

Drug Price Transparency (DPT) program Annual Report 2022

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Executive summary

Purpose

Washington State has an interest in the rising drug costs and consumer's ability to access to prescription drugs. The State legislature created a Drug Price Transparency (DPT) program under <u>Chapter 43.71C RCW</u> and tasked the program with developing a better understanding of the drivers and impacts of drug costs. Health Care Authority (HCA) created this report, in accordance with <u>RCW 43.71C.100</u>, to analyze and report on the overall impact of drug costs, rebates, and other discounts on health care premiums. Data was submitted to HCA by, <u>pharmacy benefit managers (PBM</u>), drug <u>manufacturers</u>, and <u>pharmacy service administrative organizations (PSAO)</u>, collectively referred to as "<u>Reporting Entities</u>". This data was analyzed and presented in the Results section.

Results

Key findings from carrier analysis:

The average statewide premium for health insurance per person in 2017 was approximately \$5,301.38, in 2018 it was \$5,627.65 (a 6.2% increase), and in 2019 it was \$5,816.83 (a 3.4% increase). The proportion of the average statewide premium attributable to prescription drugs rose from \$1,058.69 in 2017 to \$1,103.20 in 2018 (a 4.2% increase) and to \$1,135.57 in 2019 (a 2.8% increase). The proportion of the health care premium attributable to prescription drugs remained steady in the reporting period, at approximately 20% of the annual premium. Much of the increase in prescription drug spending can be attributable to specialty drugs, which increased as a proportion of total drug spend rising from 43.0% in 2017 to 49.3% in 2019. Specialty drugs were also among the highest costs and highest rebated drugs for carriers.

Key findings from PBM analysis:

In Washington State, the majority of pharmacy benefit management is performed by four PBMs. Our analysis shows the top 4 PBMs account for 98.5% of all PBM submitted prescription drug claims reported for 2018 and 2019, a total of \$2.61 billion.

Pharmacies submitted 87,568 appeals between 2018 and 2019 for reconsideration of inadequate reimbursement for claims to PBMs, with 8.2% of the appeals approved for adjustment, 88.0% denied, and 3.8% overturned by the Office of the Insurance Commissioner (OIC).

Key findings from manufacturer analysis:

By December 1, 2021, HCA received 269 notifications of New Drug Applications (NDAs) and Biologics License Applications (BLAs) submitted to the Food and Drug Administration (FDA) for review and approval to be marketed. Of these submissions, 90 drugs are expected to have a significant impact on prescription drug expenditure for Washington State programs.

A total of 62 manufacturers reported 290 <u>Covered Drugs</u> to HCA, including 217 that were due to price increases and 73 that were due to prices exceeding \$10,000 per month at the time of market entry. Of the 217 Covered Drugs reported with price increases:

- 86 drugs met the definition of Covered Drug by having a 20% WAC increase within a 1-year period,
- 34 drugs met the definition of Covered Drug by having a 50% WAC increase within a 3-year period, and
- 97 drugs met both criteria for 20% increase in a 1-year period and a 50% increase in a 3-year period.

Conclusion

HCA's DPT program recognizes some limitations with the DPT program and structural challenges and HCA has outlined recommendations to improve the function of this program later in the report. One limitation in the data is how to account for the impact of utilization management, performed by the carriers and PBMs, and used to control the cost and utilization of drugs.

The data reported to HCA suggests that drug price increases may lead to increases in health care premiums, but the exact relationship is unclear. Health care premiums are typically set using cost and utilization data two years in the past (e.g., 2020 premiums are set in 2019 using 2018 data). The effect of drug price increases in this period (i.e., 2019 to 2021) may not be reflected in health care premiums until 2023. This means the premium increases reported in this report may be the result of drug price increases, increases in utilization, and new-to-market drugs that occurred in 2016 and 2017.



DPT Program Limitations

HCA wants to acknowledge some of the limitations in this first year of the Drug Price Transparency program and offer recommendations to address these concerns to better align with our mission of increasing transparency around drugs.

First, there are inherent challenges with attempting to draw robust conclusions about the relationship of drug price increases and health care costs from the limited and fragmented data reported to HCA. Data regarding health care costs is to be reported by carriers and PBMs, which leads to potentially mismatching data at a health plan level. This report is unable to link data between the carriers and the PBMs at the health plan level since they may not have a one-to-one matching, meaning that the exact relationship and nature between carrier and PBM cannot be ascertained from this data. To ensure total drug costs, rebates, pharmacy reimbursement, and other factors are reported consistently for each health plan with set premiums, the carrier should be responsible for gathering data from PBMs specific to their health plan and submit together as one report. There are challenges with data access and transparency between certain carriers and PBMs; therefore, carriers are unable to see or report this data. PBMS should be required to report NDC specific rebate information to carriers. Additionally, <u>Chapter 43.71C RCW</u> would need to be amended to better account for this change in reporting given that the statute stipulates what data is to be reported by whom.

Second, HCA is limited in what it is able to present in this report given the requirement to aggregate data and to not reveal the identities of any reporting entity. <u>RCW 43.71C.100(2)</u> limits the ability for HCA to describe in detail about some of the observations and patterns in the data submitted, which may have led to strategies that help address the impact of rising drug costs of health care premiums. However, other state drug price transparency programs are able to publicly report data which may help the public understand individual drugs and their price increases, including the price increases of drugs that do not meet Covered Drug status in Washington.

Another significant limitation in the ability of this program to draw conclusions about how drug prices affect health care premiums is that not all drug prices are reported to HCA. Only drug prices that meet the definition of a Covered Drug are to be reported, which is a limited subset of drug price increases. According to the <u>California Prescription Drug Cost Transparency</u> program, 2,004 price increases occurred during this reporting period 1,767 more than were reported in Washington. There is likely material change in prescription drug spend within these drug price increases that are not reflected in the data submitted to HCA or in the body of this report. In addition, private label distributors are not required to report any price increases. This may incentivize manufacturers to license the sale of their drugs to private label distributors in order to avoid reporting requirements.

The amount of data reported to HCA may only reflect the experience of 2.07 million Washingtonians, which was approximately 27% of the state population in 2019. The data reported here does not include any of the lives covered by public health plans like Medicare or Medicaid, nor does it encompass any meaningful self-insured health plans governed by ERISA. As a result of who is required to report under <u>Chapter 43.71C RCW</u>, only approximately 53.1% of the private health insurance market was reported. It is worth noting that a full data submission of all private lives in Washington State may show different results in how premiums changed from 2017 to 2019 or how PBMs actively managed those health plans. Given these numbers, it is worth noting there is some uncertainty in the results presented here if they were to be applied to a state-wide population given the unknown characteristics of these health plans, their premiums, and their management.

Legislative attention to correct these limitations would be integral to expanding the ability of the DPT program to identify and report on the impact of drug price increases on health plan premiums. HCA has reviewed the existing statute and drafted recommendations HCA believes would be beneficial to the operations of the DPT program, to improve the information provided in this report, and to the states and its citizens' abilities to having material impact on health care costs. The Appendix contains a detailed revision of how these changes should be used to amend <u>Chapter 43.71C RCW</u>.



Background Purpose

Washington State and its residents do not have clear visibility into drug price increases and how they impact health care premiums. Though the state is aware of rising drug costs, lack of transparency around rebates and increasing premiums, there was no mechanism to collect, analyze, and report on data. The Washington State legislature created a state Drug Price Transparency program in 2019, codified in <u>Chapter 43.71C RCW</u>, that authorized the state to receive data, conduct analytics, and create a report to the public. This program was created with the goal to help the state and its residents understand drug costs and how to use this information as the first step toward cost containment and greater consumer access to prescription drugs through their health plans.

The DPT program is tasked with receiving data, in accordance with the requirements as described in <u>Chapter 43.71C RCW</u>, by:

- carriers (organizations that issue health insurance plans),
- PBMs (organizations that manage the pharmacy benefit of health insurance plans),
- drug manufacturers (companies that create and produce drug products), and
- PSAOs (organizations that negotiate reimbursement rates with PBMs on behalf of pharmacies),

collectively referred to as "Reporting Entities". The data from each of these Reporting Entities was described in statute to help identify the different components about how drug prices and all related costs and services performed by these Reporting Entities may ultimately affect health plan premiums. This public report was created, in accordance with <u>RCW 43.71C.100</u>, to describe the overall impact of drug costs, rebates, and other discounts on health care premiums.

For background information about how health care premiums are set by carriers, how the pharmacy supply chain works, and other relevant information, please refer to the <u>Background section of the Appendix</u>.

Who needs to report?

The four reporting entity types identified in <u>Chapter 43.71C RCW</u> play integral roles in the United States health care industry and are primarily responsible for how drug costs are calculated and collected from Washingtonians.

Drug manufacturers are the entities responsible for developing, producing, and selling drugs. They also set the price of drugs sold in the United States. Many different types of drug manufacturers exist, including manufacturers that develop and sell new brand-name drugs, ones that focus entirely on <u>generic drugs</u>, and others who may focus on specialty drugs, biologic drugs, and biosimilar drugs. Drug manufacturers meeting the definition of "covered manufacturer" in RCW 43.71C.010, were required to submit data for Covered Drugs to HCA. A Covered Drug, as described in <u>RCW 43.71C.010(2)</u>, is:

- any prescription drug that was introduced to the market at a <u>wholesale acquisition cost (WAC)</u> of ten thousand dollars or more for a course of treatment lasting less than one month or a thirty-day supply, whichever period is longer; or
- is currently on the market, has a WAC of more than one hundred dollars for a course of treatment lasting less than one month or a thirty-day supply, and the manufacturer increases the WAC
 - o at least 20% over one calendar year prior to the date of the proposed increase or
 - 50% over three calendar years prior to the date of the proposed increase

Manufacturers must also report new drug applications and new biological license applications submitted to the Food and Drug Administration for approval to market in the US per <u>RCW 43.71C.050</u> and <u>RCW 43.71C.060</u>. Of note, the definition of Covered Manufacturer excludes repackagers and private label distributors. Data on drug price increases from repackagers and private label distributors is not included in this report.

Carriers are businesses that design, sell, and manage health insurance offered to individuals or employers. Every year, carriers are responsible for setting a monthly premium for enrollment in each health plan offered based off the services covered, the population served, and the employer or member costs Carriers may administer many different types of health plans depending on the eligibility and risk of its population, and several carriers are contracted with government agencies to service public health plans, such as Medicare Advantage or managed <u>Medicaid</u> plans available in Washington State. Carriers may also be contracted with employers to administer <u>self-funded plans</u>, where the employer is responsible for the costs of the claims of its membership. It is important to note that, for the purposes of the DPT program, carriers were only required to submit data on their fully insured health plans, where the carrier sets the monthly premium and assumes the risk of the claims while the member is enrolled. Carriers were required to submit to HCA various types of data related to prescription drug cost, rebates, utilization, and the impact of drug prices on health care premiums, but this does not necessarily reflect the entirety of their business in Washington State <u>RCW 43.71C.020</u>.



PBMs are businesses that manage the prescription drug benefits for carriers, and they may be responsible for a variety of services depending on their contractual relationship. Usually, PBMs negotiate the reimbursement of drugs with pharmacies, contract for rebates with drug manufacturers, provide clinical and operational services to carriers, set and manage the pharmacy formulary or preferred drug list (PDL), and perform utilization management, such as develop and administer prior authorizations. PBMs may operate in-house of a carrier, or they may be contracted by the carrier to administer the pharmacy benefit on their behalf. Some PBMs may be owned by carriers, or they may have ownership interest in carriers or pharmacies. This vertical integration of the pharmacy supply chain has led to concern and speculation about how they impact drug costs, especially when information about rebates is not typically available. PBMs are required to submit data regarding drugs on the PBM formulary including reimbursement to retail pharmacies, negotiated prices with health plans, and rebates collected from manufacturers among other details about their business in Washington State <u>RCW 43.71C.030</u>.

PSAOs are organizations that negotiate with PBMs on behalf of a pharmacy or group of pharmacies on drug reimbursement rates, network participation, and other fees. These businesses act on behalf of the pharmacy to help ensure the PBM provides a fair reimbursement to the pharmacy. PSAOs use their network of client pharmacies and pharmacy chains to boost their ability to negotiate better reimbursement rates from PBM on behalf of their clients. PSAOs that receive a percentage of the reimbursement of the drugs were required to report to HCA the negotiated reimbursement rate for the 25 prescription drugs with the highest reimbursement rate and the 25 drugs with the largest year-over-year change in reimbursement, in addition to any fees charged to pharmacies for services provided by the PSAO <u>RCW 43.71C.080</u>.

Why the Drug Price Transparency program matters?

Without federal drug pricing controls available, drug price transparency is one of the few options available to state governments to help the public understand how drug prices are set and how rising drug prices impact the monthly premiums Washingtonians pay for health insurance. This report attempts to connect drug price increases to their impact on health care premiums. This program is the first of its kind in Washington State that can help inform Washingtonians about how and why drug prices affect their health care spending. As described in the Results section of this report, there are details that help the public understand some of the changes observed in health insurance premiums between 2017 and 2019 and the nature of drug price increases.

What data is HCA allowed to share or not share in this report?

<u>RCW 43.71C.100(2)</u> limits what HCA can include in this report. The statute requires that data described in this report be aggregated and prohibits HCA from revealing to the public information specific to Reporting Entities, individual prescription drugs, individual prescription drug classes, or discounts paid in connection with individual prescription drugs. With the exception of this report and upon request of a Washington State Legislator, HCA is restricted from disclosing any data submitted pursuant to <u>RCW 43.71C.020</u> through <u>RCW 43.71C.080</u>. HCA protects the confidentiality of this data as described in <u>WAC 182-51-0900</u>.

Methods

This section describes the methods used by HCA to analyze data to create this report. HCA is authorized to collect information from carriers, PBMs, PSAOs, and drug manufacturers under <u>Chapter 43.71C RCW</u>. <u>WAC 182-51</u> further defines how the data is collected.

Data received by HCA was reviewed for completeness prior to being included in the various analyses. Reporting Entities who did not complete reporting requirements had their data excluded from the final analyses included in this report.

Data analyses were performed in Microsoft Excel and were summarized by aggregating totals, reporting proportion of totals for groups of Reporting Entities, reporting on the range of values reported, and determining the mean and median of certain data sets. For longitudinal analyses from 2017 to 2019, the values for 2017 and 2018 were reported from the data submission for plan year 2018, and the data for 2019 were reported from the data submission for plan year 2019. Data presented in this report may contain discrepancies due to rounding between different data elements and when following calculations.

Data for the carrier reports were analyzed by:

- each carrier,
- each <u>line of business</u>, and
- drug class.



Lines of business by carrier were weighted by <u>member-months</u> reported, as to adequately address differences in health plans due to enrollment size. The premium analyses was calculated with weights relative to the size of the population in the health plans to create total dollar amounts for each line of business for each year.

Data for the PBM formulary reports were analyzed by:

- total WAC paid to pharmacies,
- average reimbursement discount of total WAC,
- gross amount paid to pharmacies and net amount paid to pharmacies,
- total dollar spread between carrier and pharmacy, retained by PBM
- sum of rebate received, and rebates retained by PBM
- sum of member cost share,
- basis for pricing benchmarks for pharmacy reimbursement, and
- basis for administrative fees for carriers.

PBM data was aggregated and reported with different groupings of PBMs based on each analysis. Every measure groups at least two PBMs for each measure analyzed, including the top two PBMs together, as a method to not reveal information specific to individual pharmacy benefit managers, consistent with RCW 43.71C.100(2).

Data for the manufacturer reports were analyzed by:

- WAC increase over one-year and three-years,
- WAC price of new-to-market drugs,
- developmental costs by Covered Drugs, and
- financial and non-financial reasons for qualifying price increases.

Additionally, this report used publicly available information on WAC price increases from the <u>Prescription Drugs Cost</u> <u>Transparency program in the Department of Health Care Access and Information managed by the State of California³</u>.

Visualizations for this report were produced in Microsoft Excel.

Results

Data submission summaries

HCA received registrations from 24 carriers, 47 PBMs, 492 manufacturers, and three PSAOs as described in **Tables 1** and **2**. The carriers, PBMs, and PSAOs were required to submit their reportable information by the deadlines as communicated by HCA. Entities requesting an extension for technical assistance with submissions were granted on a case-by-case basis. Some entities that registered did not have data to report during this data period because they did not meet the requirements in <u>Chapter 43.71C RCW</u>.

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lable 1. Summary	/ of registration	and data re	ported to HCA	from Carriers,	PBMs, and PSAOs ¹

Reporting Entity Type	Entities Registered with DPT Program	Entities Required to Report this Reporting Period	Entities that Submitted all Required Reports
Carriers	24	17	17
PBMs	47	24	20
PSAOs	3	0	N/A

Table 2. Summary of registration and data reported to HCA from Manufacturers

Reporting Entity Type	Entities Registered with DPT	Manufacturers Successfully	Manufacturers Successfully Submitting
	Program	Submitting Covered Drug Report	New Drug Report
Manufacturers	492	88	98

Drug manufacturers were required to report to HCA based on the timing of a drug price increase, a new-to-market drug becoming available, or on the acceptance of a new drug application (NDA) or biologics license application (BLA) to be reviewed by the FDA. In total, HCA received 88 reports on Covered Drugs and 98 reports on new drug applications from 156 registered drug manufacturers.

¹ https://app.leg.wa.gov/WAC/default.aspx?cite=182-51-0800

Carrier report

Trends in health insurance premiums

From the data reported by the 17 carriers, HCA received information on health care premiums for approximately 2.03 million Washingtonians for 2018 and 2.07 million Washingtonians for 2019. Approximately 78% of these Washingtonians were enrolled in Large Group plans in both 2018 and rose to 80% in 2019, approximately 11% of these Washingtonians were enrolled in <u>Small Group</u> plans in both 2018 and 2019, and approximately 11% of these Washingtonians were enrolled in Individual plans in both 2018 and decreased to 9% in 2019. Other Washingtonians may be enrolled in other health plans that are not required to report, including Medicare, Medicaid, Employee Retirement Income Security Act (ERISA) health plans offered by employers, other public or private health care, or are uninsured. This is presented in **Table 3** and **Figure 1** below.

In both 2018 and 2019, health insurance premiums and the proportion of prescription drug spend in these premiums rose across Washington State. **Table 3**, **Figure 2**, and **Figure 3** summarizes the observations in the data.

Figure 1. Percentage of Washington population by Line of Business (2018 to 2019)²



On average, annual health insurance premiums rose by \$326.27 (6.2%) from \$5,301.38 to \$5,627.65 statewide in 2018 and increased another \$189.18 (3.4%) annually to \$5,816.83 statewide in 2019.

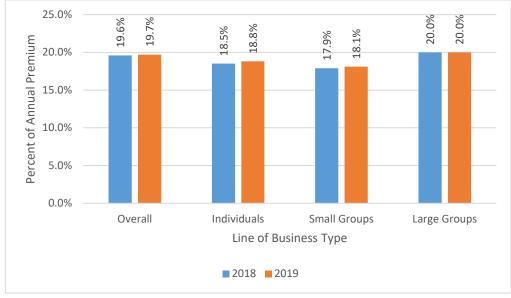
Carriers reported changes in premiums as shown in **Table 3**. Carrier data indicated the health insurance annual premium attributable to drug costs versus all other health care costs was 19.6% (\$1,103.20) of the 2018 health insurance premium and 19.7% (\$1,143.73) of the 2019. This measure helps us understand how rising drug prices and increased utilization of drugs affects health insurance premiums. On average, the amount of health insurance premiums attributable to prescription drugs statewide increased \$44.52 (4.2%) annually in 2018 and another \$40.53 (3.7%) annually in 2019. During this period (2018-2019), the proportion of a members' premiums attributed to prescription drugs remained steady, meaning prescription drug costs rose similarly to other benefits covered in their health care premiums (**Figure 2**). However, the data does indicate that a component of the rise in health care premiums is attributable to the rise in prescription drug spend.

Carrier Lines of Business	of Percent of Population		Premium Change (All care)		Premium Change (Pharmacy Only)		Premium Change (All Non-Pharmacy care)		Proportion of Premium Attributable to Pharmacy	
	2018	2019	2017 to 2018	2018 to 2019	2017 to 2018	2018 to 2019	2017 to 2018	2018 to 2019	2018	2019
Overall	100%	100%	6.2%	3.4%	4.2%	3.7%	6.6%	3.5%	19.6%	19.7%
Individuals	11%	9%	30.4%	10.1%	28.8%	12.4%	30.8%	9.6%	18.5%	18.8%
Small Groups	11%	11%	4.4%	1.7%	-2.0%	2.7%	6.0%	1.5%	17.9%	18.1%
Large Groups	78%	80%	3.4%	2.9%	2.2%	2.8%	3.7%	3.0%	20.0%	20.0%

Table 3. Change in health insurance monthly premium by line of business (2017 to 2019)

² Does not include Medicare, Medicaid, ERISA health plans, other public or private health care, or uninsured.

Figure 2. Change in Proportion of Premium Attributable to Prescription Drug Spend by Line of Business from 2018 to 2019



Carriers reported changes in health insurance premiums for three different lines of business: Individuals, Small Groups, and Large Groups. Health insurance premiums for 2017-2018 and 2018-2019 are summarized in **Figure 3**. The data reported for 2018 and 2019 shows the volatility in how health care premiums can change between years. Individual health plans offered in Washington State in 2018 and 2019 were more likely to experience volatile changes in health insurance premiums between years whereas health plans offered as Small Groups or Large Groups were more insulated from drastic changes in health insurance premiums in both 2018 and 2019 were reported as Individual health plans, meaning these health plans have the greatest potential for change depending on the populations enrolled each year.

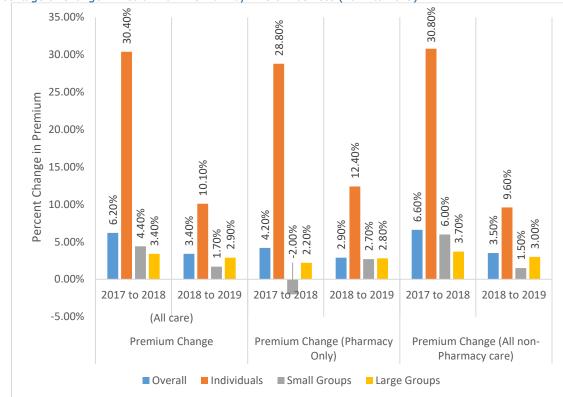


Figure 3. Percentage of Change in Health Plan Premium by Line of Business (2017 to 2019)

Furthermore, it appears as though health plans with higher percentages of costs attributable to drugs were more likely to see drastic changes between years. The reasons why these health plans were affected greater than the others may be because they are more prone to increased spend due to rising drug costs or are limited in strategies in managing appropriate utilization of prescription drugs by enrollees.

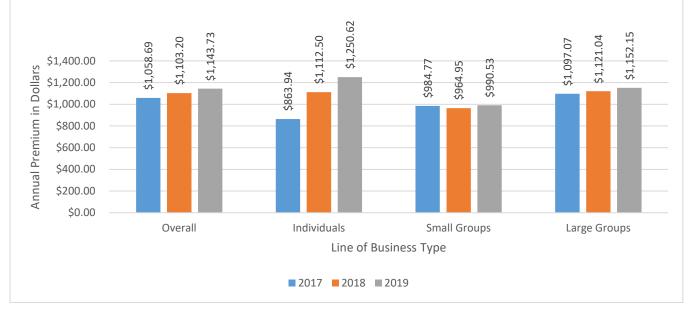
Trends in health insurance premiums by drug type

Carriers reported health insurance premium change among three different types of drugs: brand-name drugs (brand), generic drugs (generic), or specialty drugs (specialty). These changes can be seen in **Table 4** and **Figure 4** below.

Carrier Lines of Business				Pharmacy Premium (Brand)			Pharmacy Premium (Generic)			Pharmacy Premium (Specialty)		
	2017	2018	2019	2017	2018	2019	2017	2018	2019	2017	2018	2019
Overall	\$1,058.69	\$1,103.20	\$1,143.73	\$351.32	\$362.35	\$359.79	\$239.39	\$223.39	\$208.47	\$455.05	\$506.10	\$563.56
Individual	\$863.94	\$1,112.50	\$1,250.62	\$237.72	\$308.04	\$340.12	\$153.06	\$158.79	\$195.27	\$461.17	\$638.59	\$699.14
Small Group	\$984.77	\$964.95	\$990.53	\$266.94	\$270.13	\$270.87	\$191.06	\$148.53	\$135.01	\$512.88	\$535.21	\$572.28
Large Group	\$1,097.07	\$1,121.04	\$1,152.15	\$379.43	\$382.99	\$374.27	\$258.56	\$243.11	\$220.06	\$446.15	\$482.93	\$546.46



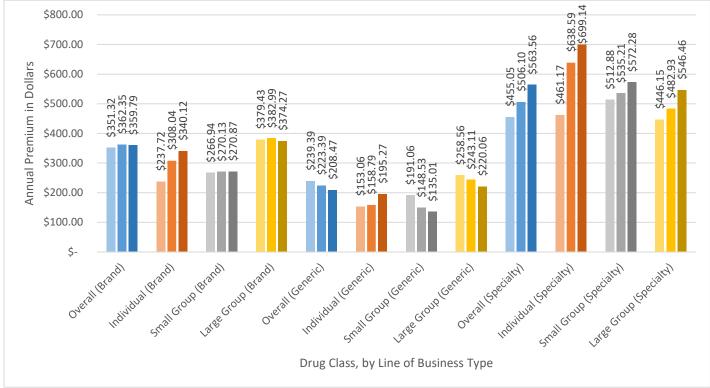




On average, of the overall health insurance premiums attributable to drugs, brand drugs accounted for 33.2%, 32.8%, and 31.5% of the premium in years 2017, 2018, and 2019 respectively. Generic drugs attributed to 22.6%, 20.2% and 18.2% of the overall health insurance premiums for those same years. Lastly, specialty drugs accounted for nearly half of health insurance premiums attributable to drugs, with 43.0%, 45.9% and 49.3% in 2017, 2018, and 2019 respectively. Of note, these values do not total 100% because non-drug related costs (e.g., diabetic supplies and other non-drug supplies) are not included in this drug mix.







The range of percent of health insurance premium attributable to drug costs varied by type of plan in 2018 and 2019. For example, plans with smaller populations had more volatility in drug utilization and costs. Between 2018 and 2019, Individual health plans saw a decrease in percent of the premium attributable to specialty drugs due to increase in the amount of premium attributable to brand and generic drugs. This was the opposite experience for Individual plans in 2018 and different than what Small Group and Large Group health plans experienced. Although all types of health plans saw increases in prescription drug spending by these drug categories from 2017 to 2019, the rate at which they increased was variable. Large Group health plans saw the greatest increase in proportion attributable to specialty drugs between 2017 and 2019, rising from 40.7% of prescription drug spending to 47.4%. Small Group health plans have the highest proportion attributable to specialty drugs, seeing a rise from 52.1% of prescription drug spend in 2017 to 57.8% in 2019.

Lines of Business	Pharmacy Premium (Brand)			Pharmacy Premium (Brand) Pharmacy Premium (Generic)				Pharmacy Premium (Specialty)		
	2017	2018	2019	2017	2018	2019	2017	2018	2019	
Overall	33.2%	32.8%	31.5%	22.6%	20.2%	18.2%	43.0%	45.9%	49.3%	
Individual	27.5%	27.7%	27.2%	17.7%	14.3%	15.6%	53.4%	57.4%	55.9%	
Small Group	27.1%	28.0%	27.3%	19.4%	15.4%	13.6%	52.1%	55.5%	57.8%	
Large Group	34.6%	34.2%	32.5%	23.6%	21.7%	19.1%	40.7%	43.1%	47.4%	

Table 5. Percent drug mix by Line of Business (2017 to 2019)

Based on these observations mentioned above, Individual health plans are more likely to see drastic changes in their health care premium attributable to drugs than Small Group or Large Group health plans. Although Small Group health plans represent about the same proportion of Washingtonians as in the Individual health plans, the proportion of their premium attributable to drugs is less volatile and show gradual decreases in generic spending that is offset by rises in specialty spending. Large Group premiums showed the least amount of volatility in the proportion of the premium attributable to drugs.



Trends in top 25 drugs by cost, utilization, rebates, and price

Next, we analyzed how the carriers reported individual drugs ranked by cost, utilization, rebate dollars received, and by increase in WAC, a standard of drug pricing set by manufacturers. Drugs used to treat various conditions appeared throughout these carrier reports, helping demonstrate what disease states may be attributable to higher drug expenditure, and therefore, higher health insurance premiums.

- Among the reports from the 17 carriers who reported drugs with the highest utilization, as defined by the total days of drug supply used per patient (days' supply), the top 25 drugs most commonly listed are used to:
 - treat thyroid conditions,
 - \circ treat depression,
 - treat high blood pressure,
 - o lower high cholesterol, and
 - prevent pregnancy.
- Among the reports from the 17 carriers who reported drugs with the highest costs, as defined by the total amount of money paid by the member and health plan for each prescription (allowed amount), the top 25 drugs most commonly listed are used to:
 - o treat autoimmune conditions,
 - o treat cancers,
 - o treat diabetes mellitus,
 - \circ prevent blood clots, and
 - treat or prevent HIV.
- Among the reports from the 17 carriers who reported drugs with the highest amounts of rebates retained, as defined by the total amount of money paid by the manufacturer that ultimately was received by the health plan for each prescription in which the health plan qualified for rebate (rebate amount). The top 25 drugs most commonly listed are used to:
 - o treat autoimmune conditions,
 - o treat diabetes mellitus,
 - o treat asthma and chronic obstructive pulmonary disease (COPD),
 - treat hepatitis C, and
 - treat multiple sclerosis.
- Among the reports from the 17 carriers who reported drugs with the highest increases in price, as defined by the total change in WAC for each <u>National Drug Code (NDC)</u> for which they had a claim in that year (WAC increase amount), the drug lists were populated with many different types of therapeutic category. From the data reported, no patterns emerged within or between carriers.

Ranking	Top 25 by Utilization	Top 25 by Cost	Top 25 by Rebates Retained	Top 25 by WAC Price Increase
1 st	Thyroid conditions	Autoimmune conditions	Autoimmune conditions	
2 nd	Depression	Cancer	Diabetes mellitus	
3 rd	High blood pressure	Diabetes mellitus	Asthma and COPD	Indeterminate
4 th	Cholesterol	Blood clots	Hepatitis C	
5 th	Birth control	HIV	Multiple sclerosis	

Table 6. Therapeutic categories for Top 25 Drugs as reported in aggregate by carriers (2018 to 2019)

These results help illustrate some of the dynamics observed with the change in health insurance premium, especially with how predominant <u>brand name</u> drugs and specialty drugs are represented in the drugs with highest costs and highest rebates.

Among the top 25 drugs in **Table 6**, specialty drugs (as reported by the carriers in their specialty drug lists) were represented as some of the highest cost and highest rebate retained, while very few specialty drugs were submitted with a high utilization

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ranking. Single-source non-specialty drug types were represented as some of the highest cost and highest rebate retained rankings. Multi-source generics were predominately represented in the top utilization rankings.

In summary, HCA observed a statewide increase in health care premiums attributable to prescription drug spending by 4.2% in 2018 and 3.7% in 2019. The proportion of the health care premium attributable to pharmacy remained steady at 19.6% in 2018 and 19.7% in 2019. Much of the increase in prescription drug spending can be attributable to specialty drugs, which increased in spend 43.0% in 2017 to 49.3% in 2019. These specialty drugs were reflected among the highest costs and highest rebated drugs for carriers.

Pharmacy Benefit Managers report

PBMs reported data to HCA pursuant to <u>RCW 43.71C.030 through RCW 43.71C.040</u>. These required data elements were divided into a formulary management report, a PBM ownership report, and a pharmacy <u>appeals</u> report. These reports were analyzed, and their findings are described in the sections below.

Trends in pharmacy benefit management

PBMs manage access and cost-sharing to prescription drugs covered under health plans by using formularies or <u>preferred</u> <u>drug lists (PDLs)</u>. These tools are methods of structuring cost-shares and utilization management to optimize costs and utilization of drugs. Drugs that are proven to be safe, effective, and cost-effective for the general population are often placed on the lowest tier of a formulary whereas drugs that are less cost-effective or have questionable safety or efficacy will be placed on higher tiers or have prior authorization to justify their medical necessity for the patient.

HCA received data from PBMs regarding how money was collected, distributed, and retained between different businesses within the health care industry, including with carriers, manufacturers, pharmacies, and patients. This data helps us understand how PBMs serve health plans and generate revenue.

As described in the Methods section above, the results of the PBM analyses were aggregated consistent with RCW 43.71C.100(2), and the results displayed in this section represent different groupings of at least two PBMs together, including the top two PBMs in each analysis. This means that each analysis does not necessarily reflect the same two PBMs throughout the report.

Trends in total WAC paid to pharmacies and reimbursement discount

Of the data reported to HCA, the approximate dollar value of drug claims processed by PBMs, defined as the total WAC of all paid drug claims in a year, was \$937 million dollars in 2018 and \$1.716 billion in 2019, a difference of 83.1%. The change in \$779 million between 2018 and 2019 is likely due to the changes to the number of covered lives served by PBMs in Washington State, though the population sizes of these PBMs were not reported in this data. In the 2018 and 2019 data reported to HCA, the top two PBMs in terms of dollar value accounted for 77.4% of the PBM market and the top four PBMs account for 98.5% of the PBM market. 10 PBMs reported payments to pharmacies in 2018 and 2019, which account for the remaining 1.5% in Washington State. This data highlights the sheer difference in magnitude between the top two PBMs, the subsequent two PBMs, and the remaining 10 that reported data for 2018 and 2019. This market dominance of these four PBMs can be seen in **Figure 6** below.

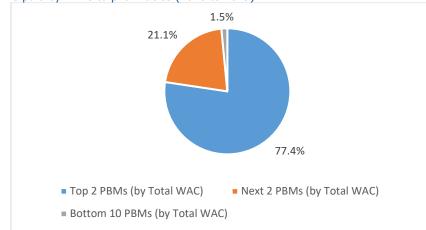


Figure 6. Sum of total WAC paid by PBMs to pharmacies (2018 to 2019)

The amount of money PBMs pay pharmacies is typically a percentage of the WAC that is negotiated between the pharmacy or a PSAO. The pharmacy reimbursement percentage varies from PBM to PBM, from pharmacy to pharmacy, and from drug to drug, and even from prescription to prescription. In aggregate of all data submitted by PBMs for 2018 and 2019, pharmacies receive about 65.6% of the cost of the WAC, meaning that pharmacies only received \$1.74 billion when the total WAC paid by PBMs was \$2.65 billion. The reimbursement percentage from the top four PBMs ranged between approximately 35% to 85% of WAC on aggregate, but individual drugs ranged from 0% (no reimbursement) to more than 100% of WAC. Part of the reason that pharmacies are not reimbursed the full amount for the cost of the drug may be due to the prices they are able to purchase from their wholesaler (see **Trends in pharmacy appeals to PBM 2018 to 2019** section), due to direct and indirect fees assessed by PBMs on pharmacies, or other reasons.

Trends in gross and net paid to pharmacies, and direct and indirect fees

The gross amount paid by PBMs to pharmacies is the amount of all reimbursements paid by the PBM to the pharmacy for each drug dispensed. The net amount paid by the PBMs is the amount of all reimbursements paid to pharmacies minus all direct and indirect fees. Direct fees may be fees assessed by the PBM to the pharmacy for each claim, such as a cost to submit a claim to a PBM for them to process. Indirect fees are fees that may be assessed by the PBM to the pharmacy that are not attributable to any specific claim, such as a fee to be in the PBM's preferred pharmacy network. To account for this indirect relationship, the PBMs are instructed to report the total indirect fees to a pharmacy or pharmacy chain by the total number of claims dispensed by that pharmacy or pharmacy chain.

The gross amount paid by PBMs to pharmacies reported to HCA was \$709 million in 2018 and was \$1.035 billion in 2019, a difference of 45.9%, which is similar with the increase in total WAC paid to pharmacy in the section above. The net amount paid by PBMs reported to HCA was \$701 million in 2018 and \$1.027 billion in 2019. The difference between these amounts is the fees assessed by the PBMs on pharmacies, which totaled \$8.8 million in 2018 and \$8.3 million in 2019.

The top two PBMs for collecting these fees accounts for 88.5% of the total statewide for both 2018 and 2019. A visualization of the top four PBMs versus the bottom six PBMs can be seen in **Figure 7**.

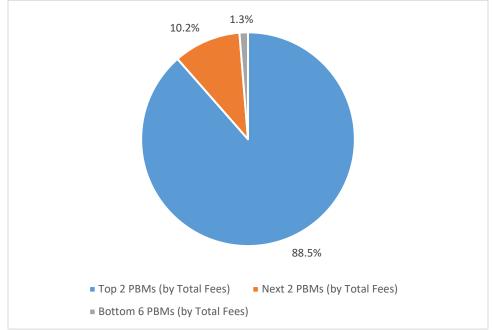


Figure 7. Total Dollar in Fees Assessed on Pharmacies (2018 to 2019)

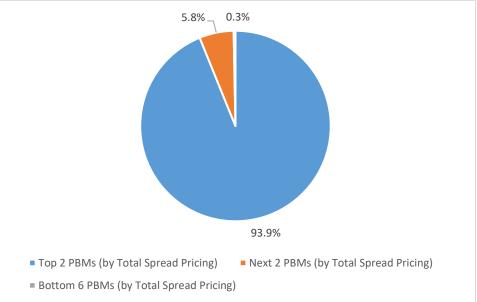
Trends in spread pricing between carriers and pharmacies

The spread amount, or the difference between what the carrier pays the PBM for a claim and the amount reimbursed to a pharmacy for that same claim, was also reported. Ten PBMs reported retaining a spread amount, nine PBMs reported that they did not retain a spread amount. The total spread amount retained by the nine PBMs was \$115 million in 2018 and \$155 million in 2019. Unfortunately, the way the data is reported to HCA does not allow HCA to analyze the impact of spread pricing on health insurance premiums.



The top two PBMs in terms of dollars retained from spread pricing accounted for 94.1% of the total spread amount in the state in 2018 and 93.7% of the total spread amount in 2019. This data seems to demonstrate that only a couple of PBMs dominate the state in retaining dollars through spread pricing, though this is similar to the pattern to the market size of the PBMs in Washington as determined by the dollar value of claims processed. The spread amount retained by PBM across these two years is shown in **Figure 8**.

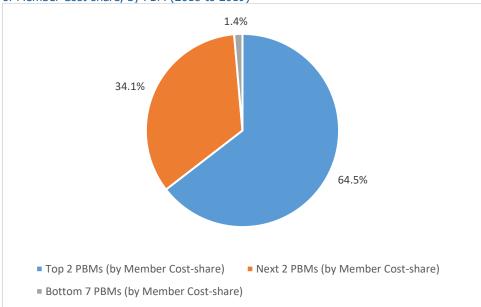




Trends in member cost share

The amount members pay for prescription drugs at pharmacies or member cost share was also reported. In 2018 Washingtonian's member cost share totaled \$36.9 million and \$58.2 million in 2019. The top four PBMs for member cost share were attributable to 98.8% of statewide member cost share in 2018 and 98.5% in 2019.







Trends in rebates received and retained by PBMs

Of the <u>rebate</u> data reported to HCA, PBMs received \$48.3 million in 2018 and \$194.4 million in 2019. The increase in rebate dollars received by the PBMs is largely attributable to the increase in claims processed. Of the rebate data received by PBMs, approximately \$311,000 were retained by PBMs in 2018 and \$493,000 were retained by PBMs in 2019. This means that PBMs collectively retained 0.6% and 0.3% of all rebate dollars received in 2018 and 2019 respectively.

The PBM that retained the most dollars in both years made up 94.9% of this dollar value in 2018 and 71.9% in 2019. Three other PBMs reported retaining rebates in 2018 and 7 other PBMs reported retaining rebates in 2019. The top four PBMs by total rebate dollars retained in 2018 and 2019 are shown in **Figure 10**, though it is important to note that different PBMs are represented in these positions in these graphs as PBMs that did not retain any rebate may appear in the rebate received graph. This is why there are 12 PBMs that reported receiving rebate dollars but only eight PBMs that reported retaining rebate dollars. As an assumption, the remainder of the rebate dollars received by PBMs were delivered to the carriers contracted with these PBMs.

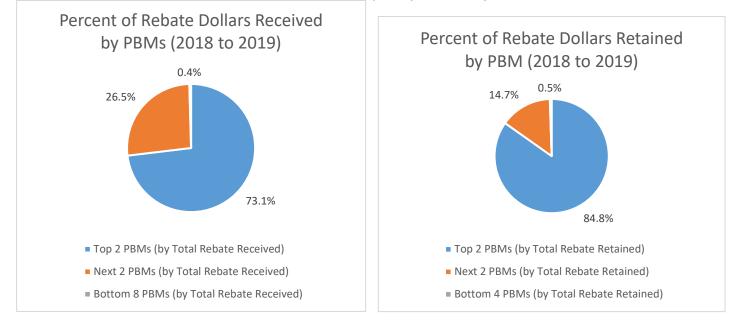


Figure 10. Percentages of Rebate Dollars Received and Retained, by PBM (2018 to 2019)

Trends in administrative fees paid by carriers

PBMs may offer carriers different options for paying for their services and charging administrative fees is a common method as reported by PBMs. These fees can be collected or assessed in several different ways, but the most common methods in Washington are by drug claim. This means that a PBM charges a carrier for every claim processed, and the amount of revenue is generated depending on how many prescriptions the members of the health plan use. Another type of administrative fees are annual fees, which are set prior to a plan year. Only one PBM manages their contract with a carrier using a 'per-member-per-month' fee, which is similar to a health plan premium as it charges a set amount depending on the number of members enrolled in the plan for that month.

In summary, four PBMs dominate prescription drug benefits in Washington State, as demonstrated by the volume of claims processed by dollar amount, by fees assessed to pharmacies, by spread pricing between carriers and pharmacies, by member cost share, and by rebate dollars received and retained. Several other PBMs exist that serve smaller populations and may not use all of the methods measured, which explains why the size of the bottom grouping of PBMs is different between measures.

Since the PBM data and carrier data are not linked at a health plan level, which is where annual premiums, covered services, and benefit designs are determined, it is challenging to draw conclusions between the data reported in the carrier section and the data reported in the PBM section.

Trends in PBM ownership 2018 to 2019

HCA received data from PBMs regarding their ownership interests in carriers and pharmacies and any ownership interest in them from carriers or pharmacies. Of the 23 PBMs that reported, 10 reported different ownership entities than the PBM as



defined by different Employer Identification Number (EIN). The different EIN does not necessarily represent whether a carrier or pharmacy has ownership in the PBM or whether the PBM has ownership in a carrier or pharmacies. Of the 10 that reported different ownership EIN, only half had some type of ownership interest in a carrier or pharmacy or a carrier or pharmacy had ownership in the PBM. Of the data reported, there did not appear to be any changes in ownership interests between 2018 and 2019.

Trends in pharmacy appeals to PBM 2018 to 2019

In 2014, Washington State created a law, now codified as <u>RCW 48.200.280(3)</u>, by which PBMs must have a process for pharmacies to appeal predetermined reimbursement costs for multisource generic drugs. Pharmacies may need to appeal to a PBM to be reimbursed the actual acquisition costs of a drug when a PBM sets the reimbursement rate below what a pharmacy may be able to pay when acquiring a generic drug. For example, if a PBM sets the reimbursement for Drug A at \$0.10 per unit and the pharmacy can only acquire the drug at \$0.12 per unit, the pharmacy would lose money dispensing the drug on every prescription because they would be reimbursed \$0.02 less per unit dispensed. With this law in effect, the pharmacy could appeal to the PBM and request a reimbursement rate that is appropriate to reflect what the pharmacy may be able to purchase. This law was made as an attempt to help ensure pharmacies are reimbursed appropriately for their services, but no analysis on the effectiveness of this law has been published to date.

HCA received data from PBMs regarding the number of appeals and their outcomes under this law. Of the data HCA received, there were 35,277 appeals in 2018 and 52,309 appeals in 2019. Of the 87,586 total appeals made in this reporting period, 79.2% were made to only two PBMs and 99.9% were made to five PBMs. Among the other PBMs, eight reported the remaining 0.1% of appeals while 11 PBMs reported no appeals. Of the 87,568 appeals made, which equates to approximately 120 appeals per day, only 7,186 (8.2%) were approved, 77,047 (88.0%) were denied, and 3,353 (3.8%) were originally denied before being overturned by the <u>Office of Insurance Commission (OIC</u>). The outcomes of these appeals can be seen in **Figure 11** below.

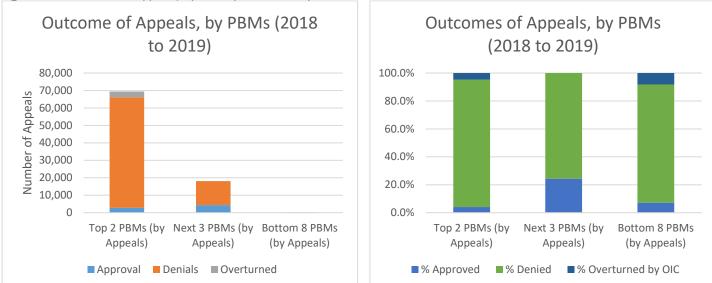
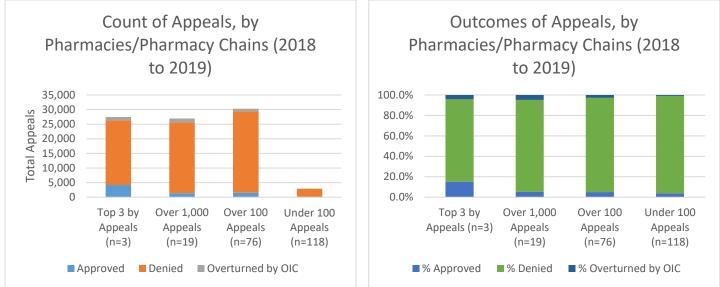


Figure 11. Outcomes of Appeals, by PBMs (2018 to 2019)

A total of 217 pharmacies or pharmacy chains submitted at least one appeal to any PBM during this period. Of the 87,586 appeals submitted, 98 pharmacies or pharmacy chains submitted at least 100 appeals, and 22 submitted at least 1,000 appeals. The top three pharmacy chains with the most appeals submitted had 27,439 in this two-year reporting period, which is about 38 appeals per day. Of the 27,439 appeals they submitted, 4,159 (15.2%) were approved, 22,128 (80.7%) were denied, and 1,140 (4.2%) were overturned by OIC. The results of this analysis can be seen in **Figure 12**.



Figure 12. Outcomes of Appeals, by Pharmacies/Pharmacy Chains (2018 to 2019)



The top two PBMs with the most appeals received 69,415 appeals during this two-year reporting period, of which, 91.2% were denied, 4.0% were approved, and 4.8% were originally denied but overturned by OIC. A total of 192 pharmacies or pharmacy chains submitted at least one appeal to either of these PBMs with 93 having submitted at least 100 appeals, and 18 having submitted at least 1,000. The top three pharmacy chains submitted 16,022 appeals to these two PBMs, which equates to about 22 appeals per day. Of the 16,022 appeals submitted to these two PBMs by these three pharmacies or pharmacy chains, 88.7% were denied, 4.2% were approved, and 7.1% were originally denied but overturned by OIC.

Drug information was also reported, and a total of 7,548 drug products (as determined by unique NDC), were reported to have at least one appeal, with 96 NDCs having at least 100 appeals each. A wide range of therapeutic classes of drugs appeared to have over 100 appeals each, including drugs to treat thyroid disorders, severe pain, dermatological conditions, hypertension, hypercholesterolemia, and many others.

The data suggests that many pharmacies are using the appeal process, with approximately 120 appeals being made every day over the two-year reporting period. Despite this process, many of these claims are denied with few being overturned by OIC, meaning that pharmacies may not be adequately reimbursed by PBMs for the claims they dispense. Given the high rate of denials and subsequent appeals to OIC, one wonders if pharmacies are discouraged from submitting appeals and that these numbers may actually be suppressed compared to the frequency at which pharmacies are not adequately reimbursed for the prescriptions they dispense.

Drug manufacturers report

Trends in manufacturer drug pricing 2017 to 2019

By December 1, 2021, 89 drug manufacturers submitted price data for 1,286 drugs, defined as unique NDCs, to HCA using the Covered Drugs template. Of the data received by HCA, 290 Covered Drugs submitted by 62 manufacturers were identified by the cutoff for writing this report. 217 drugs met the definition of Covered Drug due to a WAC increase, and 73 drugs met the definition of a new-to-market drug costing \$10,000 or more per course of treatment lasting less than one month or for a 30-day supply. The other 996 drugs submitted to HCA were considered voluntary as they were not required to report their price increases or decreases.

On average, manufactures reported about 5 Covered Drugs per report, with a median of two Covered Drugs per report, and a range from 1 to 49 per report. Six manufacturers had 10 or more Covered Drugs reported as of December 1, 2021. A total of 11 manufacturers reported drug price increases for drugs with only a one-year change of 20% or greater, while a total of 14 manufacturers reported drug price increases for drugs with only a three-year change of 50% or greater. A total of 19 manufacturers reported drug price increases for drugs that met both the one-year and three-year change criteria. A total of 33 manufacturers reported new-to-market Covered Drugs.



Of the 73 covered drugs due to prices of \$10,000 or more for a course of treatment lasting less than one month or a 30-day supply, whichever period is longer, were also reported to HCA. Of these 73 Covered Drugs, the price of these new-to-market drugs ranged from just over \$10,000 to over \$130,000, with an average price of \$22,675 and a median of \$20,950.

Of the 217 drugs that met the definition of Covered Drug through WAC increase:

- 86 drugs met the definition of Covered Drug by having a 20% WAC increase within a 1-year period,
- 34 drugs met the definition of Covered Drug by having a 50% WAC increase within a 3-year period, and
- 97 drugs met both criteria for 20% increase in a 1-year period and a 50% increase in a 3-year period.

Of the 86 Covered Drugs with only qualifying price increase of 20% over one-year, the range of price increases was from 20% to 87%. The average price increase of these drugs was 31% and the median was 28%. Of the 34 Covered Drugs with only qualifying price increase of 50% over three-years, the range of price increases was from 50% to 300%. The average price increase of these drugs was 112% and the median was 90%. Of the 97 Covered Drugs with both qualifying price increase criteria, the one-year range was from 20% to 2,535% and the three-year range was from 50% to 2,535%. The average price increase of these drugs in one-year was 136% and the median was 33%, whereas the three-year average was 162% and the median was 60%.

Of the 183 Covered Drugs with qualifying price increases over a one-year period, the average price after increase was \$1,285 with a median cost of \$303. Of these Covered Drugs, the drugs increased on average by \$190 with a median increase of \$39. Of the 131 Covered Drugs with a qualifying price increase over a three-year period, the average price after increase was \$1,634 with a median cost of \$257. Of these Covered Drugs, the drugs increased on average by \$806 with a median increase of \$112.

It is important to note that drugs that did not meet the definition of Covered Drug in <u>Chapter 43.71C RCW</u> were not required to be reported by manufacturers. To supplement our review of drug price increases, HCA reviewed all drug price increases during calendar year 2019 and 2020 to better understand the relationship of the drugs with the highest cost and rebate relative to the health plans who were impacted and how it was reflected in their premium increases. Using publicly available WAC increase data from the <u>Prescription Drugs Cost Transparency program in the Department of Health Care Access and Information managed by the State of California</u>, HCA identified 2,004 WAC increases and estimated that approximately 237 drugs may have met the criteria of having a 20% WAC increase within a 1-year period. When comparing this analysis to the one of the data HCA received for the years 2019 and 2020, HCA identified an additional 197 drugs which may meet Covered Drug status and may need to be reported to HCA. **Figure 13** below highlights the proportion of drugs HCA received data on from this period versus the other drugs identified in the California data.

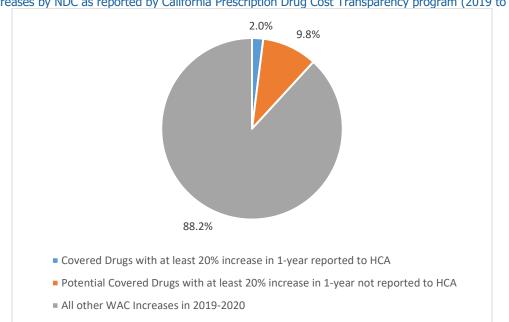


Figure 13. WAC increases by NDC as reported by California Prescription Drug Cost Transparency program (2019 to 2020)

It is important to note that some of these manufacturers that raised the drug price by 20% or greater may be private label distributors who are exempt from reporting price increases and pricing rationale to HCA. HCA actively works with Reporting

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Entities to ensure timely and accurate submissions if they are required by law to report, and HCA is developing a price check tool to help aid in identifying manufacturers who may need to report Covered Drugs to HCA.

However, the California analysis does help identify the entire scope of drug price increases that occur in the United States, and the proportion of which are at or over 20% in a single year. This analysis highlights the limited subset of data that HCA is able to receive for the purposes of analyzing how drug price increases impact health care premiums. It is worth noting that a majority of drug price increases are below the thresholds stated in statute, and that these drug price increases likely do have an impact on health care premiums.

Trends in manufacturer submitting NDAs and BLAs from 2017 to 2019

Drug manufacturers submitting new NDAs or new BLAs to the FDA to review for approval to be marketed in the United States was reported to HCA pursuant to <u>RCW 43.71C.060</u>. The data was analyzed and reported below to describe potentially impactful drugs to Washington State expenditures.

By December 1, 2021, HCA received 269 New Drug Reports, notifications of new NDAs and BLAs being accepted for review by the FDA. Of these submissions, manufacturers identified 90 (33.5%) drugs that are estimated to have a significant expenditure on Washington State programs once approved for marketing. Of the 90 drugs of potentially significant expenditure, 30 were submitted as a BLA whereas the remaining 60 were submitted as an NDA. The most common condition being studied by these new investigational therapies are for the treatment of various cancers, though there was a vast range of conditions represented in this data.

Of note, 54 (20.1%) of the new drug reports received by HCA may not have been for new chemical entities as other versions of these chemical entities were already marketed in the US, either by the current manufacturer or by another company. These submissions may be related to new dosage forms of existing chemical entities or requests for the FDA to review new indications for use.

Pharmacy services administrative organizations report

HCA did not receive any data from PSAOs during this reporting period. HCA assumes PSAOs did not report because they are exempt from reporting under <u>RCW 43.71C.080(2)</u> due to their payment structure with pharmacies. The statute does not require that PSAOs who identify as exempt from attesting or proving their exemption status, nor does it allow for HCA to require the PSAOs attest or prove their exemption status.

Conclusions

Overall impact of drug costs on health care premiums

In this report, HCA analyzed data the agency received from the Reporting Entities serving Washingtonians for the purpose of describing how drug pricing impacts health care premiums.

HCA acknowledges that drug price increases may have an impact on health care premiums, but the exact relationship and the nature of this impact is indeterminate from the data that HCA can receive under this Drug Price Transparency program. HCA is limited in its ability to properly analyze all components of change in health care premiums without a complete and comprehensive set of claims data for all health plans in the state, where these changes in drug costs and drug utilization is identifiable.

With a more complete data set, HCA may be able to determine changes in carrier or PBM behavior in reflection to a drug price increase. For example, a drug price may experience an increase in one year, and a PBM or carrier may respond by not covering the drug and requiring patients to switch to a lower-cost and equally-effective alternative. This type of information is not reportable under the current requirements of <u>Chapter 43.71C RCW</u>, yet it would help explain how carriers and PBMs are responding to drug price and drug cost increases. To properly identify the exact relationship and nature of how drug prices impact health care premiums, and other aspects of health care costs and access, a more robust data set of health claims data and all drug price increases would be required.



Appendix Additional background information

Prescription drugs are one of the most frequently utilized health care services and are a major component of health care spending worldwide. According to the <u>Medicine Spending and Affordability in the U.S. report</u>³, total net payer spending (the total spending after accounting for rebates and other discounts) was \$509 billion in 2019, approximately 2.3% of US gross domestic product⁴(BEA.gov). Prescription drug spending has risen 41.8% since 2010 (\$359 billion in 2010 to \$509 billion in 2019)⁵, almost 4% annually. Given the continued rise of drug expenditure, due in part to the emergence of <u>new molecular</u> entities (<u>NMEs</u>) and rising prices, the state of Washington seeks a better understanding of the drivers and impacts of these costs, with the goal of ultimately reducing costs and improving consumer access.

Health insurance plans are often managed by carriers, by government agencies, or by employers. Americans may be eligible for health plans through their employer, and their employer may help offset the monthly cost paid by an enrollee depending on their benefits to their employees. This can either be through fully insured health plans, where the carrier managing the health plan is at risk for the total cost of claims, or through self-funded health plans, where the sponsor is responsible for the total cost of all claims. Employers may contract with carriers to offer multiple health plans to employees with varying levels of benefit structures, and employees are allowed to select one based on their anticipated health needs. Other Americans may be eligible for public health plans, such as through <u>Medicare Part D</u>, or through entitlement programs, such as Medicaid, which help pay for some or all their health care needs.

Prescription drugs are typically covered services for patients with health insurance, meaning the health plans help offset drug costs through contracting with pharmacies on allowed costs and through cost-sharing with utilizers of prescription drugs. Payment and reimbursement for prescription drugs is different between private and public health insurance, with programs like Medicaid, the Veterans' Administration, and the Department of Defense having special pricing that helps control drug costs. Private health insurance is not able to participate in those pricing or purchasing strategies and must rely on other methods to control drug costs and utilization.

Administering prescription drug benefits for private health plans has become increasingly complex over the last few decades due to the increase in available drugs, drug launch prices, and drug price increases. The methods employed by these entities includes various tasks, such as:

- contracting with networks of pharmacies,
- creating and maintaining prescription drug formularies or PDL,
- creating and applying utilization management for appropriate use of benefits,
- adjudicating prescription drug claims electronically,
- contracting with drug manufacturers for rebates or discounts on drugs, and many other services.

As a result, carriers often subcontract some or all these tasks to PBMs. PBMs may be separate organizations within an umbrella of a health organization, or they may be independent of the carriers who work under contract with them.

However, because of the nature of these contracts between carriers and PBMs, PBMs and pharmacies, and PBMs and manufacturers, there is a lack of transparency and understanding of how drug pricing impacts overall health care costs. This asymmetry of information between the different entities can be leveraged for increasing costs and difficulty accessing drugs for patients. Given the perspective of the DPT program, this report will focus on fully insured health plans, where monthly health plan premiums are paid by employers and enrollees. Many of the drug pricing and cost considerations detailed in this report may not apply to government-funded health plans, such as Medicare, Medicaid, or the Veteran's Administration.

How monthly health plan premiums are established

³ Source: www. Institute. Medicine Spending and Affordability in the U.S. Understanding Patients' Costs for Medicines. Accessed Jun 7, 2021. <u>https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us</u>

⁴ Source. Bureau for Economic Analysis. Gross Domestic Product, Fourth Quarter and Year 2019 (Advance Estimate). Accessed Jun 7, 2021. <u>https://www.bea.gov/news/2020/gross-domestic-product-fourth-quarter-and-year-2019-advance-estimate</u>

⁵ Source. Bureau for Economic Analysis. Gross Domestic Product, Fourth Quarter and Year 2019 (Advance Estimate). Accessed Jun 7, 2021. <u>https://www.bea.gov/news/2020/gross-domestic-product-fourth-quarter-and-year-2019-advance-estimate</u>

Health plan premiums are determined by the carrier. Carriers that manage health plans are primarily paid through monthly premiums based on the services covered by that health plan. Premiums for individual health plans are determined by carriers who estimate an actuarily-sound rate of payment to pay for all the services that a health plan would cover for that plan year. Health plans that cover the same services may have different premiums due to their benefit structure, including:

- monthly premium
- <u>annual deductible</u> (costs patients must pay prior to the plan to begin cost sharing)
- <u>out-of-pocket costs</u> (e.g., copays at medical appointments or coinsurance for prescription drugs)
- size of the provider or pharmacy network

These health plans may also have different premiums based on the <u>risk-scores</u> of the populations that select these plans and the services they are expected to use in a year.

Each year, health plan <u>actuaries</u> review the demographics of the population and the cost and utilization of health care services covered in the year. From this foundation, actuaries project what changes may occur to the population in the health plan for a future year, including people enrolling or disenrolling. Actuaries also project future costs due to increased utilization of existing services or services that may begin to be covered in the future, such as the emergence of NMEs. Understanding the pharmaceutical pipeline is essential for proper planning, as new-to-market drugs can create significant budget impacts depending on the annual cost of the drug and the amount of patients in a population who may receive the drug. This can be particularly challenging for small health plans where drugs with drug costs over \$100,000 per patient per year may increase the premium for all the employees in that health plan.

PBM services are included within this monthly premium. PBMs are often subcontractors for health plans, and they design their benefit structure to cover prescription drugs consistent with the benefit structure of that health plan. PBMs are paid through a variety of methods:

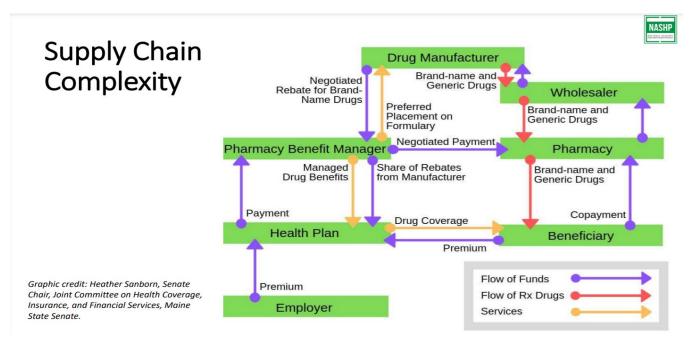
- monthly payment from the carrier (e.g., a <u>per-member-per-month (PMPM)</u> fee); or
- claim-by-claim basis (e.g., administrative fee paid per claim); or
- manufacturer rebates (e.g., retaining manufacturer rebates for covered drugs); or
- spread pricing (e.g., retaining the difference between what the carrier pays the PBM and what the PBM pays the pharmacy).

Depending on the contract between the carrier and PBM, each payment methodology may create incentives by the PBM to structure pharmacy services to their benefit. This has been reported in the past with certain PBMs preferred drugs that have higher costs for patients due to PBMs retaining manufacturer rebates for more expensive drugs, which was the subject of <u>Washington State House Bill 2464</u> (2020), now codified in <u>Chapter 48.43.430 RCW</u>.

Prescription drug supply chain

The prescription drug supply chain ensures that safe and effective drugs are made available to patients. However, many different and parallel steps occur that result in the drug being sold by a manufacturer to being administered by a patient or provider. In Diagram 1 below, a simplified model shows the complexity of the prescription drug distribution system.





In **Diagram 1**, three of the four Reporting Entities for the DPT program are represented. In this model, PSAOs who may or may not be part of a <u>wholesaler</u>, help contract between pharmacies and PBMs.

Tracking the flow of a prescription drug (red arrows), the journey begins with the manufacturer who sells their products to wholesalers. Wholesalers purchase from many different manufacturers and sells their products to pharmacies who often order daily from wholesalers. Wholesalers then distribute the selected drugs to pharmacies who keep the drugs in storage until a prescription for a patient arrives. When the prescription is processed, the pharmacy dispenses the drug to the patient.

Following the flow of funds (purple arrows), employers and patients pay a monthly premium to the carrier for the health plan. Carriers, who subcontract services to a PBM, provide the PBM with the funds to reimburse pharmacies for a paid claim on a covered drug. The pharmacies use these funds to replenish their stock of prescription drugs by purchasing from wholesalers, who purchase directly from manufacturers. PBMs make their revenue through either:

- 1. The administrative fees charged to the carrier;
- 2. PBMs collecting a spread between the carrier and the pharmacy on claims processed;
- 3. Rebates from manufacturers retained by the PBM; or
- 4. A combination of the three.

The four reporting entity types identified in <u>Chapter 43.71C RCW</u> may have information pertaining to how drug prices affect health care costs. Drug manufacturers, the entities responsible for developing, producing, and selling drugs set the price of drugs sold in the United States. Carriers are businesses that offer health insurance and manage health plans, where they set a monthly premium for enrollment based off the services provided and the employer or member cost. PBMs are businesses that manage the prescription drug benefit for carriers, and they help negotiate the reimbursement of drugs with pharmacies, contract for rebates with drug manufacturers, and provide clinical and operational services to carriers. PSAOs are organizations that negotiate with PBMs on behalf of a pharmacy or group of pharmacies on drug reimbursement rates, network participation, and other fees.



Suggested statutory changes for DPT program

Below are some initial draft suggested changes to amend RCW 43.71C to address the limitations discussed in the report.

RCW 43.71C.010:

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

- (1) "Authority" means the health care authority.
- (2) "Covered drug" means any prescription drug that:

(a) A covered manufacturer intends to introduce to the market at a wholesale acquisition cost of ten thousand dollars or more for a course of treatment lasting less than one month or a thirty-day supply, whichever period is longer; or

(b) Is currently on the market, is manufactured by a covered manufacturer, and has a wholesale acquisition cost of more than one hundred dollars for a course of treatment lasting less than one month or a thirty-day supply, and, taking into account only price increases that take effect after July 28, 2019, the manufacturer increases the wholesale acquisition cost at least:

(i) Twenty percent, including the proposed increase and the cumulative increase over one calendar year prior to the date of the proposed increase; or

(ii) Fifty percent, including the proposed increase and the cumulative increase over three calendar years prior to the date of the proposed increase.

(3) "Covered manufacturer" <u>has the same meaning as manufacturer in RCW 18.64.011</u>. means a person, corporation, or other entity engaged in the manufacture of prescription drugs sold in or into Washington state. "Covered manufacturer" does not include a private label distributor or retail pharmacy that sells a drug under the retail pharmacy's store, or a prescription drug repackager.

(4) "Health care provider," "health plan," "health carrier," and "carrier" mean the same as in RCW 48.43.005.

(5) "Pharmacy benefit manager" means the same as in *RCW 19.340.010.

(6) "Pharmacy services administrative organization" means an entity that contracts with a pharmacy to act as the pharmacy's agent with respect to matters involving a pharmacy benefit manager, third-party payor, or other entities, including negotiating, executing, or administering contracts with the pharmacy benefit manager, third-party payor, or other entities and provides administrative services to pharmacies.

(7) "Prescription drug" <u>has the same meaning as "legend drug" in RCW 69.41.010</u>. means a drug regulated under chapter 69.41 or 69.50 RCW, including generic, brand name, specialty drugs, and biological products that are prescribed for outpatient use and distributed in a retail setting.

(8) "Qualifying price increase" means a price increase described in subsection (2)(b) of this section.

(9) "Wholesale acquisition cost" or "price" means, with respect to a prescription drug, the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, excluding any discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of prescription drug pricing.

RCW 43.71C.020:

Beginning October 1, <u>2023</u>2019, and on a yearly basis thereafter, a health carrier must submit to the authority the following prescription drug cost and utilization data for the previous calendar year<u>s</u> for each health plan it offers in the state:

- a. <u>The total number of claims, the total number of days supply, the total number of clients, the total allowed</u> <u>amount, the total paid amount, the total member cost share, and the total amount of rebate collected for:</u>
 - i. The twenty-five prescription drugs most frequently prescribed by health care providers participating in the plan's network;
 - ii. (2) The twenty-five costliest prescription drugs expressed as a percentage of total plan prescription drug spending, and the plan's total spending for each of these prescription drugs;
 - iii. (3) The twenty-five drugs with the highest year-over-year increase in wholesale acquisition cost, excluding drugs made available for the first time that plan year, and the percentages of the increases for each of these prescription drugs; and
 - iv. <u>The twenty-five most frequently prescribed drugs for which the health plan received rebates from pharmaceutical manufacturers.</u>
 - v. <u>All prescription drugs covered within the reporting year.</u>
- b. The portion of the premium that is attributable to each of the following categories of covered prescription drugs, after accounting for all rebates and discounts



- i. Brand name drugs;
- ii. Generic drugs; and
- iii. Specialty drugs;
- c. The year-over-year increase, calculated on a per member, per month basis and expressed as a percentage, in the total annual cost of each category of covered drugs listed in subsection (4) of this section, after accounting for all rebates and discounts;
- d. A comparison, calculated on a per member, per month basis, of the year-over-year increase in the cost of covered drugs to the year-over-year increase in the costs of other contributors to premiums, after accounting for all rebates and discounts;
- e. The name of each covered specialty drug; and
- f. <u>Total member months.</u>

RCW 43.71C.030:

<u>Beginning October 1, 2023 and annually thereafter</u>, a pharmacy benefit manager must submit to the authority the following data from the previous calendar years for each health plan it services in the state as determined by the authority:

- All discounts, including the total dollar amount and percentage discount, and all rebates received from a manufacturer for each drug on the pharmacy benefit manager's formularies <u>attributable to each health plan</u> in Washington;
- b. The total dollar amount of all discounts and rebates <u>paid to health plans, and that amount are</u> retained by the pharmacy benefit manager for each drug on the pharmacy benefit manager's formularies;
- c. Actual total amount the pharmacy benefit manager <u>paid</u> retail pharmacies, <u>for each drug on a health plan's or</u> <u>pharmacy benefit manager's formularies</u>, after all direct and indirect <u>remuneration</u>, <u>performance guarantees</u>, administrative and other fees that have been retrospectively charged to the pharmacies are applied;
- d. The <u>total amount the pharmacy benefit manager charged</u> health plans for each drug on the <u>health plan's or</u> pharmacy benefit manager's formularies;
- e. The <u>total</u> amount <u>of member cost-share collected above the actual cost of each drug on the health plan's or</u> <u>pharmacy benefit manager's formularies</u> <u>, terms, and conditions relating to copayments, reimbursement</u> options, and other payments or fees associated with a prescription drug benefit plan;
- f. Disclosure of any ownership interest the pharmacy benefit manager has in a pharmacy or health plan with which it conducts business;
- g. <u>Any network participation fee charged to pharmacies, however classified, to be the pharmacy benefit</u> <u>manager's network including but not limited to:</u>
 - i. <u>credentialing fees;</u>
 - ii. per transaction fees or claims submission fee:
 - iii. origination fees:
 - iv. direct and indirect remuneration; and
 - v. performance based fees.
- h. The results of any appeal filed pursuant to RCW <u>19.340.100(3)</u>.
- i. The information collected pursuant to this section is not subject to public disclosure under chapter <u>42.56</u> RCW.
- j. The authority may examine or audit the financial records of a pharmacy benefit manager for purposes of ensuring the information submitted under this section is accurate. Information the authority acquires in an examination of financial records pursuant to this subsection is proprietary and confidential.

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RCW 43.71C.040:

Pharmacy benefit managers—Compliance.

(1) No later than <u>October</u> March 1st of each calendar year, each pharmacy benefit manager must file with the authority, in the form and detail as required by the authority, a report for the preceding calendar year stating that the pharmacy benefit manager is in compliance with this chapter.

(2) A pharmacy benefit manager may not cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading.

(3) An employer-sponsored self-funded health plan or a Taft-Hartley trust health plan may voluntarily provide the data described in subsection (1) of this section.

RCW 43.71C.050:

Manufacturers—Data reporting.

(1) Beginning October 1, 2023 a covered manufacturer must submit to the authority the following data for each covered drug:

(a) A description of the specific financial and nonfinancial factors used to make the decision to set or increase the wholesale acquisition cost of the drug. In the event of a price increase, a covered manufacturer must also submit the amount of the increase and an explanation of how these factors explain the increase in the wholesale acquisition cost of the drug;

(b) The patent expiration date of the drug if it is under patent;

(c) Whether the drug is a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug;

(d) The total sales volume for the drug for each year for the past 5 years including total units sold, revenue, and profits:

(<u>ed</u>) The itemized cost for production and sales, including the annual manufacturing costs, annual marketing and advertising costs, total research and development costs, total costs of clinical trials and regulation, <u>total amount of public</u> <u>funds received for research and development of the drug</u>; and total cost for acquisition of the drug; and

(ef) The total financial assistance given by the manufacturer through assistance programs, rebates, and coupons.

(2) For all qualifying price increases of existing drugs, a manufacturer must submit the year the drug was introduced to market and the wholesale acquisition cost of the drug at the time of introduction.

(3) If a manufacturer increases the price of an existing drug it has manufactured for the previous five years or more, it must submit a schedule of wholesale acquisition cost increases for the drug for the previous five years.

(4) If a manufacturer acquired the drug within the previous five years, it must submit:

(a) The wholesale acquisition cost of the drug at the time of acquisition and in the calendar year prior to acquisition; and

(b) The name of the company from which the drug was acquired, the date acquired, and the purchase price.

(5) Except as provided in subsection (6) of this section, a covered manufacturer must submit the information required by this section:



(a) At least sixty days in advance of a qualifying price increase for a covered drug; and

(b) At least thirty days prior to the release of a new covered drug to the market.

RCW 43.71C.060:

Manufacturers—Notice of new drug applications.

(1) Beginning October 1, <u>2023</u>2019, a manufacturer must submit written notice, in a form and manner specified by the authority, informing the authority that the manufacturer has filed with the FDA:

(a) A new drug application or biologics license application for a pipeline drug; or

(b) A biologics license application for a biological product.

(2) The notice must be filed within sixty days of the manufacturer receiving the applicable <u>Prescription Drug User Fee</u> <u>Act FDA</u> approval date <u>from the food and drug administration</u>.

(3) Upon receipt of the notice, the authority may request from the manufacturer the following information if it believes the drug will have a significant impact on state expenditures:

(a) The primary disease, condition, or therapeutic area studied in connection with the new drug, and whether the drug is therapeutically indicated for such disease, condition, or therapeutic area;

(b) Each route of administration studied for the drug;

(c) Clinical trial comparators for the drug;

(d) The date at which the FDA must complete its review of the drug application pursuant to the federal prescription drug user fee act of 1992 (106 Stat. 4491; P.L. 102-571);

(e) Whether the FDA has designated the drug an orphan drug, a fast-track product, or a breakthrough therapy; and

(f) Whether the FDA has designated the drug for accelerated approval, priority review, or if the drug contains a new molecular entity.

(4) A manufacturer may limit the information reported pursuant to this section to that which is otherwise in the public domain or publicly reported.

(5) The information collected pursuant to this section is not subject to public disclosure under chapter <u>42.56</u> RCW.

RCW 43.71C.070:

Manufacturers—Notice of price increases.

(1) Beginning October 1, <u>2023</u> 2019, a manufacturer of a covered drug must notify the authority of a qualifying price increase in writing at least sixty days prior to the planned effective date of the increase. The notice must include:

(a) The date of the increase, the current wholesale acquisition cost of the prescription drug, and the dollar amount of the future increase in the wholesale acquisition cost of the prescription drug; and

(b) A statement regarding whether a change or improvement in the drug necessitates the price increase. If so, the manufacturer shall describe the change or improvement.

(2) For any drug approved under section 505(j) of the federal food, drug, and cosmetic act, as it existed on July 28, 2019, or a biosimilar approved under section 351(k) of the federal public health service act, as it existed on July 28, 2019, if



notification is not possible sixty days before the price increase, that submission must be made as soon as known but not later than the date of the price increase.

(3) The information submitted pursuant to this section is not subject to public disclosure under chapter <u>42.56</u> RCW <u>unless otherwise is already in the public domain or publicly reported</u>.

(4) By December 1, 2020, the authority must provide recommendations on how to provide advance notice of price increases to purchasers consistent with state and federal law <u>HCA</u> may post information about qualifying price increases on its website.

RCW 43.71C.080:

Pharmacy services administrative organizations—Data reporting.

(1) Beginning October 1, <u>2023</u> 2019, and on a yearly basis thereafter, a pharmacy services administrative organization representing a pharmacy or pharmacy chain in the state must submit to the authority the following data from the previous calendar year:

(a) The negotiated reimbursement <u>rate the PSAO is to pay to pharmacies for brand, generic, and specialty drugs for</u> <u>each Pharmacy Benefit Manager's pharmacy network; and of the twenty-five prescription drugs with the highest</u> <u>reimbursement rate</u>;

(b) The twenty-five prescription drugs with the largest year-to-year change in reimbursement rate, expressed as a percentage and dollar amount; and

(b)The negotiated reimbursement rate the pharmacy benefit manager is to pay the PSAO for brand, generic, and specialty drugs for each Pharmacy Benefit Manager's pharmacy network;

(c) The schedule of fees charged to pharmacies for the services provided by the pharmacy services administrative organization.

(2) Any pharmacy services administrative organization whose revenue is generated from flat service fees not connected to drug prices or volume, and paid by the pharmacy, is exempt from reporting.

RCW 43.71C.100:

Annual report—Data confidentiality.

(1) The authority shall compile and analyze the data submitted by health carriers, pharmacy benefit managers, manufacturers, and pharmacy services administrative organizations pursuant to this chapter and prepare an annual report for the public and the legislature synthesizing the data to demonstrate the overall impact that drug costs, rebates, and other discounts have on health care premiums.

(2) The data in the report must be aggregated and must not reveal information specific to individual health carriers, pharmacy benefit managers, pharmacy services administrative organizations, individual prescription drugs, individual classes of prescription drugs, individual manufacturers, or discount amounts paid in connection with individual prescription drugs.

(3) Data received pursuant to this section must only be used for the enumerated purposes of this chapter and other statutorily authorized purposes.

(34) Beginning January 1, 2021, and by each January 1st thereafter, the authority must publish the report on its web site.

(4<u>5</u>) Except for the report, and as provided in subsection (<u>56</u>) of this section, the authority shall keep confidential all data submitted pursuant to RCW <u>43.71C.020</u> through <u>43.71C.080</u>.

(65) For purposes of public policy, upon request of a legislator, the office of the governor, the office of the attorney general, or a committee or subcommittee of the legislature with jurisdiction over matters relating to drug transparency, the authority must provide all data provided pursuant to RCW <u>43.71C.020</u> through <u>43.71C.080</u> and any analysis prepared by the authority. Any information provided pursuant to this subsection must be kept confidential within the legislature office of the governor, the office of the attorney general, or a committee or subcommittee or subcommittee of the legislature with jurisdiction over matters relating to drug transparency.

(67) The data collected pursuant to this chapter is not subject to public disclosure under chapter 42.56 RCW.

(8) Recipients of data received pursuant to subsection (6) of this section must:

(a) Follow all rules adopted by the authority regarding appropriate data use and protection; and

(b) sign a nondisclosure agreement that includes acknowledgements that the recipient is solely responsible for any liability arising from misuse of the data, that the recipient does not have any conflicts under the ethics in public service act that would prevent them from accessing or using the data, and that violations of the nondisclosure agreement may result in losing the right to access or use data.



Glossary of terms

Actuaries – a person who compiles and analyzes statistics and uses them to calculate insurance risks and premiums.

Amazon Web Services (AWS S3) - Cloud computing platform for individuals, companies, and government.

Analytical Tools – Microsoft Excel, Tableau, DataGrip, SQL, Power BI, SAS.

Annual Deductible – The total amount that family members on a health plan must pay out-of-pocket for health care or prescription drugs before the health plan begins to pay.

Appeals – Washington State created a law, now codified as <u>RCW 48.200.280(3)</u>, by which PBMs must have a process for pharmacies to appeal predetermined reimbursement costs for multisource generic drugs.

Biochemical Name – Name of the drug product for the NDC reported, to include ingredient name as reported in standardized drug databases. This name should include ingredient, salt form, dosage form, strength, and any other information specific to the NDC.

Carriers – A disability insurer regulated under chapter <u>48.20</u> or <u>48.21</u> RCW, a health care service contractor as defined in RCW <u>48.44.010</u>, or a health maintenance organization as defined in RCW <u>48.46.020</u>, and includes "issuers" as that term is used in the patient protection and affordable care act (P.L. 111-148).

Blood Product Name – Name of the drug for the NDC reported.

Brand Name – A drug sold by a drug company under a proprietary name or trademark.

Chemical Name – The name of a chemical compound that shows the names of each of its elements or subcompounds.

Claim-By-Claim Basis – The procedure in which an administrative fee is charged by the PBM to the carrier for every claim received and processed for patients served by that carrier.

Covered Drugs – Any prescription drug that:

(a) A covered manufacturer intends to introduce to the market in Washington state at a wholesale acquisition cost of ten thousand dollars or more for a course of treatment lasting less than one month or a thirty-day supply, whichever period is longer; or

(b) Meets all of the following:

(i) Is currently on the market in Washington state;

(ii) Is manufactured by a covered manufacturer; and

(iii) Has a wholesale acquisition cost of more than one hundred dollars for a course of treatment lasting less than one month or a thirty-day supply, and, taking into account only price increases that take effect on or after October 1, 2019, the manufacturer increases the wholesale acquisition cost such that:

(A) The new wholesale acquisition cost is twenty percent higher than the wholesale acquisition cost on the same day of the month, twelve months before the date of the proposed increase; or

(B) The new wholesale acquisition cost is fifty percent higher than the wholesale acquisition cost on the same day of the month, thirty-six months before the date of the proposed increase.

Employee Retirement Income Security Act (ERISA) - Establishes minimum standards for pension plans in private industry

Enterprise Data Warehouse (EDW) – Data warehouse containing a company's business data, including information about its customers.

Fully-insured Health Plans – The employer and employees pay their premium obligations to the health insurance company.

Generic Drugs – Are a copy of a brand name drug.

Individual Group – A health plan offered to a single subscriber that does not belong to any group or collective risk pool. Large Group – In general, a group health plan that covers employees of an employer that has 51 or more employees. In some states large groups are defined as 101 or more.



Lines of Business – The Line of Business you are reporting on. Possible values are: Large Group, Small Group, Individual, ERISA, Medicaid, Medicare, or Other.

Manufacturers – A person, corporation, or other entity engaged in the manufacture of prescription drugs sold in or into Washington state. "Covered manufacturer" does not include a private label distributor or retail pharmacy that sells a drug under the retail pharmacy's store, or a prescription drug repackager.

Medicare Part D – Voluntary outpatient prescription drug benefit for people with Medicare, provided through private plans.

Medicaid – Health coverage for low-income adults, children, pregnant women, elderly adults, and people with disabilities.

Member-Month – The measure of each member enrolled in a health plan for that month.

National Drug Code (NDC) – 3-segment numeric identifier assigned to each medication listed under Section 510 of the U.S. Federal Food, Drug and Cosmetic Act.

New Molecular Entities (NME) - A novel compound that has not previously been approved for use in humans

New-to-Market Drugs (New Covered Drug) – Means any prescription drug that:

(a) A covered manufacturer intends to introduce to the market at a wholesale acquisition cost of ten thousand dollars or more for a course of treatment lasting less than one month or a thirty-day supply, whichever period is longer; or (b) Is currently on the market, is manufactured by a covered manufacturer, and has a wholesale acquisition cost of more than one hundred dollars for a course of treatment lasting less than one month or a thirty-day supply, and, taking into account only price increases that take effect after July 28, 2019, the manufacturer increases the wholesale acquisition cost at least:

(i) Twenty percent, including the proposed increase and the cumulative increase over one calendar year prior to the date of the proposed increase; or

(ii) Fifty percent, including the proposed increase and the cumulative increase over three calendar years prior to the date of the proposed increase.

Non-Specialty Drugs – Drugs that treat both chronic and acute diseases that affect larger populations in the U.S. In contrast to specialty medications, non-specialty drugs are typically small-molecule medications, meaning they are chemically synthesized.

Office of Insurance Commissioner (OIC) – Regulates the insurance industry.

Out-of-pocket Costs – Your expenses for medical care that are not reimbursed by insurance. These include deductibles, coinsurance, and copayments.

Preferred Drug List (PDL) – List of medications that Medicaid will cover the cost for without the need to request a prior authorization.

Pharmacy Benefit Managers (PBM) – A person that contracts with pharmacies on behalf of an insurer, a third-party payor, or the prescription drug purchasing consortium established under RCW <u>70.14.060</u>.

Pharmacy Service Administrative Organizations – An entity that contracts with a pharmacy to act as the pharmacy's agent with respect to matters involving a pharmacy benefit manager, third-party payor, or other entities, including negotiating, executing, or administering contracts with the pharmacy benefit manager, third-party payor, or other entities and provides administrative services to pharmacies.

Per-Member-Per-Month (PMPM) – The amount of money paid or received on a monthly basis for each individual enrolled in a managed care plan.

Prescription Drug – A drug regulated under Chapter 69.41 RCW or Chapter 69.50 RCW, including generic, brand, specialty, and biological products that are prescribed for outpatient use and distributed in a retail setting.



Rebate – Means negotiated price concessions or, discounts, however characterized, that accrue directly or indirectly to a reporting entity in connection with utilization of prescription drugs by reporting entity members. These include but are not limited to, rebates, administrative fees, market share rebates, price protection rebates, performance-based price concessions, volume-related rebates, other credits, and any other negotiated price concessions or discounts that are reasonably anticipated to be passed through to a reporting entity during a coverage year, as well as any other form of price concession prearranged with a covered manufacturer, dispensing pharmacy, PBM, rebate aggregator, group purchasing organization, or other party which are paid to a reporting entity and are directly attributable to the utilization of certain drugs by reporting entity members.

Reporting entity – Carriers, covered manufacturers, carriers, health plans, PBMs, and pharmacy services administrative organizations, which are required to or voluntarily submit data according to <u>Chapter 43.71C</u>.

Risk-scores – Process of attaining a calculated score that tells you how severe a risk is, based off of several factors.

Secure File Transfer (SFT) – Reliable delivery method. It is used to safeguard proprietary and personal data in transit and at rest.

Self-funded Health Plans – Employer itself collects premiums from enrollees. The employer uses their own money to cover their employee's claims.

Small Group – Most states define small group as 1-50 employees.

Specialty Drugs – High-cost prescription medications used to treat complex, chronic conditions.

Technical Validation – The data files undergo technical validation where the validation script reads each file and determines if it passes or fails technical validation based on the specifications outlined in each DSG.

Wholesale Acquisition Cost (WAC) – With respect to a prescription drug, the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, excluding any discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale acquisition cost guides or other publications of prescription drug pricing.

Wholesaler – A person or company that sells goods in large quantities at low prices, typically to retailers.

