Oregon Prescription Drug
Affordability Board

Prescription Drug Affordability Board (PDAB) legislative recommendations

Presentation to the Cost Growth Target Advisory Committee
Jan. 23, 2024

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Prescription Drug Affordability Board (PDAB)

Purpose:

- Created under Senate Bill 844 (2021) to protect Oregonians, state and local governments, commercial health plans, health care providers, pharmacies, and others within the health care system from the high costs of prescription drugs

Composition:

- Eight members appointed by the governor and confirmed by the Senate, with backgrounds in clinical medicine or health care economics

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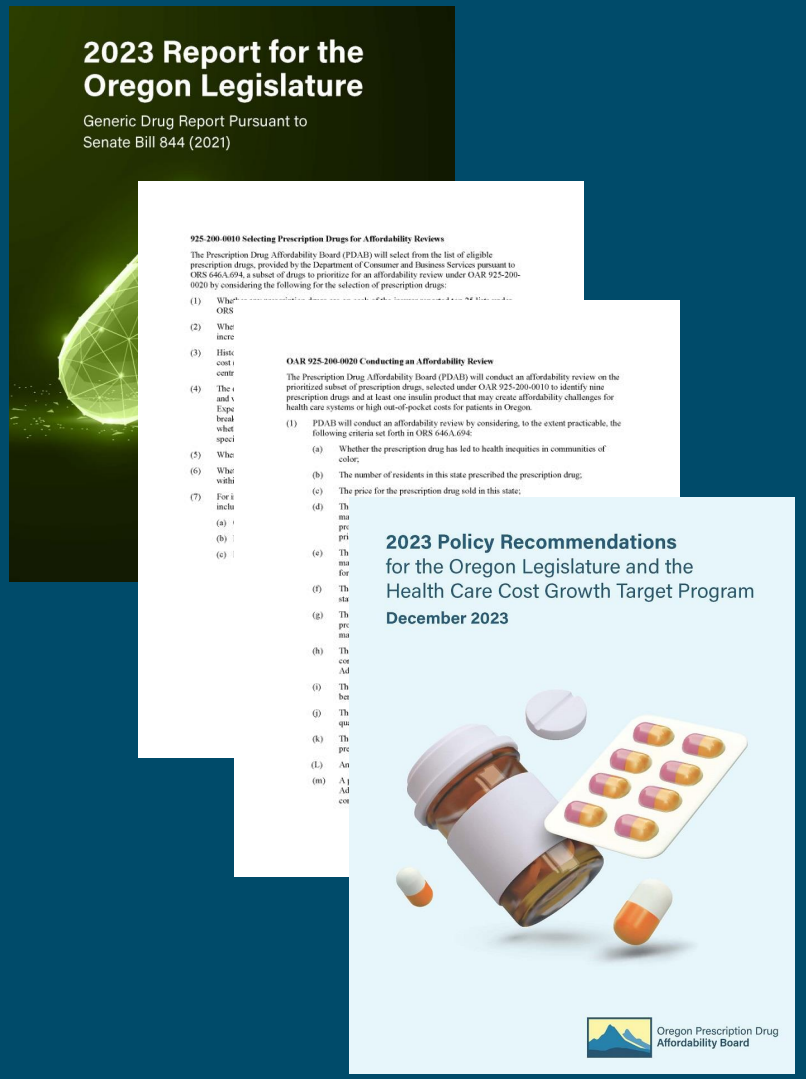
PDAB 2023 highlights

- Studied the generic drug market and presented a report to the Oregon Legislature in June
- Launched the affordability review process to identify nine drugs and at least one insulin product that may create affordability challenges for Oregonians
- Provided policy recommendations to the Oregon Legislature in December



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Generic drug report for the Oregon Legislature

- The board prepared a generic drug report that looked at drug shortages, price fixing, pay for delay, spread pricing, market disrupters, and cost savings from biosimilars. The board delivered the report to the Oregon Legislature in June.

Read the report on the PDAB website:
dfr.oregon.gov/pdab/Pages/reports.aspx

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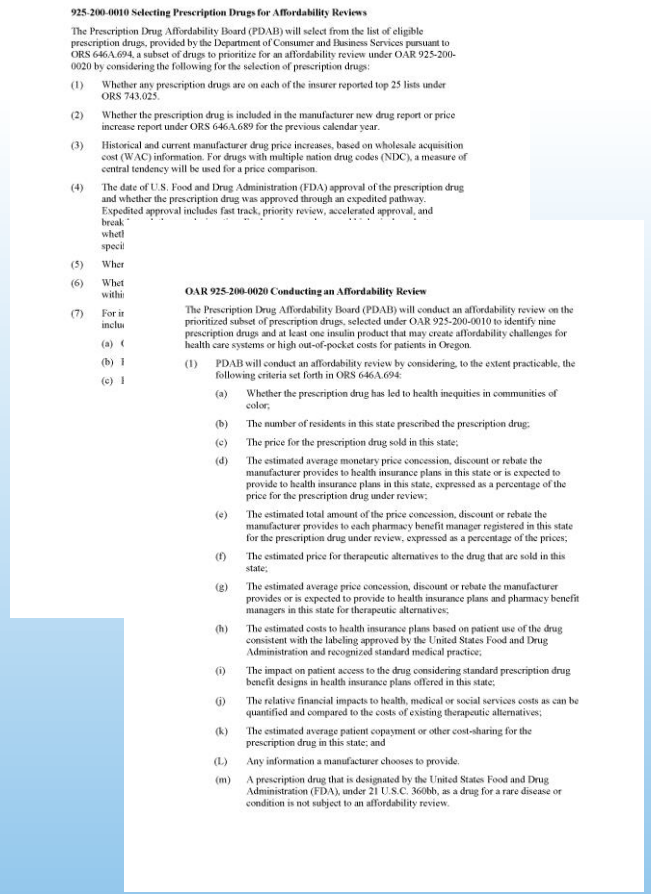
PDAB affordability reviews for insulin, prescription drugs

- The board finalized two new rules in July to select drugs and establish the framework for conducting affordability reviews. OAR 925.200.0010 and OAR 025.200.0020 took effect Aug. 1, 2023.
- Based on these rules, the board narrowed the list of prescription drugs from 300 to 12, and insulin products from 66 to three.
- The selection process ended in December. Affordability reviews will take place in 2024, from Jan. 26 through May 15. The board will vote on whether these drugs create affordability challenges and then present a final list of nine drugs and at least one insulin product to the Oregon Legislature in June.

Find the board calendar for affordability review: dfr.oregon.gov/pdab/Pages/affordability-review.aspx



925-200-0010 Selecting Prescription Drugs for Affordability Reviews

The Prescription Drug Affordability Board (PDAB) will select from the list of eligible prescription drugs, provided by the Department of Consumer and Business Services pursuant to ORS 646A.694, a subset of drugs to prioritize for an affordability review under OAR 925-200-0020 by considering the following for the selection of prescription drugs:

(1) Whether any prescription drugs are on each of the insurer reported top 25 lists under ORS 743.025.

(2) Whether the prescription drug is included in the manufacturer new drug report or price increase report under ORS 646A.689 for the previous calendar year.

(3) Historical and current manufacturer drug price increases, based on wholesale acquisition cost (WAC) information. For drugs with multiple nation drug codes (NDC), a measure of central tendency will be used for a price comparison.

(4) The date of U.S. Food and Drug Administration (FDA) approval of the prescription drug and whether the prescription drug was approved through an expedited pathway. Expedited approval includes fast track, priority review, accelerated approval, and break

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OAR 925-200-0020 Conducting an Affordability Review

The Prescription Drug Affordability Board (PDAB) will conduct an affordability review on the prioritized subset of prescription drugs, selected under OAR 925-200-0010 to identify nine prescription drugs and at least one insulin product that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon.

(1) PDAB will conduct an affordability review by considering, to the extent practicable, the following criteria set forth in ORS 646A.694:

(a) Whether the prescription drug has led to health inequities in communities of color;

(b) The number of residents in this state prescribed the prescription drug;

(c) The price for the prescription drug sold in this state;

(d) The estimated average monetary price concession, discount or rebate the manufacturer provides to health insurance plans in this state or is expected to provide to health insurance plans in this state, expressed as a percentage of the price for the prescription drug under review;

(e) The estimated total amount of the price concession, discount or rebate the manufacturer provides to each pharmacy benefit manager registered in this state for the prescription drug under review, expressed as a percentage of the prices;

(f) The estimated price for therapeutic alternatives to the drug that are sold in this state;

(g) The estimated average price concession, discount or rebate the manufacturer provides or is expected to provide to health insurance plans and pharmacy benefit managers in this state for therapeutic alternatives;

(h) The estimated costs to health insurance plans based on patient use of the drug consistent with the labeling approved by the United States Food and Drug Administration and recognized standard medical practice;

(i) The impact on patient access to the drug considering standard prescription drug benefit designs in health insurance plans offered in this state;

(j) The relative financial impacts to health, medical or social services costs as can be quantified and compared to the costs of existing therapeutic alternatives;

(k) The estimated average patient copayment or other cost-sharing for the prescription drug in this state; and

(L) Any information a manufacturer chooses to provide.

(m) A prescription drug that is designated by the United States Food and Drug Administration (FDA), under 21 U.S.C. 360bb, as a drug for a rare disease or condition is not subject to an affordability review.

PDAB policy recommendations for the Oregon Legislature

In December, the board provided three policy recommendations to the Oregon Legislature and Health Care Cost Growth Target Program:

1. Lower insulin co-pay limit to $35 and/or decouple from inflation index
2. Change Oregon's statute language regarding substitution requirements for biological products and biosimilars
3. Expand pharmacy benefit manager (PBMs) reporting requirements for more transparency

Read the report dfr.oregon.gov/pdab/Pages/reports.aspx

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1. Lower insulin co-pay limit to $35 and/or decouple from inflation index

- PDAB supports the American Diabetes Association's proposal to lower Oregon's statutory insulin co-pay maximum to $35 or decouple insulin copay from the Consumer Price Index. This would align Oregon law with the federal Medicare maximum and help reduce insulin copays for Oregonians.
- Background: ORS 743A.069 capped patient out-of-pocket insulin cost for enrollees of state-regulated health plans in 2021 and tied annual increases to the Consumer Price Index. Also, more generic insulins came to market and manufacturers dropped list prices for brand-name insulins. As a result, Oregon's insulin cap will be $85 in 2024, which is significantly higher than the actual acquisition cost for most Oregon prescriptions.

Read the report: dfr.oregon.gov/pdab/Pages/reports.aspx

2. Change Oregon's statute for substitution requirements for biological products and biosimilars

- The board proposes updating ORS 689.522 to include biosimilar products and interchangeable biosimilar language, using definitions consistent with the Federal Drug Administration's 42 USC 262(i)(2). Biosimilars are comparable to the FDA-approved reference product and provide more availability for treatment options and have the same safety and effectiveness as the reference product.
- Increased adoption of biosimilars and interchangeable biosimilars has the potential to generate significant savings for the whole health system.

Read the report: dfr.oregon.gov/pdab/Pages/reports.aspx

3. Expand pharmacy benefit managers (PBMs) reporting requirements for more transparency

- PDAB proposes improving transparency of pharmacy benefit manager (PBM) activity by expanding reporting requirements.
- Collecting additional data could generate more insight into the role of PBMs in drug pricing and support the development of more substantive policy recommendations concerning PBMs in the future.
- In October, PDAB solicited policy recommendations from the public. Four responses called for the collection of additional data, pointing to the Oregon Secretary of State's 2023 audit of PBMs serving Medicaid.

Read the report: dfr.oregon.gov/pdab/Pages/reports.aspx

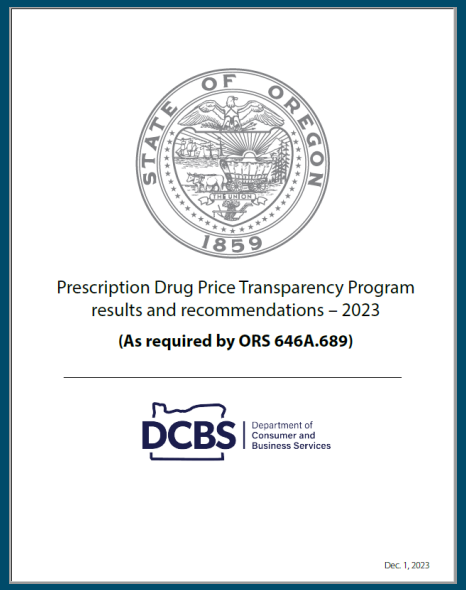
SB 192 upper payment limit analytic, implementation planning

- ❑ Structure-Submit plan to Legislature by Sept 15, 2024 including:
  - Methodology
  - Analysis of resources, enforcement options, impact on PEBB/OEBB; other state administered health benefits, health benefit plans/
  - Must include a detailed explanation of the plan and savings/cost analysis for
    - ✓ State
    - ✓ Insurers
    - ✓ Hospitals
    - ✓ Pharmacies
    - ✓ Consumers
    - ✓ 340B Covered Entities (not statutorily called out)

SB 192 upper payment limit analytic, implementation planning

- Anticipated process
  - Vendor procurement for stakeholder engagement and analytics (October-December)
  - Communications and outreach (January)
  - Stakeholder meetings (February-April)
  - Analytics and report/plan writing (May-June)
  - Board review and acceptance of report (July-August)
  - Submission to Legislature (September)

Drug Price Transparency (DPT) Program

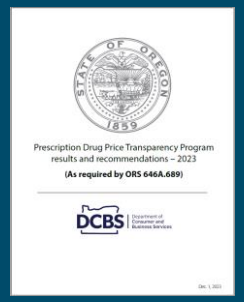

Prescription Drug Price Transparency Program
results and recommendations – 2023
(As required by ORS 646A.689)

DCBS | Department of Consumer and Business Services

Dec. 1, 2023

- Operates under ORS 646A.680 to 646A.692 and OAR 836-200-0500 to 836-200-0560. ORS 743.025 requires insurers to file annual reports with the program
- Reporting manufacturers are required to register, file certain reports, and pay an annual billing to cover program costs
- Reporting manufacturers are those who meet all the following:
  - Registered with the Oregon Board of Pharmacy
  - Manufacture prescription drugs for sale in Oregon
  - Set the drug's price (wholesale acquisition cost (WAC)

DFR | Division of Financial Regulation
Department of Consumer and Business Services



Drug Price Transparency reporting

Program is directed by statute to receive:

- Manufacturer reports:
  - New specialty drug reports: More than $670 for 30-day supply
  - Annual price increase reports: $100 or more and 10 percent net yearly increase
  - 60-day price increase notices: 10 percent or $10,000 increase for brand name, 25 percent and $300 increase for generic
- Insurer reports: Top 25 most costly and most prescribed drugs, and the effect of drug costs on premium rates
- Pharmacy benefit manager (PBM) reports: Amounts received from manufacturers and how they were distributed
  - New reporting starting in 2024
- Consumer reports: Personal price increase in Rx purchased

DFR Division of Financial Regulation
Department of Consumer and Business Services

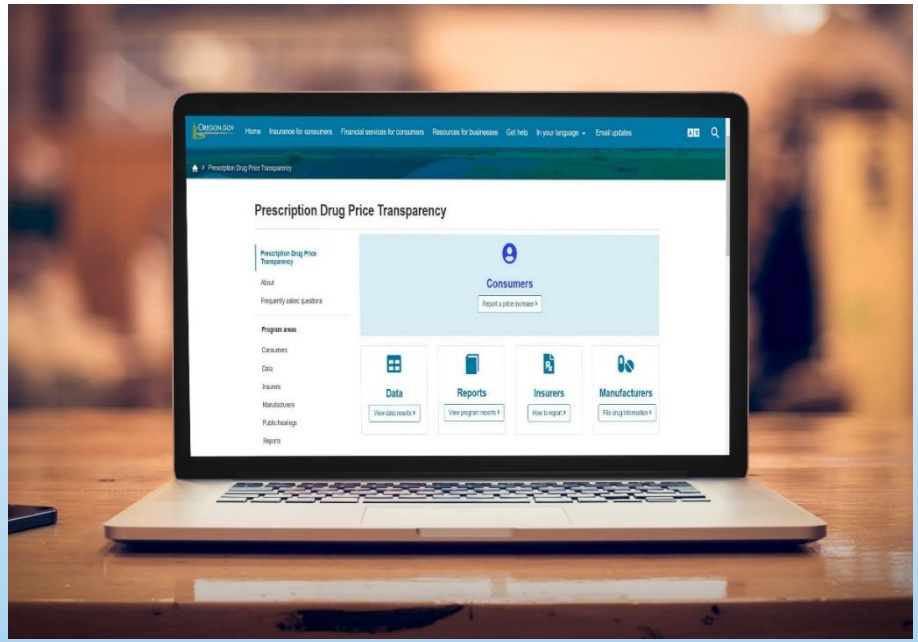
Consumers and transparency

Consumers

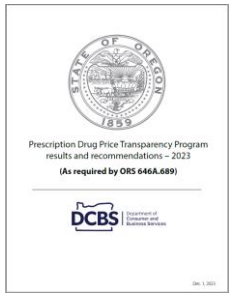
- Price increase reporting
- Stories about high drug prices

Transparency website

- Reported data from manufacturers (non-trade secret)
- Information from insurers
- Consumer price increase reports



DFR Division of Financial Regulation
Department of Consumer and Business Services



Key findings for 2023 DPT report

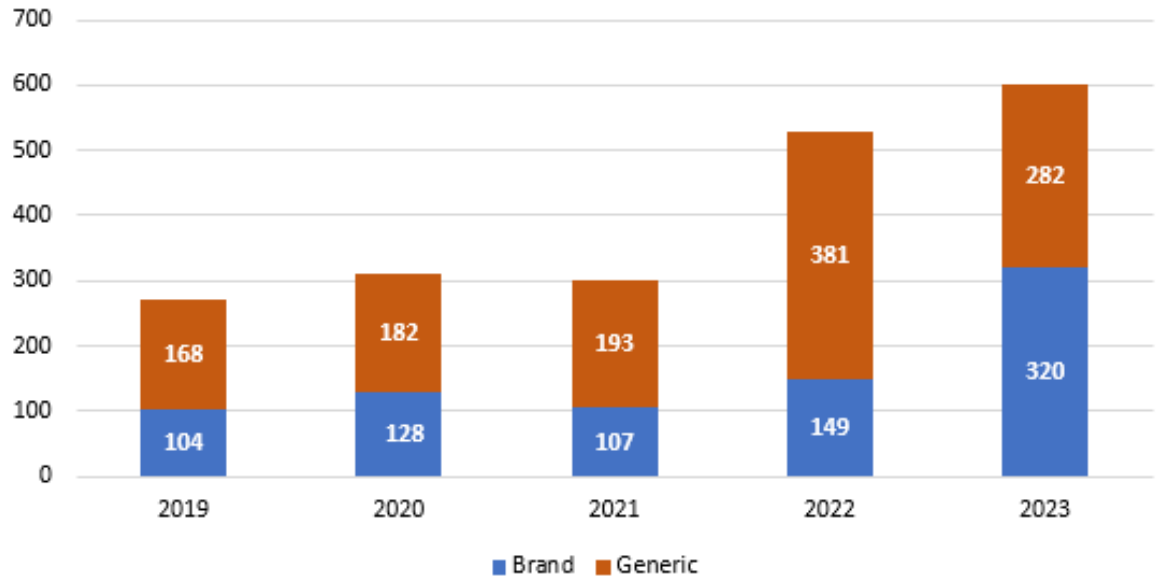
- New specialty drug report highlight: Antineoplastics and adjunctive therapies, used to treat cancer, were the most frequent category of new specialty drugs reported to the program. The highest WAC for a brand name drug was $3.5 million for **Hemgenix**, a treatment for hemophilia B, manufactured by **CSL Behring LLC**.

- Annual increase report highlight: The largest price increase reported to the program in 2022 was a 25 percent increase from $575 to $718.75. This price increase was for a generic drug, **Aquasol A**, a generic vitamin A solution, manufactured by **Casper Pharma**.

- Insurer report highlight: **Humira,** manufactured by **AbbVie Inc**, continues to be the most costly drug, contributing to more plan spending than any other drug for five years running. In 2022, health insurance companies in Oregon reported $75.24 million in spending on **Humira**.

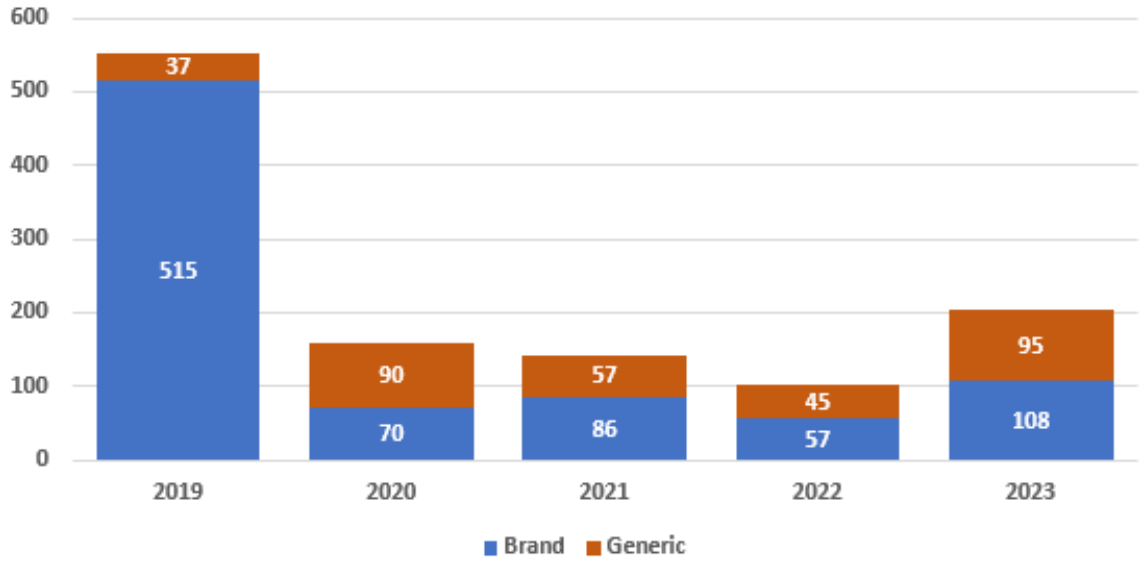
Read the report: https://dfr.oregon.gov/drugtransparency/Documents/20231207-dpt-hearing/Prescription-Drug-Price-Transparency-Annual-Report-2023.pdf

Manufacturer report filings



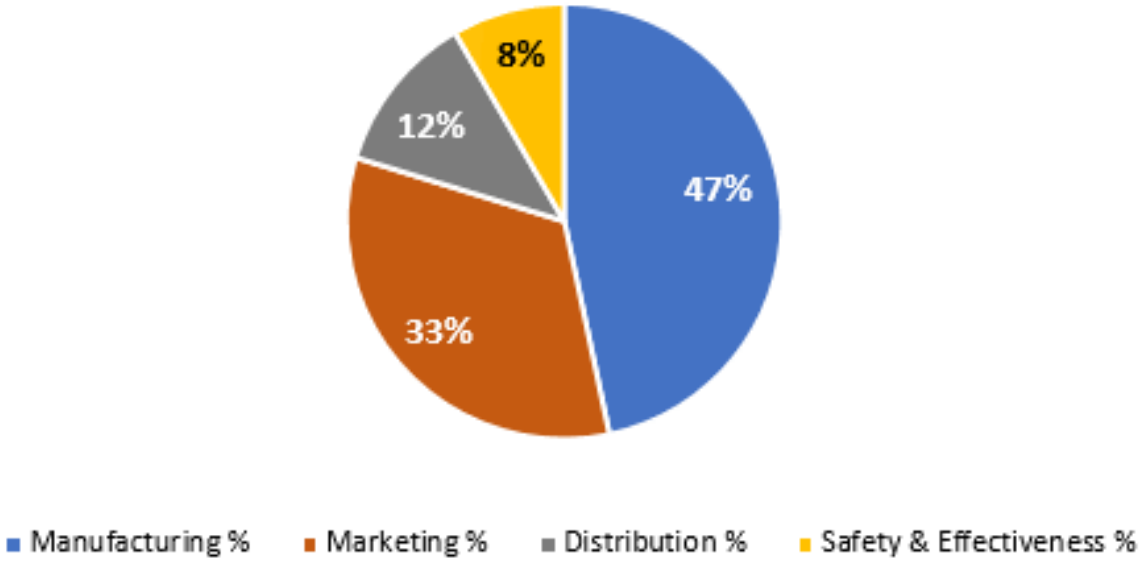
Count of new specialty drug reports each year

Count of annual price increase reports each year



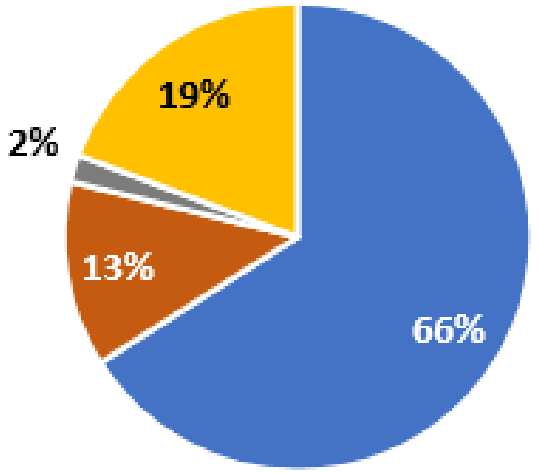
DFR Division of Financial Regulation
Department of Consumer and Business Services

Manufacturer direct cost breakdown



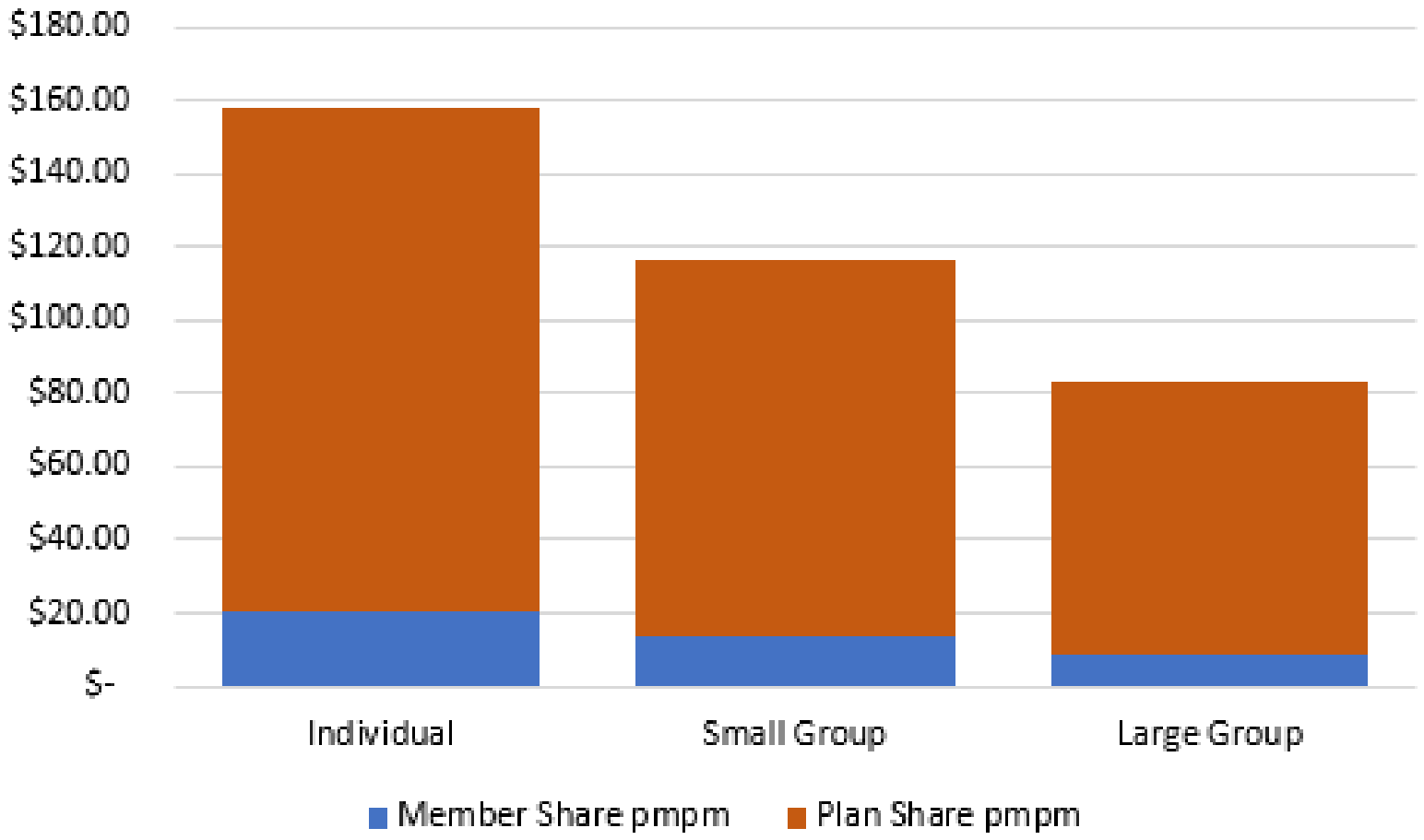
Brand Name Direct Costs

Generic Direct Costs



DFR Division of Financial Regulation
Department of Consumer and Business Services

Plan prescription spending per member per month



- Individual Market:
  - Member share – $20.79
  - Plan share – 136.93
- Small Group Market:
  - Member share – $13.86
  - Plan share – $102.34
- Large Group Market:
  - Member share – $8.38
  - Plan share – $75.10

Most costly prescription drugs

Drug	Class	Total Annual Plan Spending
Brand name: **Humira** Adalimumab	Analgesics – AntiInflamatory	$75,241,110
Brand name: **Stelara** Ustekinumab	Dermatologicals	$28,957,943
Brand name: **Keytruda** Pembrolizumab	Antineoplastics & Adjunctive Therapies	$28,248,898
Brand name: **Biktarvy** Bictegravir-Emtricitabine-Tenofovir Alafenamide Fumarate	Antivirals	$26,988,465
Brand name: **Enbrel** Etanercept	Analgesics – AntiInflamatory	$22,017,823
Brand name: **Trikafta** Elexacaftor-Tezacaftor-Ivacaftor	Respiratory Agents	$21,559,651
Brand name: **Cosentyx** Secukinumab	Dermatologicals	$18,723,855
Brand name: **Entyvio** Vedolizumab	Gastrointestinal Agent	$17,655,131
Brand name: **Inflectra** Infliximab-dyyb	Gastrointestinal Agent	$16,516,923
Brand name: **Skyrizi** Risankizumab-rzaa	Dermatologicals	$15,517,811

Prescription drugs with increased plan spending

Drug	Class	Year-over-Year Increase
Brand name: **Keytruda** Pembrolizumab	Antineoplastics & Adjunctive Therapies	$11,840,653
Brand name: **Skyrizi** Risankizumab-rzaa	Dermatologicals	$8,385,287
Brand name: **Inflectra** Infliximab-dyyb	Gastrointestinal Agents	$5,489,239
Brand name: **Trikafta** Elexacaftor-Tezacaftor-Ivacaftor	Respiratory Agents	$4,417,699
Brand name: **Gammagard** Immune Globulin (Human) IV	Passive Immunizing & Treatment Agents	$4,312,556
Brand name: **Humira** Adalimumab	Analgesics - AntiInflammatory	$3,682,844
Brand name: **Dupixent** Dupilumab	Dermatologicals	$3,333,668
Brand name: **Rybelsus/Ozempic** Semaglutide	Antidiabetics	$3,238,534
Brand name: **Stelara** Ustekinumab	Dermatologicals	$3,077,394
Brand name: **Adcetris** Brentuximab Vedotin	Antineoplastics & Adjunctive Therapies	$3,020,976

2023 public hearing on prescription drug prices

Cost and coverage for weight loss drugs

- These are useful drugs for many patients who struggle with obesity and/or have diabetes.
- How to make sure those who need these expensive drugs can get them. How can we reduce costs.
- How to make sure there is enough supply for all patients regardless of which condition they have.

Watch the hearing: dfr.oregon.gov/drugtransparency/Pages/public-hearings-past.aspx

Consumer impact

- How to make sure PBM formularies include brand name and generics for all approved drugs (for all conditions, not just obesity/diabetes).
- Some are having a hard time getting alternatives or needed medications.
- Those with obesity have seen reduced health care costs and prolonged life because of anti-obesity medications.

DPT policy recommendations

1. **Increase transparency of patient assistance programs:**
   - Only 18 patient assistance programs were reported this year (more than 200 estimated).
   - Require annual reporting on all patient assistance programs, instead of just those with price increases.

2. **Require insurers and PBMs to report on their use of "copay accumulator" programs:**
   - These programs may increase costs for certain consumers.

3. **Transparency across the pharmaceutical supply chain**:
   - Add more of the layers in the supply chain

Read the report: dfr.oregon.gov/drugtransparency/Documents/20231207-dpt-hearing/Prescription-Drug-Price-Transparency-Annual-Report-2023.pdf

DPT policy recommendations continued

4. **Study feasibility of state generic manufacturing and expanded bulk purchasing:**
   - Allow state to leverage bulk purchasing power.
   - Explore uniform drug lists for all state programs and PBM services.
   - Establish centralized office of pharmacy purchasing for coordination and oversight of all state purchasing.
5. **Update reporting thresholds to align 60-day notice and annual increase reporting:**
   - Match the reporting thresholds for these reports to reduce administration issues and increase compliance.

   Read the report: dfr.oregon.gov/drugtransparency/Documents/20231207-dpt-hearing/Prescription-Drug-Price-Transparency-Annual-Report-2023.pdf

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Questions and discussion

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