Providence Health Plan
- Regence BlueCross BlueShield of Oregon
- Samaritan Health Plans
- UnitedHealthcare Insurance Company
- Cigna Global Health Service Company

Due to our changes in data collection methodology for insurer reports between 2019 and 2020, the data is not directly comparable between the two years of the program, and our analysis is limited to information reported by insurers in 2020. The program released several aggregated lists based on our insurer reports last month, and the underlying data is available on our website.

Most prescribed drugs

The tables below were created using aggregated data across the lists submitted by all 10 reporting insurers in 2020. The most frequently prescribed generic drug in 2019 was levothyroxine, a treatment for hyperthyroidism, with 231,684 prescriptions across our 10 reporting insurers, while the most frequently prescribed brand-name drug was the seasonal flu vaccine with 342,608 prescriptions. This represents multiple NDCs and manufacturers for each compound.

The most prescribed specialty drugs in 2019 included Humira with 17,435 prescriptions and Enbrel with 7,986 prescriptions. Both products are anti-inflammatory drugs used in the treatment of autoimmune diseases such as rheumatoid arthritis. Also notable on this list is Truvada, most well known for its use for Pre-Exposure Prophylaxis ("PrEP") to prevent the transmission of HIV to sexual partners. All three of these drugs were also among the most costly for Oregon's insurers in 2019.

Figure 20: Most frequently prescribed drugs

Generic drugs

Drug	Drug class	Prescriptions
Levothyroxine	Thyroid Agents	231,684
Lisinopril	Antihypertensives	229,247
Atorvastatin	Antihyperlipidemics	228,075
Metformin	Antidiabetics	186,926
Hydrocodone-Acetaminophen	Analgesics - Opioid	163,648

Brand-name drugs

Drug	Drug class	Prescriptions
Influenza Virus Vaccine	Vaccines	342,608
Albuterol (multiple brands)	Antiasthmatic And Bronchodilator Agents	162,415
Adacel/Boostrix	Toxoids	41,364
Basaglar/Lantus/Toujeo	Antidiabetics	38,084
Shingrix	Vaccines	27,953

Specialty drugs

Drug	Drug class	Prescriptions
Humira	Analgesics - Anti-Inflammatory	17,435
Enbrel	Analgesics - Anti-Inflammatory	7,986
Mirena	Contraceptives	6,573
Truvada	Antivirals	6,352
Infliximab	Gastrointestinal Agents	5,094

Source: Oregon Prescription Drug Price Transparency Program

Most expensive drugs

The table below shows the most expensive prescription drugs reported by insurers for 2019. Since insurers included total dollars spent and prescription counts for each of the drugs they reported in their most costly and most prescribed lists, the program was able to determine what insurers paid for each of those prescriptions, on average. Note: The program did not explicitly request information regarding which drugs cost the most per prescription, and the program limited this analysis to drugs reported to be prescribed to 10 or more enrollees.

Figure 21: Most expensive prescriptions, on a per-prescription basis

Drug	Drug class	Avg. spent per prescription
Yervoy	Antineoplastics And Adjunctive Therapies	\$43,525
Ocrevus	Psychotherapeutic And Neurological Agents	\$39,701
Soliris	Hematological Agents	\$34,985
Kalydeco	Respiratory Agents	\$24,154
Trikafta	Respiratory Agents	\$23,362
Symdeko	Respiratory Agents	\$22,513
Keytruda	Antineoplastics And Adjunctive Therapies	\$15,613
Revlimid	Miscellaneous Therapeutic Classes	\$15,001
Xyrem	Psychotherapeutic And Neurological Agents	\$12,643
Mavyret	Antivirals	\$12,565

Source: Oregon Prescription Drug Price Transparency Program

For the second year in a row, the most expensive drug reported in Oregon was a cancer treatment. In 2020, this was Yervoy, most often used to treat melanoma, with an average of \$43,525 in claims paid by insurers per prescription. The top 10 list also included the cancer drugs Keytruda and Revlimid, at around \$15,000 in claims per prescription. The list also includes three treatments for cystic fibrosis – Kelydeco, Trikafta, and Symdeko – and a recently developed treatment for multiple sclerosis, Ocrevus, with a per-prescription cost of \$39,701, making it the second most expensive drug in Oregon in 2019.

Figure 22: Most expensive generic drugs, on a per-prescription basis

Drug	Drug class	Avg. spent per-prescription
Glatiramer	Psychotherapeutic And Neurological Agents	\$2,804
Temozolomide	Antineoplastics And Adjunctive Therapies	\$2,661
Lanthanum	Gastrointestinal Agents	\$1,552
Phytonadione	Vitamins	\$1,426
Imatinib	Antineoplastics And Adjunctive Therapies	\$1,218

Source: Oregon Prescription Drug Price Transparency Program

The table above show the five most expensive generic drugs reported by insurers in 2020. As with generics, the most frequently listed therapeutic class for most expensive generics was cancer drugs, with Temozolomide at \$2,661 and Imatinib at \$1,218.

Glatiramer, a generic treatment for multiple sclerosis, also appears on this list with a per-prescription cost of \$2,804 as the most expensive generic drug in Oregon in 2019. ICER performed a clinical and economic review of multiple sclerosis drugs in 2017, and concluded that Ocrevus, the second most expensive name-brand drug in Oregon in 2019, showed a clear therapeutic benefit relative to Glatiramer. However, the per-prescription

cost of Ocrevus for Oregonians is approximately 1,415 percent higher than the per-prescription cost of generic Glatiramer. Even considering the potential benefits, this could raise concerns of access inequities for multiple sclerosis patients.

Most costly drugs

The table below shows the most costly drugs for Oregon insurers in 2019, calculated by aggregating the total spent reported by our 10 insurers. These numbers are reported net of rebates and other price concessions, to the extent the information is available, and are the most accurate data we have available regarding the cost of particular drugs to insurers.

Figure 23: Most costly drugs

Drug	Drug class	Amount spent
Humira	Analgesics - Anti-Inflammatory	\$80,509,117
Enbrel	Analgesics - Anti-Inflammatory	\$33,771,085
Stelara	Dermatologicals	\$23,399,682
Truvada	Antivirals	\$20,608,725
Biktarvy	Antivirals	\$18,042,219
Rituxan	Antineoplastics And Adjunctive Therapies	\$16,983,505
Cosentyx	Dermatologicals	\$15,746,169
Herceptin	Antineoplastics And Adjunctive Therapies	\$14,072,476
Remicade	Gastrointestinal Agents	\$13,635,198
Opdivo	Antineoplastics And Adjunctive Therapies	\$13,532,849

Source: Oregon Prescription Drug Price Transparency Program

As mentioned above, three of the drugs on this list – Humira, Enbrel, and Truvada – were also among the most frequently prescribed specialty drugs in 2019. Between Humira and Truvada, both of which treat autoimmune disorders including rheumatoid arthritis, reporting insurers paid \$114,280,202 in claims in 2019. Between Truvada and Biktarvy, used in the treatment of HIV/AIDS, insurers paid \$38,650,944 in claims. Finally, the three most costly cancer drugs on this list, which are typically the most expensive on a per-patient basis, cost Oregon insurers more than \$44,588,830 in claims.

Figure 24: Most costly generic drugs

Drug	Used to treat	Amount spent by insurance companies
Amphetamine Dextroamphetamine	Narcolepsy and ADHD	\$6,223,708
Methylphenidate	ADD and ADHD	\$6,175,683
Buprenorphine	Opioid dependence	\$4,435,548
Levothyroxine	Thyroid	\$3,742,458
Estradiol	Estrogen	\$2,979,520

Source: Oregon Prescription Drug Price Transparency Program

This final chart, showing the five most costly generic prescriptions in Oregon, has almost zero overlap with the most prescribed or most expensive per prescription lists, with the exception of the thyroid agent levothyroxine, which was the most prescribed generic drug in Oregon with 231,684 prescriptions in 2019.

Overlap with manufacturer reporting

In order to identify potential connections between price increases and increased plan spending, the program searched for drugs that appeared on our insurer lists that had also submitted price increase reports. We identified 11 NDCs across four drug manufacturers and four product families that were reported by both manufacturers and insurers.

The program received annual price increase reports for methylphenidate, buprenorphine, and hydrocodone. Mayne Pharma and Neos Therapeutics submitted price increase reports for methylphenidate, raising WAC prices for their NDCs by 89 percent and 10.65 percent, respectively.

Manufacturer	NDC	Drug	WAC	Increase
Mayne Pharma	51862026301	Methylphenidate Hydrochloride LA	\$656.41	89%
Mayne Pharma	51862026401	Methylphenidate Hydrochloride LA	\$671.35	89%
Mayne Pharma	51862026501	Methylphenidate Hydrochloride LA	\$690.00	89%
Neos Therapeutics	70165010030	Cotempla XR-ODT	\$363.80	10.65%
Neos Therapeutics	70165020030	Cotempla XR-ODT	\$363.80	10.65%
Neos Therapeutics	70165030030	Cotempla XR-ODT	\$363.80	10.65%

Par Pharmaceutical submitted a report for an 11.76 percent increase for buprenorphine (NDC 42023017905). Pharmaceutical Associates reported price increases for four NDCs containing hydrocodone.

Manufacturer	NDC	Drug	WAC	Increase
Pharmaceutical Associates	00121477240	Hydrocodone Bitartrate and Acetaminophen	\$264.85	24.50%
Pharmaceutical Associates	00121154440	Hydrocodone Bitartrate and Acetaminophen	\$297.29	22.38%
Pharmaceutical Associates	00121231640	Hydrocodone Bitartrate and Acetaminophen	\$246.72	103.56%
Pharmaceutical Associates	00121481140	Hydrocodone Bitartrate and Homatropine Methylbromide	\$198.83	131.38%

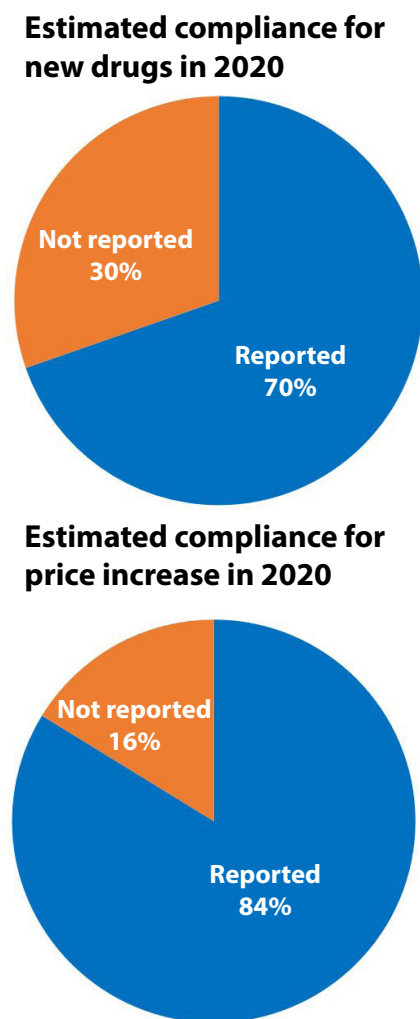
However, there was virtually no overlap with our aggregated data lists, making the analysis inconclusive, at best.

Many of the drugs that appeared on our most expensive and most costly brand-name drugs are relatively new compounds that entered the market in the past 10 years. As the program accumulates multiple years of data for new drug reports, we may attempt a similar analysis of the effect of new drugs on claims, in addition to price increases.

Compliance and enforcement efforts

While the program has the authority to impose substantial civil penalties for failures to register with the program, file required reports, or respond to program correspondence, compliance efforts for the first two years of implementation have focused on outreach and education rather than formal enforcement proceedings.

Figure 25: Estimated compliance rates for manufacturer reporting requirements



Source: Oregon Prescription Drug Price Transparency Program

In order to monitor compliance with the program's reporting requirements, the department has contracted with a private vendor, Medi-Span, for access to a database of WAC pricing data. We used algorithmic analysis of WAC data in Medi-Span to identify NDCs that met the new drug or price increase reporting requirements where a report was not received from the manufacturer in the allowed time.

The resulting lists were reviewed to eliminate NDCs not subject to program requirements, such as medical devices and dietary supplements. We also removed NDCs that appeared to meet reporting requirements, but did not actually qualify due to dosing recommendations and package size.⁵⁴

After this process, we were left with 135 NDCs that may have required a new drug report and 31 NDCs that may have required a price increase report, where none was filed. This gives an estimated compliance rate of 70 percent for new drug reports (310 received of an estimated 445 required) and 84 percent compliance for price increase reports (160 received of an estimated 191 required).

So far, the program has completed compliance outreach to 11 manufacturers regarding 25 NDCs, and all but one of the files has been closed with a favorable result – either the company provided the requested information or was able to demonstrate that they are not subject to the program's requirements.⁵⁵

Given this level of success, the program will continue to focus on outreach and education efforts to increase compliance with the reporting requirements of the Prescription Drug Price Transparency Act before referring any files to the department's enforcement unit.

⁵⁴ For example, a drug might have an WAC of \$670 for a bottle containing 100 pills, where a course of treatment is one pill. This would be pulled by our algorithm, since it meets the Medicare Part D specialty threshold on the basis of its WAC alone. However, since a typical patient takes only one pill in a course of treatment, the relevant cost for our purposes is only \$67, meaning a new drug report would not be required.

⁵⁵ For example, certain NDCs that appear in Medi-Span may refer to drugs that are sold to an unusually limited market, such as a single hospital not located in Oregon, and are not sold on the wholesale market.

Policy recommendations

Prescription drug costs continue to be an issue for Oregonians. With the information reported to the program, the department has begun to learn several things about prescription drugs such 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 in the first two years of the program help guide the department to identify areas for program improvements, and better understand the topic of drug pricing.

The Prescription Drug Price Transparency Act directs the department to provide the legislature with recommendations for legislative changes to contain the cost of prescription drugs and reduce the impact of price increases. Several of the recommendations offered are suggested improvements to the program to receive better quality data to inform policy recommendations.

Program improvements

Oregon's program is unique and one of the first prescription drug price transparency programs in the country. Since the start of implementation in 2019, several areas have been identified where changes would improve the goals and administration of the program.

General program improvements

Recommendation 1: Provide statutory access to the All Payer All Claims Database

DCBS worked with the Oregon Health Authority (OHA) to obtain and use data from the All Payer All Claims (APAC) database to provide context to the information received from health insurers. This information was useful to further understanding the effect drug prices have on Oregonians and health insurers.

Currently, DCBS does not have direct access to the APAC database, but does work closely with

OHA when this data is needed. This requires time and resources for both agencies. The statute establishing APAC provides direction for OHA to facilitate collaboration with DCBS to use the data. For the department to have direct access to the data, DCBS would need to be given explicit authority to do so in ORS 442.373. Several attempts to include DCBS into the APAC statute have occurred in recent years as both DCBS and OHA recognize the shared interest in access to this data and improving health care data analyses.

We recommend the legislature consider adding DCBS to ORS 442.373 and provide authority to directly use APAC data for department analyses. This will enable more efficient administration of program analyses and streamline processes for using APAC data between OHA and DCBS.

Recommendation 2: Evaluate the program's expenditure limitation

The Prescription Drug Price Transparency Act provides the department with an expenditure limitation to administer the program. Several unanticipated factors require the need for the department to request an expenditure limitation increase for the drug price transparency program. These factors include the following:

- Higher than expected information technology costs related to the enhanced security measures the program is taking for information claimed to be trade secret
- Higher than expected legal costs due to evaluation of several trade secret protection requests and to maintain appropriate due process safeguards
- Unanticipated costs related to procuring access to a database with marketwide information about drug prices to enable evaluation of manufacturer compliance with reporting requirements

We recommend the legislature work with the department to evaluate the program's expenditure limitation and determine how to properly adjust this based on the unanticipated factors contributing to higher expenses.

Recommendation 3: Ongoing program evaluation

We will continue to evaluate the program. This may result in recommendations to the legislature or changes the department can make to improve the overall program. Improvements may include changes to help manufacturers efficiently submit reports, internal changes to better administer the program and its deadlines, and any other changes that improve the program for the agency and its stakeholders. When evaluating any improvement to the program, the department will evaluate the time and resources needed to implement any change.

Manufacturer reporting

Recommendation 4: Clarify the threshold for annual price increase reports

The statutory threshold for reporting an annual price increase report occurs when a drug is priced at \$100 or more for a course of treatment and "there was a net increase of 10 percent or more in the price of a prescription drug over the course of the previous calendar year." The program rules further clarify that the definition for "net yearly increase" is "an increase in the wholesale acquisition cost of a drug over the course of a calendar year, calculated by dividing the average wholesale acquisition cost of the drug over the course of a calendar year by the average wholesale acquisition cost over the course of the previous calendar year." We determined this definition to be the most appropriate and accurate definition for the statutory threshold since it accounts for any increase or decreases in price that may occur throughout the year.

The advance notice requirement (HB 2685, 2019) contains different threshold price reporting terms.

We recommend changing the statutory language regarding the threshold for annual price increase reports to conform to HB 2658 terms:

- A cumulative increase of 10 percent or more over the course of the previous year

or

- When, at any point in the previous calendar year, an increase or series of increases in the price of the drug results in a price 10 percent higher than the price of the drug at any previous time during the calendar year.

Recommendation 5: Patient assistance reporting for new drug reports

The program currently receives information on patient assistance programs through the annual price increase reports. Several new high-cost drugs that come to market also have patient assistance programs to help consumers who are prescribed the drug with the cost. Unlike the annual price increase reports, the new drug reports do not report any patient assistance program information to the program.

We recommend the legislature consider including patient assistance reporting for new high-cost drugs reported to the program to improve understanding of these programs, particularly when a new drug comes to market.

Health insurer reporting

Recommendation 6: Expand reporting to additional insurers

Under the Prescription Drug Price Transparency Act, health insurance companies are required to submit specified information about prescription drug spending and utilization, including the top 25 most costly drugs and the top 25 most prescribed drugs, as part of the annual rate filing process. Since insurers 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.

Consumer notification reporting

Recommendation 7: 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 submit reports 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, the information collectively could potentially identify a consumer. We recommend clarifying that the personally identifiable information collected will be protected from public disclosure.

Other recommendations

Recommendation 8: Transparency across the pharmaceutical supply chain

The price of a prescription drug is influenced by several factors. This includes the interactions and financial negotiations between pharmaceutical supply chain entities. The information the program receives from manufacturers on the wholesale acquisition cost of a drug is the starting point before the financial aspects of the drug price move to wholesaler distributors, pharmacy services administrative organizations, pharmacy benefit

managers, health insurers, hospitals, medical providers, and pharmacies. Several of these entities can influence the price of the drug to consumers, either at the pharmacy counter, through consumers' health insurance premiums, or how drug costs contribute to overall health care system costs.

We recommend the legislature consider transparency across the pharmaceutical supply chain entities to fully understand what influences and contributes to the price of the drug. This includes the recommendations and reporting on cost factors identified by the Task Force on Fair Pricing of Prescription Drugs – coupons, discounts, fees, incentive programs, insurance benefit design, list price, markups, pharmacist gag clause, and rebates. Cost factor information from pharmaceutical supply chain entities is important to the state's understanding of drug pricing and how to best identify policy recommendations to reduce the cost of prescription drugs.

Recommendation 9: Integration of current and future transparency requirements

In 2019, the legislature passed House Bill 2658, which requires the department to receive advance notices for certain drug price increases. This new statute, while similar to the Prescription Drug Price Transparency Act, is not expressly integrated into the Oregon Prescription Drug Price Transparency Program.

As the legislature considers more prescription drug transparency requirements, we recommend to consider integrating the Prescription Drug Price Transparency Act and House Bill 2658, as well as any future transparency requirements. Integration of transparency requirements will provide a standard infrastructure to stakeholders involved and the resources needed to implement this type of reporting to the department such as funding, rulemaking, and enforcement authority.

Drug policies in other states

The following section does not represent official recommendations from the department, but rather an overview of what drug policies 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.

A 2019 Kaiser Family Foundation Poll found that significant majorities of Americans support a wide variety of policies to keep prescription drug costs down, including making it easier for generic drugs to come to market, allowing Medicare to negotiate prices with drug companies, lowering what Medicare pays for drugs based on prices in other countries, and increasing taxes on drug companies with high prices.⁵⁶

Figure 26: Public attitudes about drug price reforms

Majority Favor Most Actions To Keep Prescription Costs Down

Percent who **favor** each of the following actions to keep prescription drug costs down:



SOURCE: KFF Health Tracking Poll (conducted February 14-24, 2019). See topline for full question wording and response options.



⁵⁶ Ashley Kirzinger, et al, *KFF Health Tracking Poll – February 2019: Prescription Drugs*, March 1, 2019. Retrieved at: <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/> on December 3, 2020.

State legislatures across the country have continued to work on policies aiming to control the cost of prescription drugs in their state, even as the COVID-19 pandemic has disrupted legislative sessions. In 2020, at least 433 bills related to the cost of prescription drugs have been introduced. The broad topics addressed by state legislation introduced in states this year include:⁵⁷

- Drug affordability review board – Establishing a regulatory body to review the affordability and cost of specific prescription drugs. Maine, Maryland, and Massachusetts passed laws related to drug affordability review boards in 2019, and 21 similar bills were introduced across the states in 2020.
- Drug importation – Directing the state to examine or establish a drug importation program from Canada. Florida and Maine enacted statutes establishing drug importation programs. Colorado and Vermont passed laws to design or provide findings on drug importation. HHS has promulgated regulations for implementation of these programs, but Canada recently outlawed the mass export of prescription drugs that are subject to a current shortage.⁵⁸
- Transparency – Reporting on drug price information from specified pharmaceutical supply chain entities such as pharmaceutical manufacturers, wholesale distributors, and pharmacy benefit managers, similar to this program. Sixty bills related to prescription drug price transparency were introduced in other states in 2020, and 18 states have passed and are implementing drug price transparency programs.
- Coupons – Regulating or prohibiting the use of discounts or coupons by specified pharmaceutical supply chain entities. Seventy-one bills relating to coupons or cost sharing were introduced in state legislatures in 2020.
- Bulk purchasing – Using state or multi-state leverage to volume purchase prescription drugs. Eight bills were introduced across six states in 2020 related to bulk purchasing of prescription drugs, including a bill in California that encourages engagement with Oregon and Washington to lower prescription drug prices through joint purchasing.



⁵⁷ Sarah Lanford, "2020 State Legislative Action to Lower Pharmaceutical Costs," National Academy for State Health Policy, Updated on November 24, 2020, retrieved at: <https://www.nashp.org/rx-legislative-tracker/> on December 2, 2020. The bullets below are also largely derived from this list.

⁵⁸ Mathew S. Schwartz, "Canada Blocks Export of Medications in Short Supply in Response to Trump Plan," NPR, November 29, 2020. Retrieved at: <https://www.npr.org/2020/11/29/939890111/canada-blocks-export-of-medications-in-short-supply-in-response-to-trump-plan> on December 2, 2020.

Conclusion

Oregonians pay significant costs towards the prescription drugs they need. Oregon's Prescription Drug Price Transparency Program is one of the first in the nation to be fully implemented and has gathered insightful information about drug prices. Through the information received from prescription drug manufacturers, health insurers, and consumers, the program is starting to understand the factors influencing drug prices and how this affects Oregonians.

Based on data collected during the first two years of program implementation, the program has made the following key findings:

- Most new, high-cost drugs reported to the program are generics, but the highest cost drugs reported are all brand names. Cancer drugs were consistently the most expensive drugs in Oregon on both a list price and per-patient basis, and the highest cost drug reported in 2020 was Tecartus, a cancer drug with a per dose price of \$373,000.
- High prices for new drugs appear to be driven, in part, by the relative cost of established drugs that treat the same condition. This includes treatments for cancer, multiple sclerosis, and rheumatoid arthritis. A similar trend was found in a generic alternatives to brand-name Daraprim, a drug that gained notoriety after Turing Pharmaceuticals raised its price more than 5,000 percent.
- The number of price increases reported to the program declined 70 percent between 2019 and 2020. The reasons for this trend are unclear, but do not seem to be related to reduced compliance with reporting requirements. One explanation suggested by the data may be that manufacturers are spreading price increases more widely across their portfolio of drugs to avoid triggering the reporting requirement.
- Most drugs with price increases were profitable during 2019, with an average profit margin of 19 percent. Half reported profit margins of 37 percent or more, with six reporting a profit margin of more than 80 percent, meaning they make 80 cents of pure profit for every dollar of revenue from the drug.
- Humira and Enbrel, both treatments for autoimmune diseases, including rheumatoid arthritis, were the two most costly drugs for Oregon insurers in 2019, with more than \$114,280,202 in claims paid in 2019. The most expensive drug in Oregon in 2019 on a per-prescription basis was the cancer drug Yervoy, with \$43,525 spent on average per prescription.

Resources

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

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@oregon.gov.

Anyone can enroll for free into the [Oregon Prescription Drug Program](#), which may provide discounts on prescriptions drugs for those uninsured or for drugs not covered by the individual's insurance plan. For more information, call 800-913-4284 (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.

General information about prescription drugs

For general information on prescription drugs, visit the following pages:

- U.S. Food and Drug Administration – [Resources for Consumers](#)

- U.S. National Library of Medicine – [Drug Information for the Public](#)

Appendix

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 drug was \$500 for the first 100 days of 2017, then rose in price to \$600 on the 101st day and remained at that price for the rest of the year. The drug’s average list price in 2017 is the average of these list prices, \$500 and \$600, taking into account how much time the drug spent at each price.

So this drug’s average list price in 2017 is

$$\frac{(100 \times \$500 + 265 \times \$600)}{365} = \$572.60$$

Suppose the drug had another price increase on Jan. 25, 2018, from \$600 to \$640, and then remained at that list price for the rest of the year. The drug’s average list price in 2018 is

$$\frac{(25 \times \$600 + 340 \times \$640)}{365} = \$637.26$$

To find the 2018 net increase percentage, we compare the average price in 2017 to the average price in 2018.

The drug’s average list price in 2018, \$637.26, is 11.3 percent higher than its average list price in 2017, \$572.60:

$$\frac{(\$637.26 - \$572.60)}{\$572.60 \times 10} = 11.3\%$$

So, the 2018 net increase percentage for this drug is 11.3 percent.

In general, the formula for computing a 2018 net increase percentage is

$$\frac{(\$(\text{average 2018 list price}) - \$(\text{average 2017 list price}))}{\$(\text{average 2017 list price})} \times 100$$

