Oregon Prescription Drug Affordability Board

350 Winter Street NE, Salem, OR 97309-0405 | 971-374-3724 | pdab@dcbs.oregon.gov | dfr.oregon.gov/pdab

Agenda

Date: **July 19, 2023** | *Time*: **9:30 a.m.**
This agenda is subject to change.

Meeting name	**Prescription Drug Affordability Board**
Meeting location	Virtual
Zoom link	Register for the meeting

Board Members: Chair Akil Patterson; Vice Chair Shelley Bailey; Dr. Daniel Hartung; Dr. Richard Bruno; Amy Burns, Robert Judge (A); Dr. Rebecca Spain (A), John Murray (A)

*(A) denotes Alternate Member

Staff: Ralph Magrish, executive director; Cortnee Whitlock, policy analyst; Stephen Kooyman, project manager; Amanda Claycomb, data analyst, Brekke Berg, data analyst, Melissa Stiles, administrative specialist; Jake Gill, counsel; Pramela Reddi, counsel

	Subject	Presenter	Time Allotted
☐	Call to order, roll call, and approval of minutes	Chair Patterson	5 minutes
☐	Executive director's program update	Ralph Magrish	10 minutes
☐	Presentation by: Sustainable Health Care Cost Growth Target Program within the Oregon Health Authority (OHA). Questions from board members	Sarah Bartelmann, program manager	25 minutes
☐	Senate Bill 192 discussion	Ralph Magrish	10 minutes
☐	Board discussion and approval: • Carrier data template draft discussion • Discussion from June 22 PDAB hearing • Affordability review rule approval	Cortnee Whitlock & Amanda Claycomb	30 minutes
☐	Member and staff touch base meetings	Cortnee	15 minutes
☐	Announcements	Staff	5 minutes
☐	Public comment	Chair Patterson	10 minutes
☐	Adjournment	Chair Patterson	2 minutes

Next meeting

Aug. 23, 2023, at 9:30 a.m.

Accessibility

Anyone needing assistance due to a disability can contact Melissa Stiles at least 48 hours ahead of the meeting at pdab@dcbs.oregon.gov or 971-374-3724. advance.

How to submit public comment

Oral testimony

For oral comments, please submit the PDAB Public Comment Form no later than 24 hours before the PDAB meeting. The form is located on the Oregon Prescription Drug Affordability Board website here: https://dfr.oregon.gov/pdab/Pages/public-comment.aspx

Written testimony

For written comments, please submit the PDAB Public Comment Form no later than 72 hours before the PDAB meeting. The form is located on the Oregon Prescription Drug Affordability Board website here: https://dfr.oregon.gov/pdab/Pages/public-comment.aspx Written comments will be posted to the PDAB website.

Open and closed sessions

All board meetings except executive sessions are open to the public. Pursuant to ORS 192.660, executive sessions are closed, with the exception of news media and staff. No final actions will be taken in the executive session. When action is necessary, the board will return to an open session.

Oregon Prescription Drug Affordability Board

Oregon Prescription Drug Affordability Board (PDAB) Meeting
Wednesday, June 21, 2023
Draft Minutes

Chair Akil Patterson called the meeting to order at 9:33 am and asked for the roll call.

Board members present: Chair Akil Patterson, Vice Chair Shelley Bailey, Dr. Amy Burns, Dr. Richard Bruno, Dr. Daniel Hartung, Robert Judge (alternate), Dr. Rebecca Spain (alternate)
Board members absent: John Murray (alternate) excused

Approval of the minutes: Chair Akil Patterson asked if board members had any changes to the May 17, 2023, minutes on Pages 3-5 in the agenda packet: https://dfr.oregon.gov/pdab/Documents/20230621-PDAB-document-package.pdf and there were none. **Dr. Richard Bruno** moved to approve the minutes and **Vice Chair Shelley Bailey** provided a second.

MOTION by Richard Bruno to approve the May 17, 2023 minutes.
Board Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, Shelley Bailey, Akil Patterson
Nay: None.
Motion passed.

Program update: Executive Director Ralph Magrish said staff awarded a contract to PORTAL Harvard, starting work July 1 with technical assistance, data analysis, and visualization. The affordability review rule hearing is scheduled for 11 am, June 22, and is open to the public for providing testimony. In July, the Oregon Health Authority's (OHA) Cost Growth program director will talk to the board about the its findings on pharmacy spending. The board was interested in hearing a presentation about the Secretary of State audit. However, the audit is on hold due to recent leadership changes. For the August meeting, staff invited Sen. Ron Wyden, chairman of the United States Senate Committee on Finance, to speak about his work on prescription drug affordability. If Sen. Wyden is unavailable, the board may postpone presentations to begin work on affordability reviews.

Jane Horvath, of Horvath Health Policy, who is on contract with the Prescription Drug Affordability Board, updated the board about the new Medicare negotiation law from Pages 6-11 in the agenda packet. The law is focused on drugs that do not have competition from generics. Drugs approved as an orphan to treat a rare disease are exempt from negotiation. She anticipates seeing higher launch prices and fewer price increases partly because there are substantial penalties if the drug price increases faster than inflation. If the new Medicare law stands, manufacturers may adjust their life cycle management, how they price and market the drug through its patent life. Companies will learn how to maximize profits within the context of this law, possibly creating competitors to avoid price negotiations. It is important to think of the Medicare law in terms of everything else going on in the market. She gave the example of the three leading insulin manufacturers dramatically lowering prices. Lilly is creating its own distribution channels for getting this low-cost product to consumers. She said a biosimilar for Humira announced it will come to market in July priced at $995 for a two-vial pack, compared to Humira pricing of $7,000 for the same quantity. She summarized the lawsuits filed by Merck, Bristol Myers Squibb, and the U.S. Chambers of Commerce over the new Medicare negotiations law for the reasons listed on Page 10 of the agenda packet.

Dr. Becca Spain said if launch prices turn out to be higher, it will be counter intuitive to the goal of the Medicare law. Jane Horvath agreed and said manufacturers will not be able to have price increases as freely as they have been, so may look for profit in the launch price. **Robert Judge** asked where is CMS in this process. Jane Horvath said the federal government has issued initial guidance. This has been an expedited process. **Robert Judge** asked if there was any guidance about how that point of sale price is utilized, whether it is a rebate to the consumer, or rebate used by plans to underwrite cost of Medicare. Jane Horvath said it gets to the point of service. Part D will be different, thought she is not sure how they will administer it. **Shelley Bailey** asked about Lilly's alternative distribution models. Jane Horvath said she thinks it is similar to Civica's, with brick and mortar pharmacies around the country agreeing to abide by Lilly's rules and agreed-upon prices.

Legislative Update: Jesse O'Brien, policy manager for the Division of Financial Regulation, said Senate Bill 192 passed the Senate on June 19 and was scheduled for a public hearing in the House Committee on Rules on June 21. He said House Bill 3013, which would regulate PBMs, has passed the House and is in the Ways and Means Committee. **Vice Chair Shelley Bailey** asked about the minimum payment threshold and Jesse said options include Medicare. **Robert Judge** asked if DCBS would go through rulemaking if the bill passes and Jesse said yes, it would likely result in changes to existing rules.

Allison Hardt, advocacy manager for T1International, discussed the high cost of insulin medications and supplies for people who live with Type 1 diabetes. Her presentation is shown on Pages 12-33 of the agenda packet. Insulin is the poster child for what is wrong with the prescription drug system, she said. With Type 1 diabetes, the pancreas does not produce insulin, which is vital to survival. Therefore, patients must administer insulin themselves. Without the right balance, a patient could end up in the emergency room, become very ill, or die. Many people ration insulin because they cannot afford it or do not have access, she said. Pens, pumps, test strips, and other supplies are expensive too. Because everyone processes insulin brands differently, she recommends the board consider all insulins in its affordability reviews. The cost of insulin has increased over 1,200 percent yet the cost of production remains a low $3.69-$6.16 per vial. She said one in four people in the U.S. have had to ration insulin due to cost. Regarding Lilly's recent announcement to cut insulin prices, so far, patients have been unable to find the $25 Lispro in pharmacies, she said. Allison discussed the following solutions:

- Co-pay caps. 26 states have passed them, but they only help patients with insurance.
- Kevin's Law, which allows pharmacist to prescribe limited amounts of insulin in emergencies. In Oregon, Kevin's law does not require insurance to pay the list price but it should, she said.
- Alec's Law, which allows a short-term, 30-day supply for a co-pay of $35, once a year.
- Array RX, a month's worth of insulin is available for $88.
- The federal government could establish a co-pay cap regardless of insurance.
- States could consider manufacturing insulin, similar to California's partnership with Civica.
- States or the federal government could allow pharmacists to prescribe insulin.

Robert Judge said the presentation resonates with him. The supply chain is the issue, not only with the manufacturer, but all the way up to where the patient gets the medication, he said. He advocates for a partnership with Civica, Mark Cuban's pharmacy, or something similar. He said the current insulin situation is indefensible for the impact it has on patients. **Chair Patterson** asked about the emotional impact of needing insulin in a life-saving situation. Allison Hardt said diabetes requires 24/7 management and when additional stress such as financial is added, it impacts blood sugar, which requires more insulin She said there are networks where people help others get connected. **Dr. Richard Bruno** thanked Allison for helping the board understand the challenges and for her advocacy work. He let her know the board is working on affordability reviews for nine drugs and one insulin product.

Data call template for carriers: **Ralph Magrish, executive director, and Stephen Kooyman, project manager,** discussed the draft data call template for insurance carriers on Pages 34-42 of the agenda packets. The intention of the draft data call is to collect information not captured in the annual insurer submissions to the Drug Price Transparency program. The collected information will be presented as aggregated and will not identify individual plans. Staff will not present confidential data to the board in executive session, which are open to the media, to avoid risk of exposing confidential data. Ralph Magrish said data from the claim status page will help the PDAB team check for trends with the rate at which claims are denied for particular drugs, a possible indicator of patient access issues. For the rebates tab, staff is still determining how to best calculate average discounts and rebates expressed as a percentage of the price for the prescription drug under review. Because of the benefit of feeder information from the Drug Price Transparency Program, staff will be able to provide the board with a consolidated list of approximately 20 drugs and an insulin product for review and selection, he said. He reviewed the challenges of collecting pricing for therapeutic alternatives for drugs sold in Oregon, as shown on Page 41. He asked for board member feedback.

Robert Judge asked when considering therapeutic alternatives, could the first step be looking at the Medispan drug reference to identify a drug class and Ralph Magrish said yes. **Shelley Bailey** said for the therapeutic class reviews, she recommended MedSavvy, a subsidiary of Cambia Health Systems in Portland. She asked about adding a prior authorization column on the claims status tab to provide more information. **Dr. Amy Burns** said the column asking about denied claims overturned upon appeal would provide information because there would only be an appeal with prior authorization. However, she said it would be easy to add a column for prior authorization. For therapeutic alternatives, she recommended the board tap the expertise of OHA's Drug Use Research Management (DURM) group and Pharmacy and Therapeutics (P&T) Committee. For its review, the board could look at the therapeutic alternatives within the state's preferred drug list. Ralph Magrish said he was thinking similarly but unsure of the PDAB's ability to engage the P &T Committee or their staff for assistance. He suggested staff could look at drugs by therapeutic class and the Medicaid fee-for-service preferred drug list and potentially do a pricing exercise based on the Oregon Average Acquisition Cost (AAC) or the National Average Drug Acquisition Cost (NADAC), . He reviewed the timeline on Page 42 and said board members may email additional feedback to staff. Staff will bring a revised template to the board for approval next month.

Announcements: Cortnee Whitlock, board policy analyst, discussed the board roadmap for the remainder of 2023 from Page 43 of the agenda packet.

Public comment: The chair allocated three minutes for public comment. Dharia McGrew, state policy director, PhRMA, provided testimony to the board. PhRMA's written comments are posted online: https://dfr.oregon.gov/pdab/Documents/20230621-PDAB-public-comment.pdf.

Adjournment: The meeting was adjourned at 11:23 a.m. by **Chair Akil Patterson**, with a motion by **Robert Judge** and a second by **Richard Bruno**.

Oregon Prescription Drug
Affordability Board

Email: pdab@dcbs.oregon.gov Phone: 971-374-3724 Website: dfr.oregon.gov/pdab

Date: July 13, 2023

To: Senate President Rob Wagner
Senate Health Care Committee Chair, Deb Patterson
Senate Health Care Committee Vice-Chair, Cedric Hayden
House Speaker Dan Rayfield
House Health Care Committee Chair, Rob Nosse
House Health Care Committee Vice-Chair, Christine Goodwin
House Health Care Committee Vice-Chair, Travis Nelson

Re: Prescription Drug Affordability Board (PDAB) Update and Deliverable Extension Request

Honorable senators and representatives,

The Prescription Drug Affordability Board (PDAB) was tasked under Senate Bill 844 (2021) to identify nine drugs and one insulin product that create affordability challenges for Oregonians. We are writing to request an extension to the legislature of the drug affordability review and report findings that need to be submitted in December of 2023. A combination of staffing challenges, significant market changes this year, and a heightened need for data validation, led the PDAB staff, the board, and industry stakeholders to conclude that additional time would yield substantially higher quality data and analysis.

The PDAB is requesting an additional extension until **no later than June 30, 2024** with a commitment to make a best effort to submit prior to that date. The additional time being requested is to ensure that the data provided to the Drug Price Transparency (DPT) program by insurance carriers and drug manufacturers as required under ORS 646A.689 and 743.025 has been given the required depth and breadth of analysis and that appropriate decisions are made to identify unaffordable prescription drugs.

Contributing Factors

Staffing As discussed, the DPT program at DCBS is to provide PDAB quarterly reports of data they receive from drug manufacturers and insurance carriers. Due to delays in hiring and a lack of qualified applicants during a previous failed recruitment effort, the DPT program had gone without a data analyst from September of 2022 until June 2023. Similarly after several attempts at staffing the data and research arm of PDAB staff, that staff only joined us in April and May. With a steep learning curve and no prior experience in drug pricing data, the team has been challenged to provide meaningful analysis of carrier data submissions. As they have begun working with carriers on correcting data submissions or in some cases, needing to return them for incomplete submissions, substantial progress is being made to provide meaningful and defendable data to the board for decision making. This has included outreach and technical assistance for carriers to correctly submit all information. The depth of the data quality issues would demonstrate a sizable impact to the data's accuracy if this was not addressed. In context of risk and

exposure to the state, we have serious concerns about proceeding without taking the necessary time to fully vet and address data quality issues as it is the feeder for affordability reviews.

Delay in Contracting for Technical Assistance The PDAB is entering into a contract with the Program on Regulation, Therapeutics and Law (PORTAL) at the Harvard University medical school to provide technical assistance on both drug selection and the reviews themselves. We anticipated contracting in June, however a delay in execution of the contract has delayed their start of work into mid-July. As such, we have lacked the benefit of their technical assistance and clinical expertise which we anticipate ramping up in July into August. Attempting to proceed on a timeline to complete our work by the end of 2023 to review no fewer than 46 individual data points in drug selection without the benefit of their front-end assistance, furthers the risk that we do not complete these exercises with the quality and depth necessary.

Significant Changes In Insulin & Insulin-like Pricing As you are likely aware, there have been significant changes have occurred in the insulin market in 2023 as a result of government actions and market forces over the last six months. This shift requires additional analysis to inform selection and decisions based on the current market landscape.

The extended time will allow the new staff the opportunity to provide the depth of analysis needed with the benefit of world class technical assistance in order for PDAB to review and make thoughtful, appropriate, and defendable recommendations for unaffordable prescription drugs to the legislature. We assure you, we are dedicated to our work, and our ultimate goal remains the same: to improve the healthcare landscape in Oregon and ensure the best possible health outcomes for all residents. By granting us this additional time, you are not only enabling us to ensure the accuracy and thoroughness of our findings but also affirming the State of Oregon's commitment to prioritizing the welfare and wellbeing of its citizens.

Sincerely,

Ralph Magrish
Executive Director, Oregon PDAB

Akil Patterson
PDAB Chairperson

CC: Andrew Stolfi, Theresa Van Winkle, TK Keen,
Alex Cheng, Pramela Reddi, Rachel Currans-Henry

Updated affordability review timeline for the board

- ❑ Members meet individually with staff about prescription drug reviews: **July 20-Nov. 27**
- ❑ Affordability review rule takes effect: **Aug. 1**
- ❑ Begin reviewing 2022 prescription drug data: **Aug. 23**
- ❑ Continue reviewing 2022 prescription drug data and insulin product: **Sept. 20**
- ❑ Continue review drug data and begin to provide recommendations for annual report: **Oct. 18**
- ❑ Continue review of nine drugs and one insulin product. Review consolidated insurer data from data calls, and provide recommendations: **Nov. 15**
- ❑ Testimony opportunity from patients, caregivers, and medical professionals. Select nine drugs, one insulin product, and approve recommendation report to Legislature: **Dec. 13**
- ❑ Study nine drugs and one insulin product: **January 2024**
- ❑ Approve draft report: **February 2024**
- ❑ Approve final report: **March 2024**

Pharmacy Spending Trends in Oregon, 2018-2021

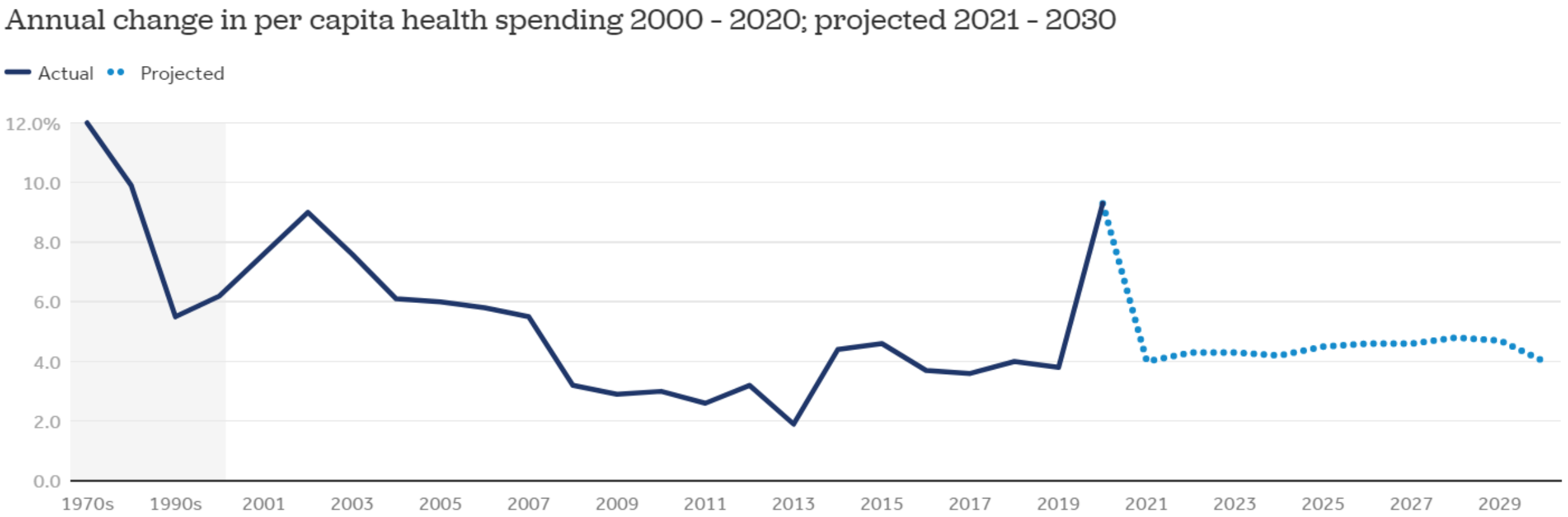
Sarah Bartelmann
Cost Growth Target Program Manager

Oregon Health Authority

HEALTH CARE COST GROWTH TARGET

Background

Nationally, health care cost growth is projected at about 5% per year



Grey region represents average growth within decade.

Source: KFF analysis of National Health Expenditure Accounts (NHEA) • Get the data • PNG

Peterson-KFF
Health System Tracker

Oregon's cost growth target says that total health care spending should not grow more than 3.4% each year.

Measure

Measure performance relative to the cost growth target

Analyze

Analyze spending to understand cost trends and cost growth drivers

Report

Publish performance against the target and analysis of cost growth drivers

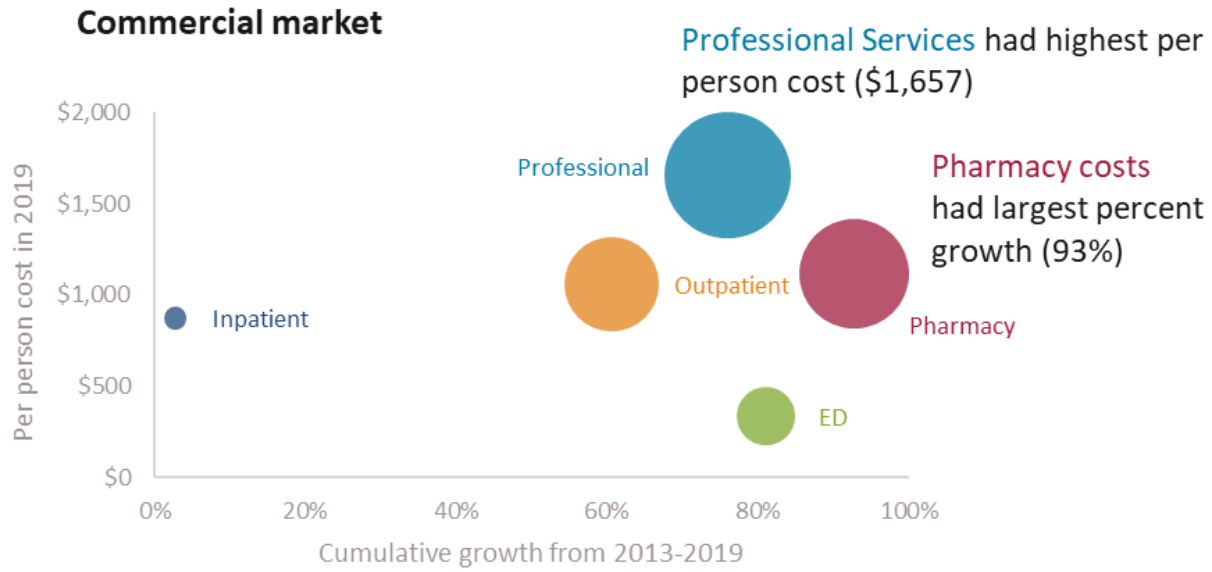
Identify

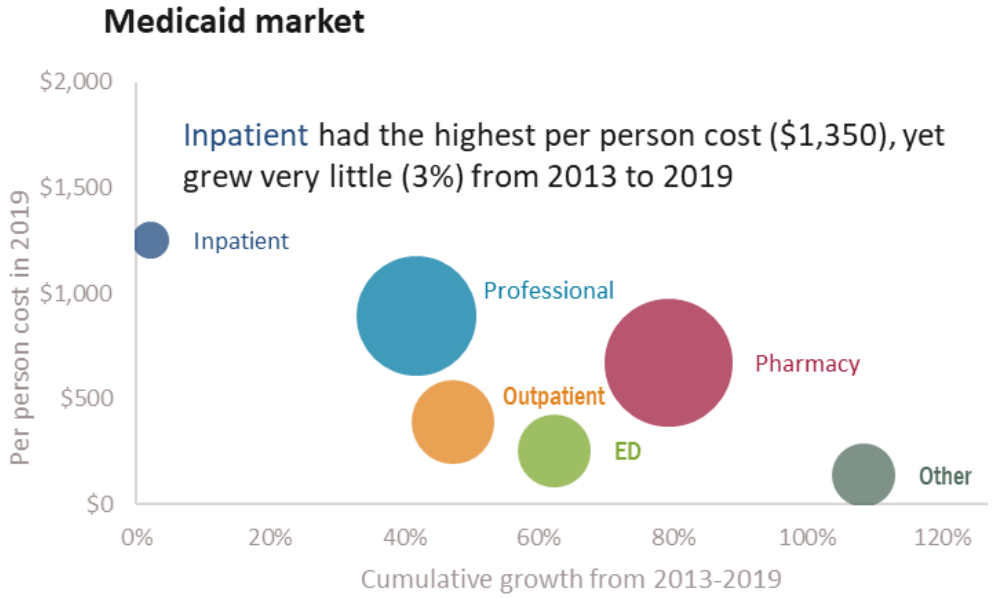
Identify opportunities and strategies to slow cost growth

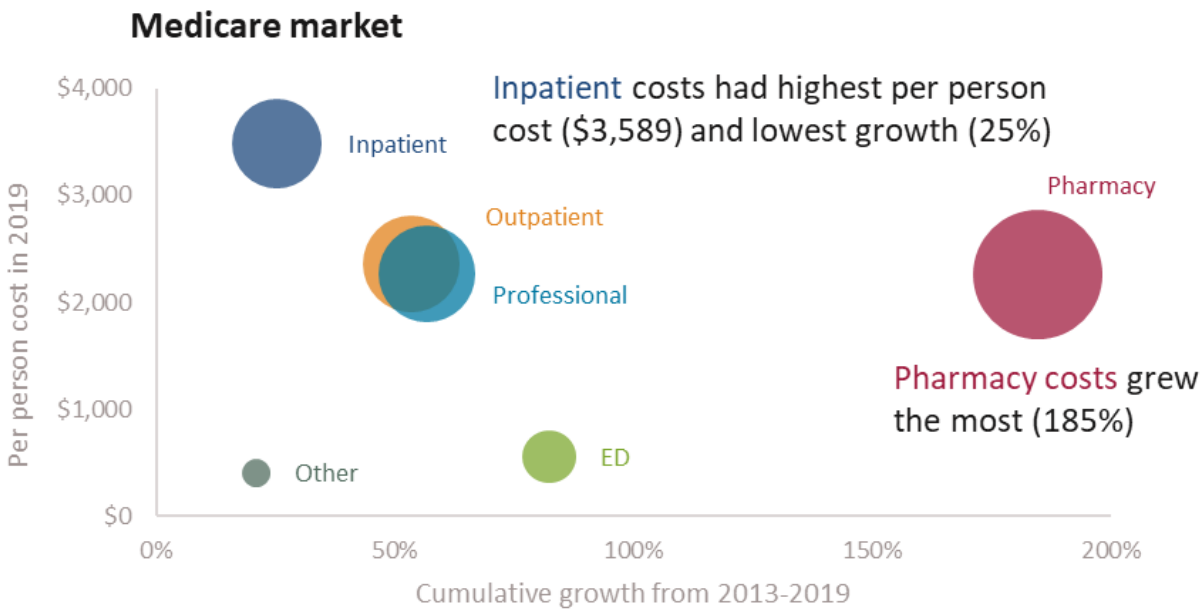
Implement

Implement strategies to slow cost growth

Pharmacy costs were a main driver of Oregon cost growth between 2013 - 2019, in all 3 markets

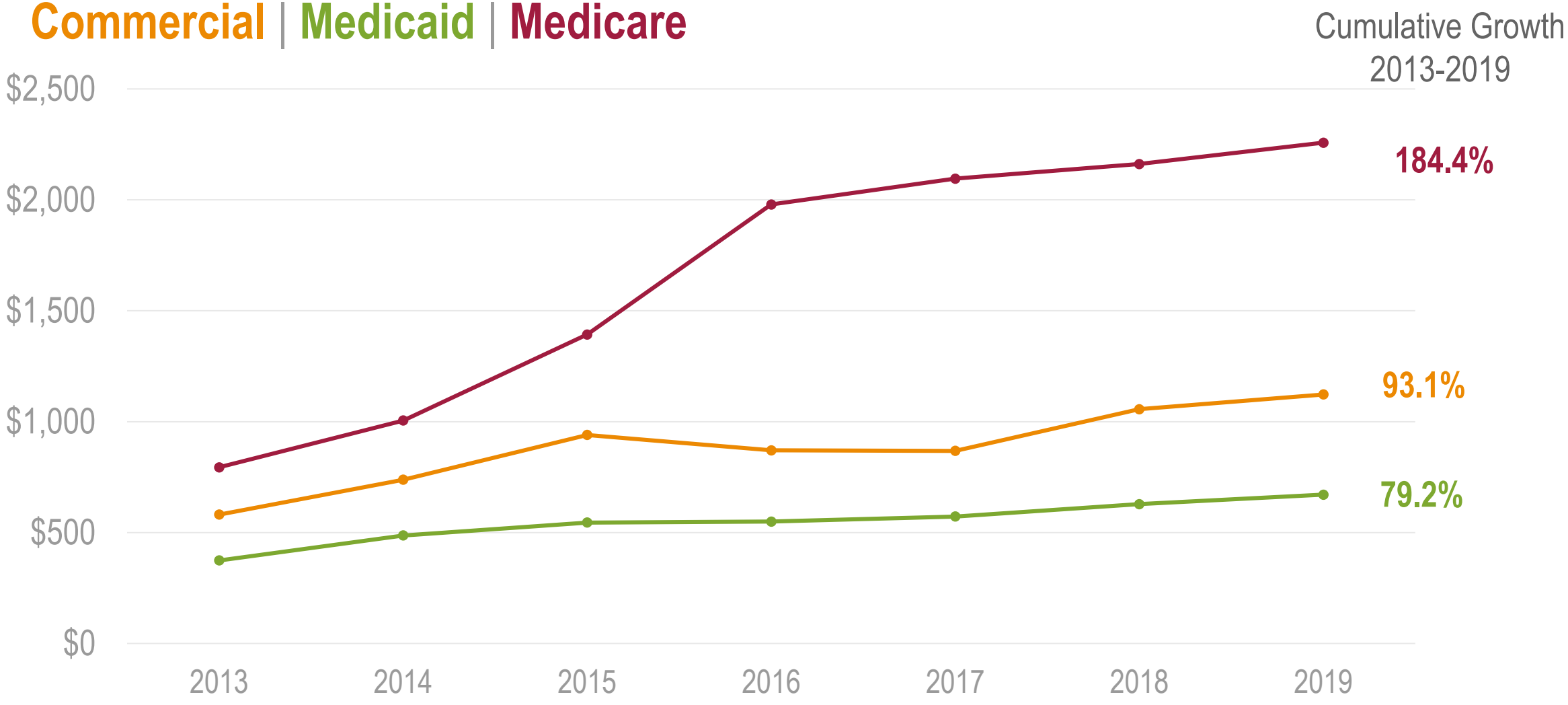






Pharmacy Service Category: Per Person Costs & Percent Growth

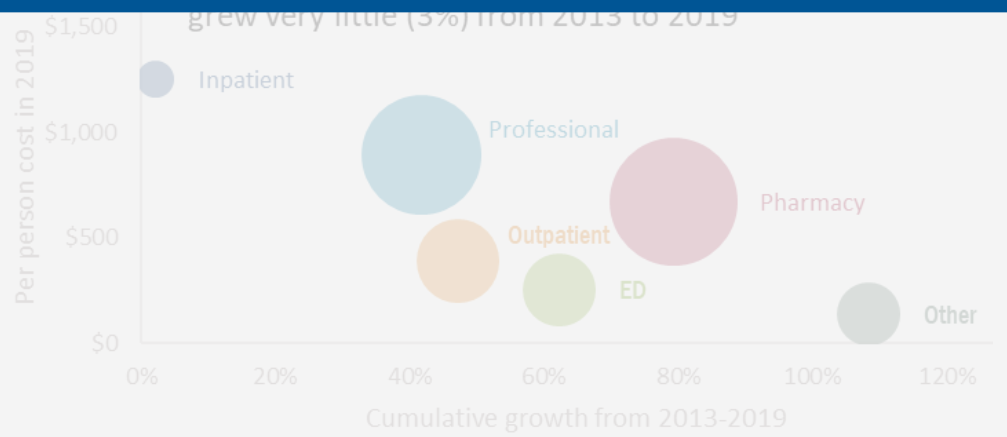
Commercial | Medicaid | Medicare

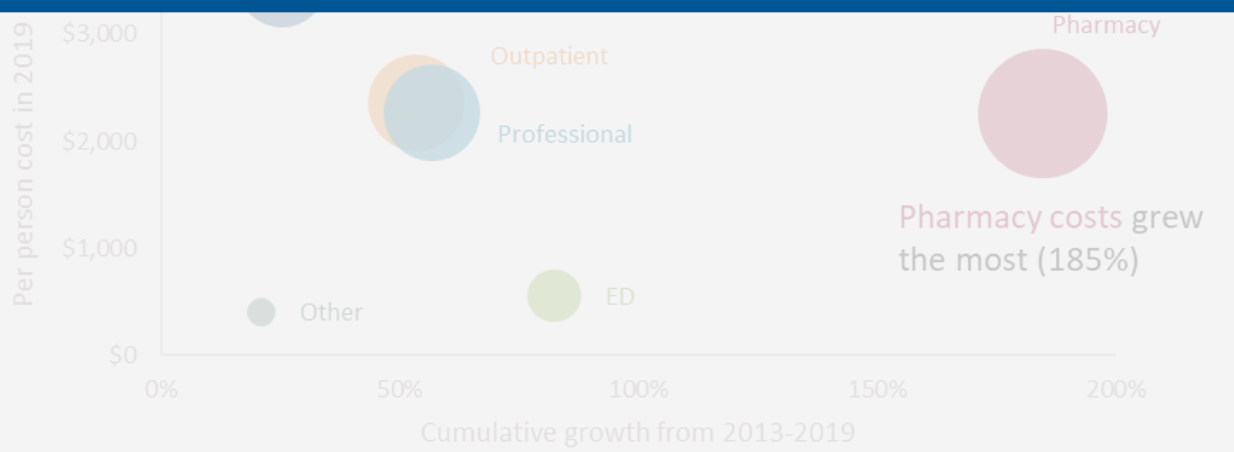


Updated, APAC Release 9 (June 2022). Values slightly different from Cost Trends Report, which used Release 7.

Pharmacy costs were a main driver of Oregon cost growth between 2013 - 2019, in all 3 markets

However,… that analysis did not include pharmacy rebates

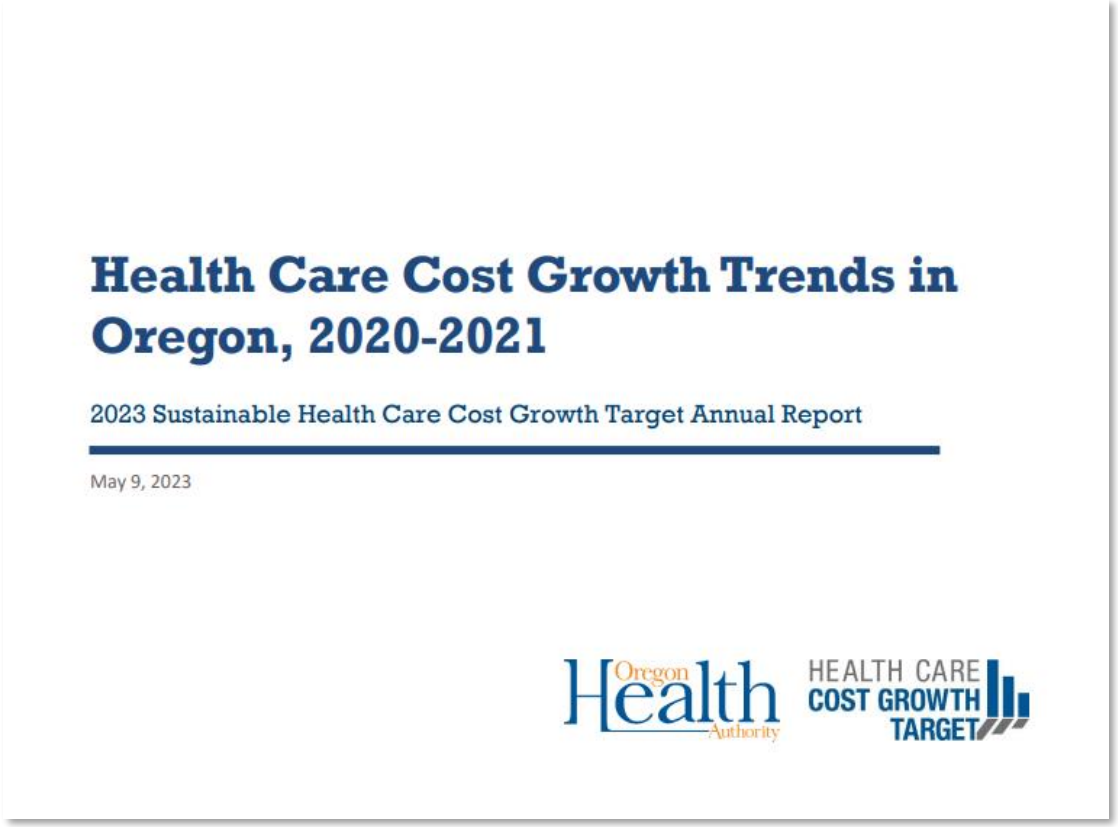




2022 Annual Report

Published May 2, 2023

2023 Annual Report

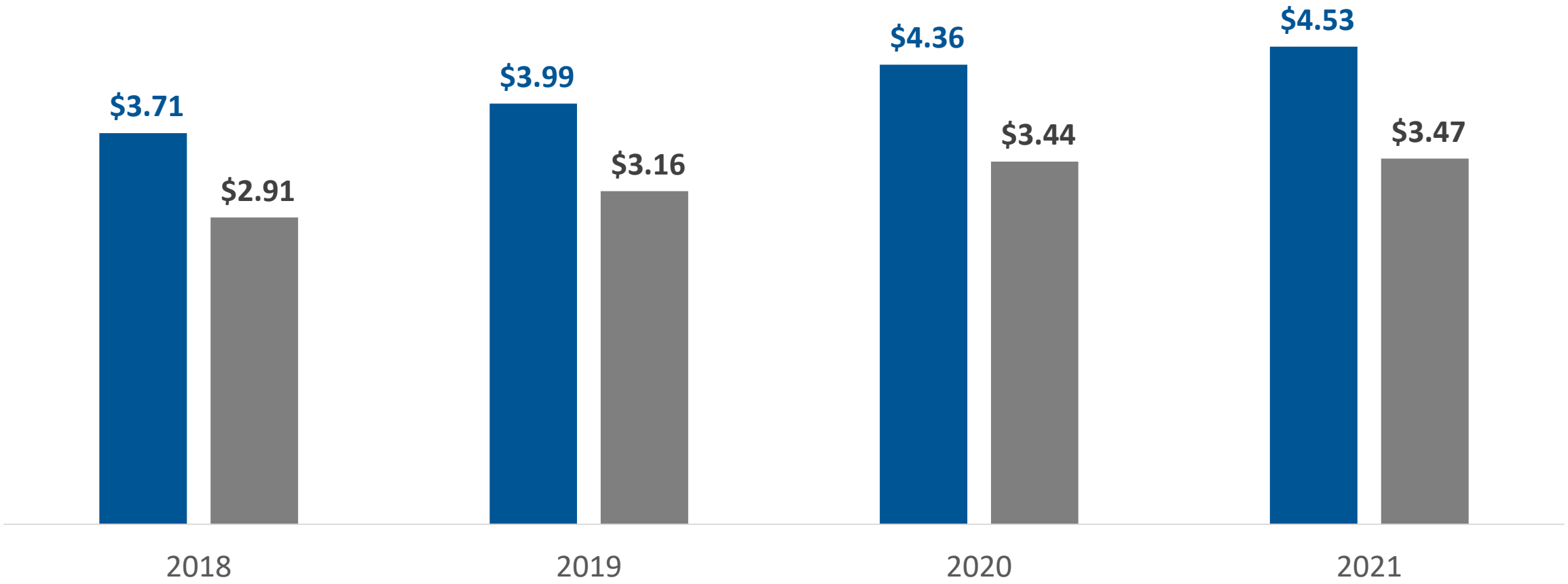


Published May 9, 2023

https://www.oregon.gov/oha/HPA/HP/Pages/cost-growth-target-reports.aspx

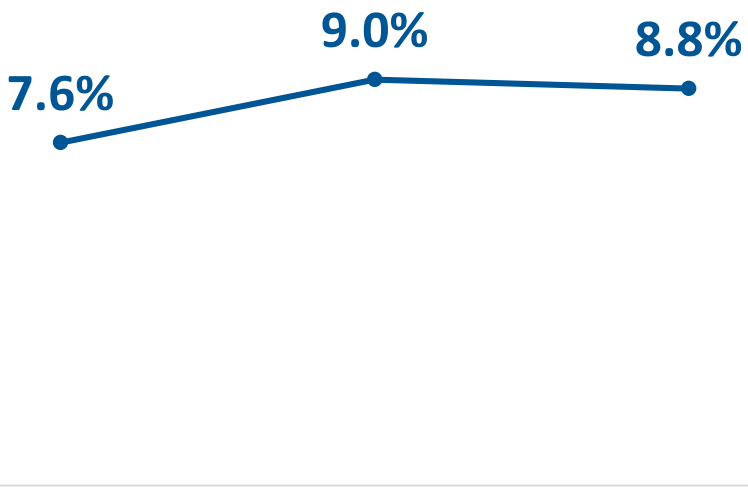
Retail Pharmacy Spending Trends

Total claims spending on retail pharmacy in Oregon, in billions
Gross *and* ***net*** *of pharmacy rebates*

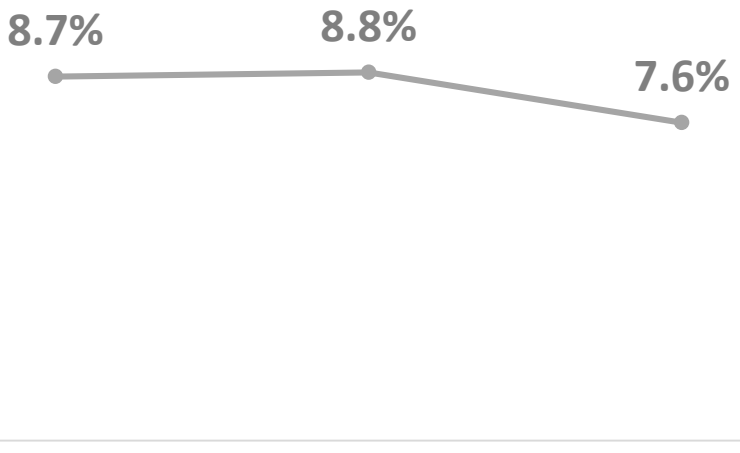


Claims spending on retail pharmacy has increased every year between 2018-2021

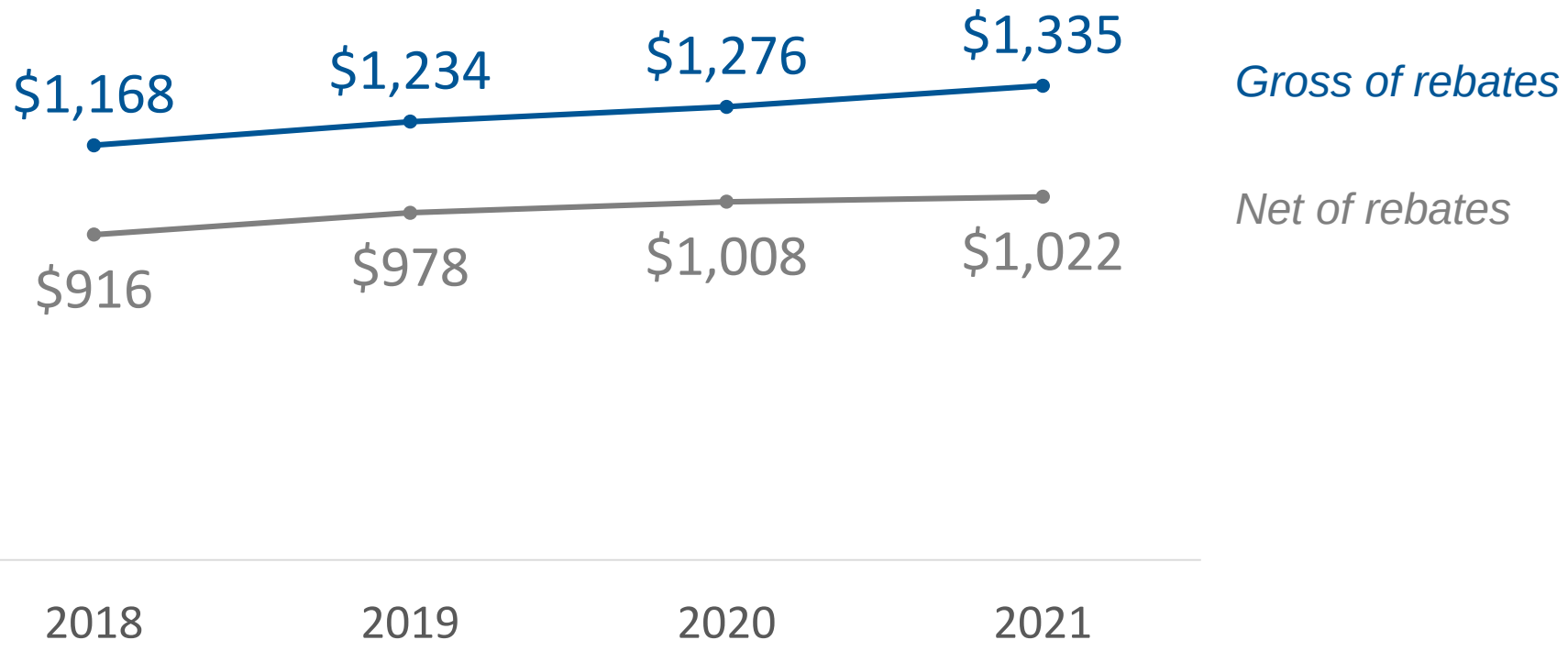
Increase in claims spending on retail pharmacy in Oregon, 2018-2021
Gross of pharmacy rebates



Increase in claims spending on retail pharmacy in Oregon, 2018-2021
Net of pharmacy rebates

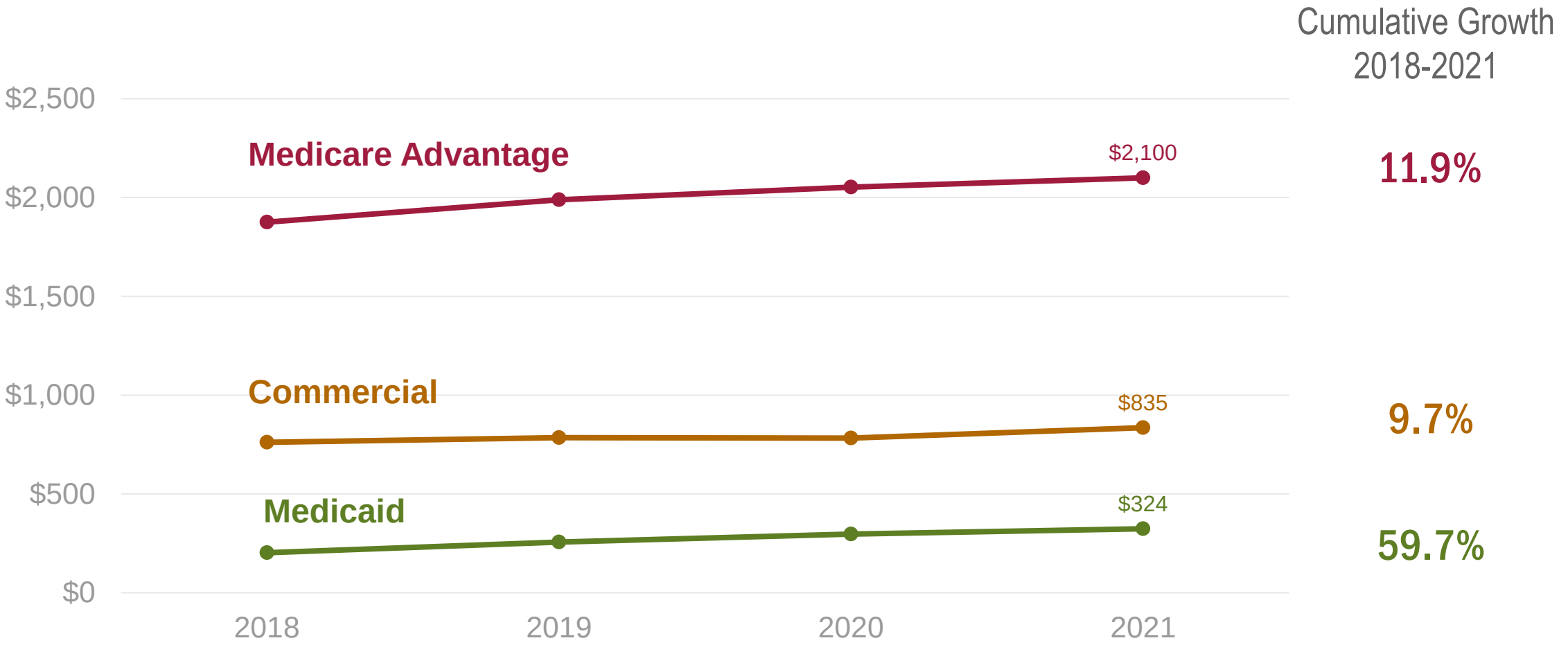


Claims spending on retail pharmacy, statewide, per person per year

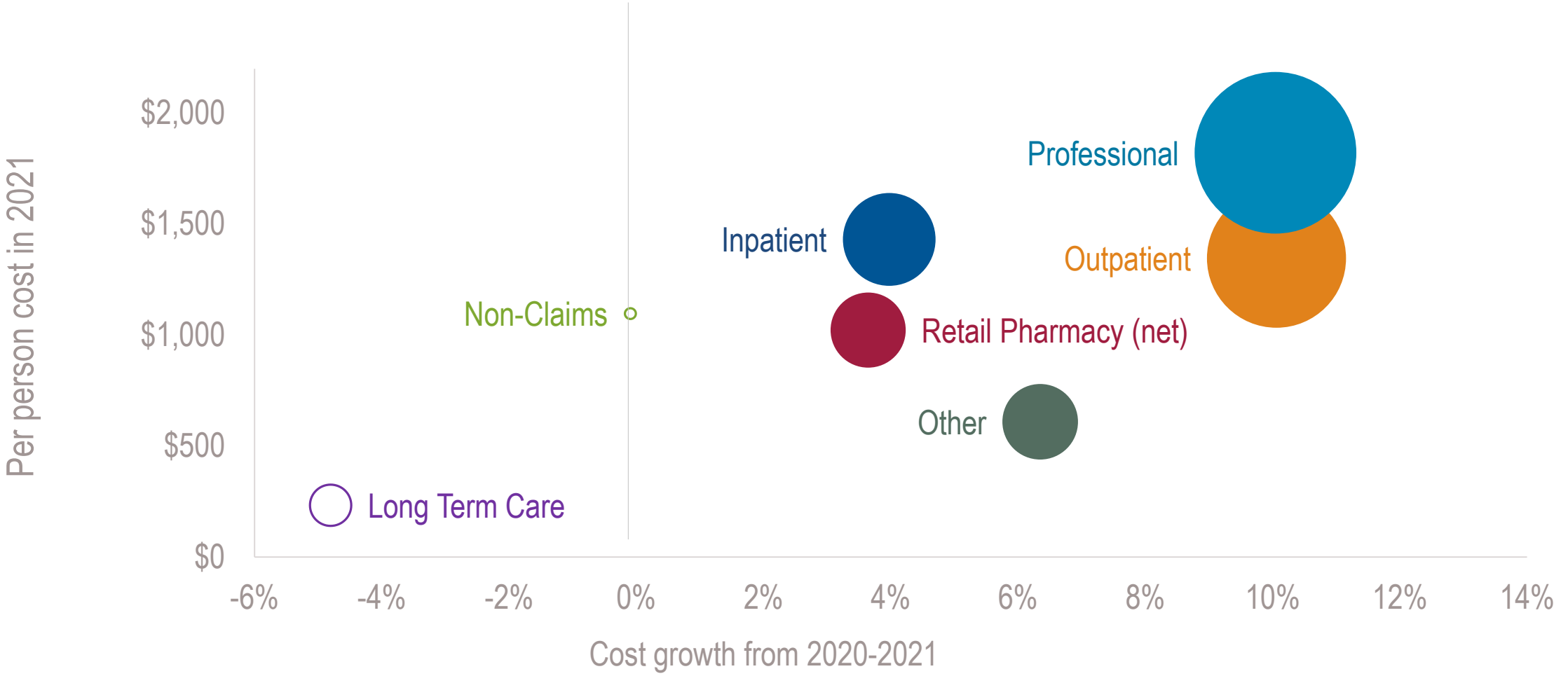


Since 2018, per person per year spending on retail pharmacy has increased 11.6% (net of rebates)

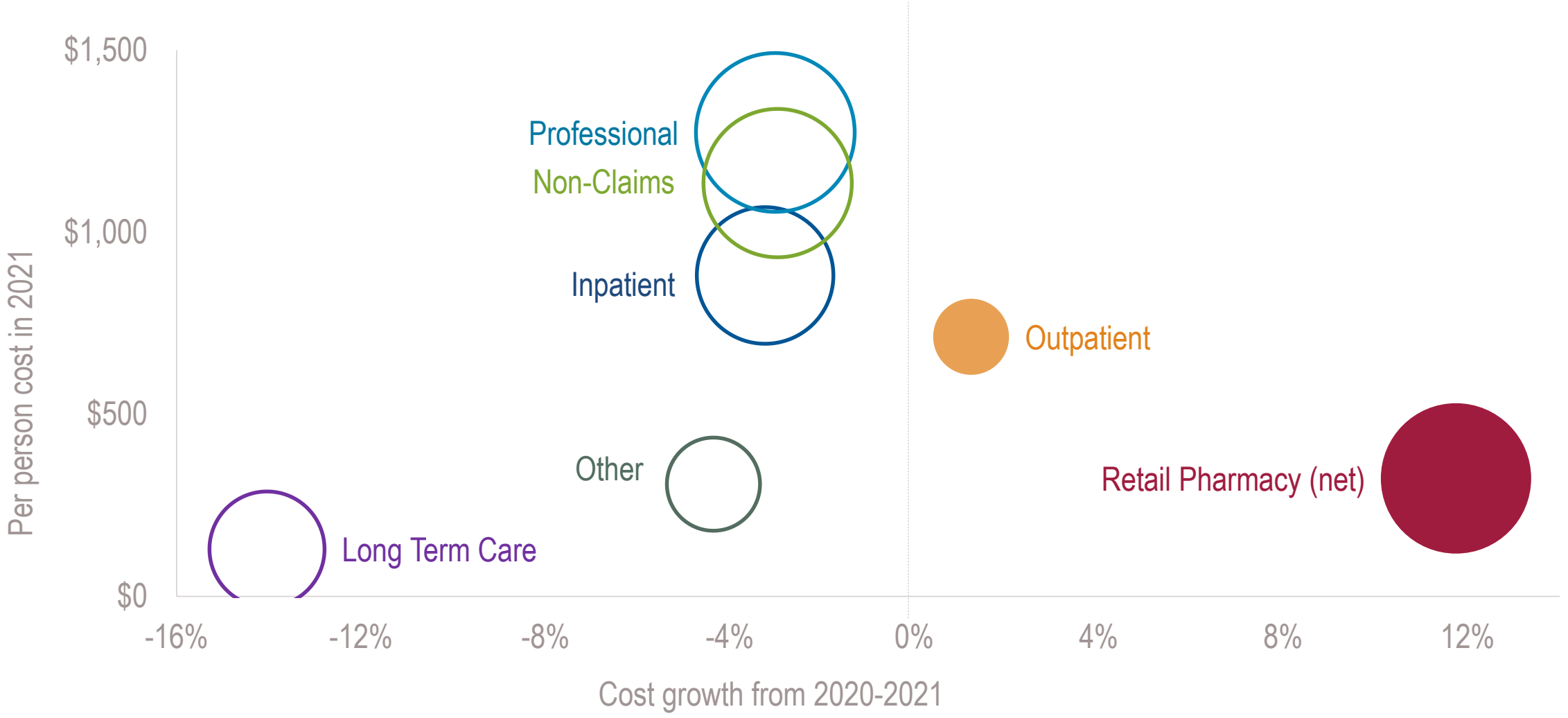
Retail pharmacy (net of rebates) spending trends per person per year, by market



Statewide, retail pharmacy (net of rebates) was not the largest driver of cost growth between 2020-2021



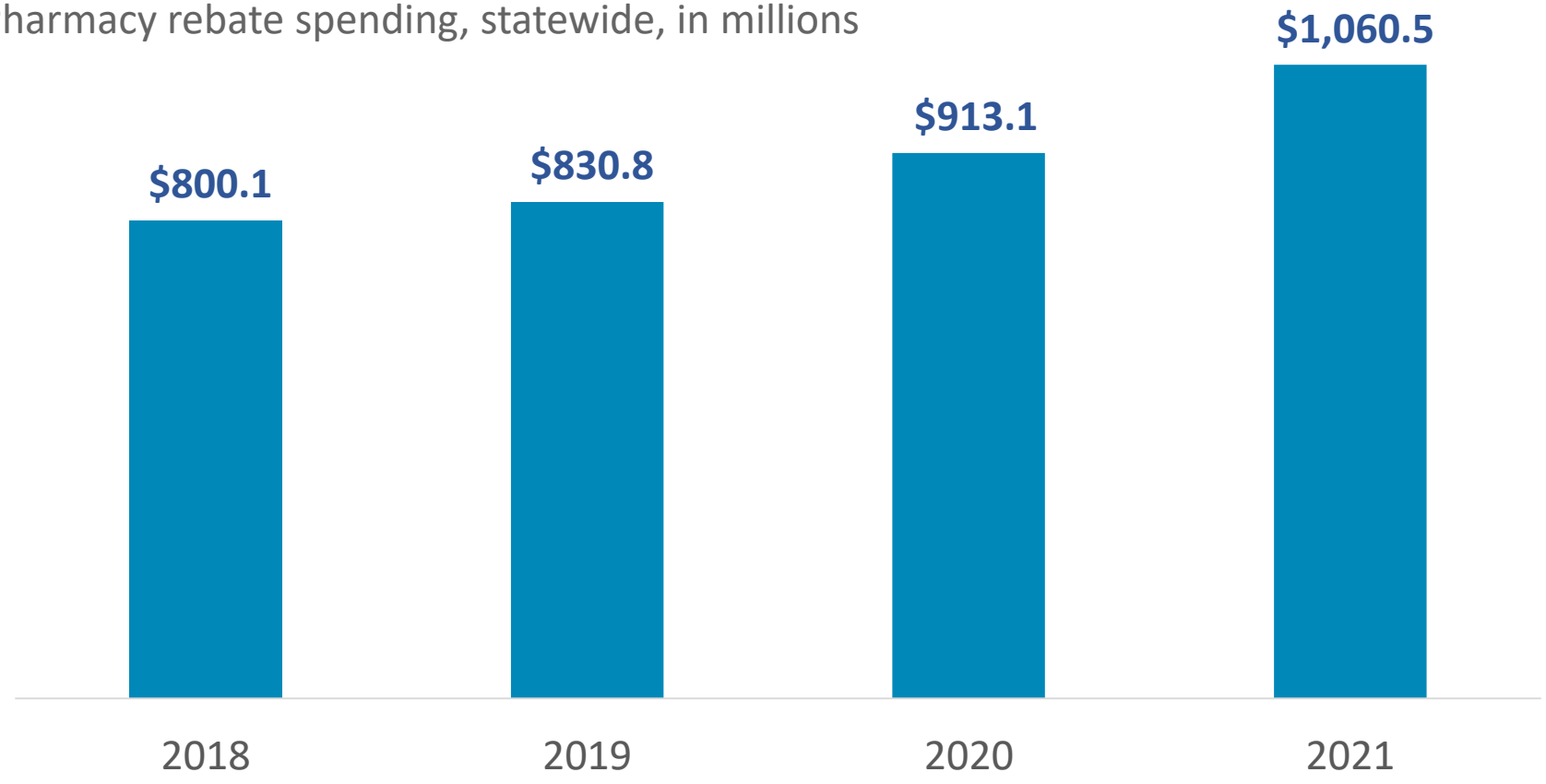
However, retail pharmacy (net of rebates) *was* a major contributor to cost growth in the Medicaid market



Pharmacy Rebates

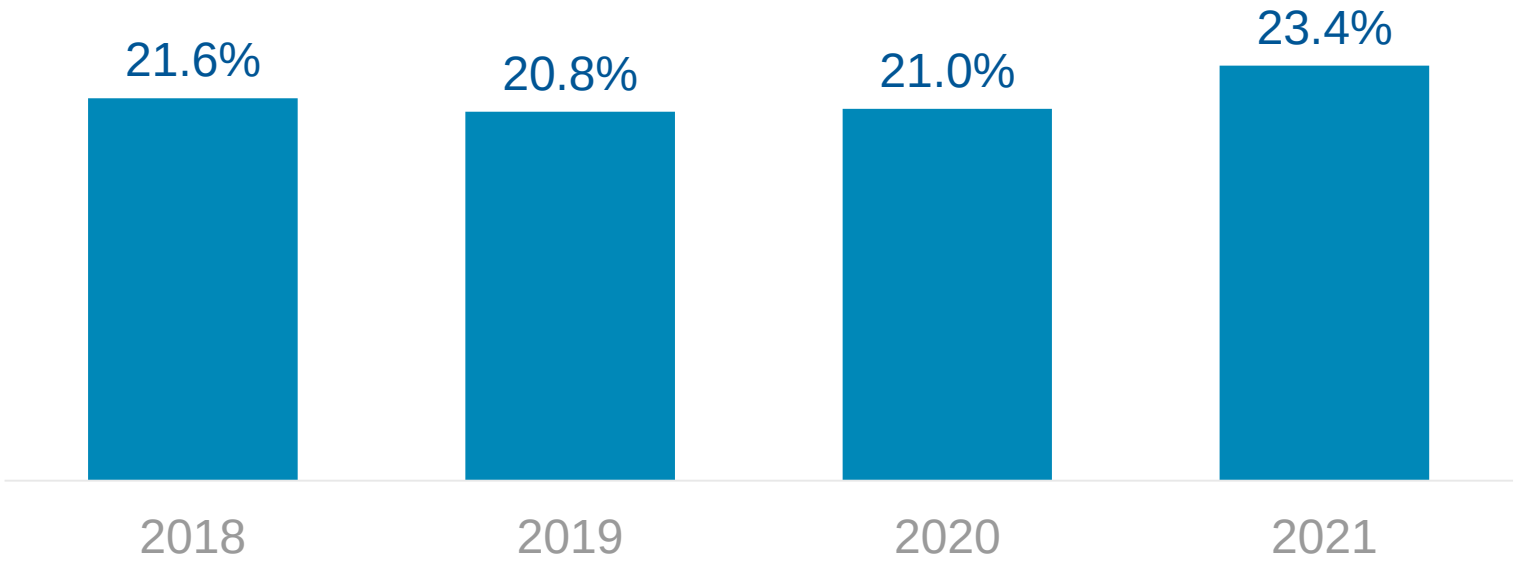
In 2021, Oregon received more than a billion dollars in pharmacy rebates

Pharmacy rebate spending, statewide, in millions



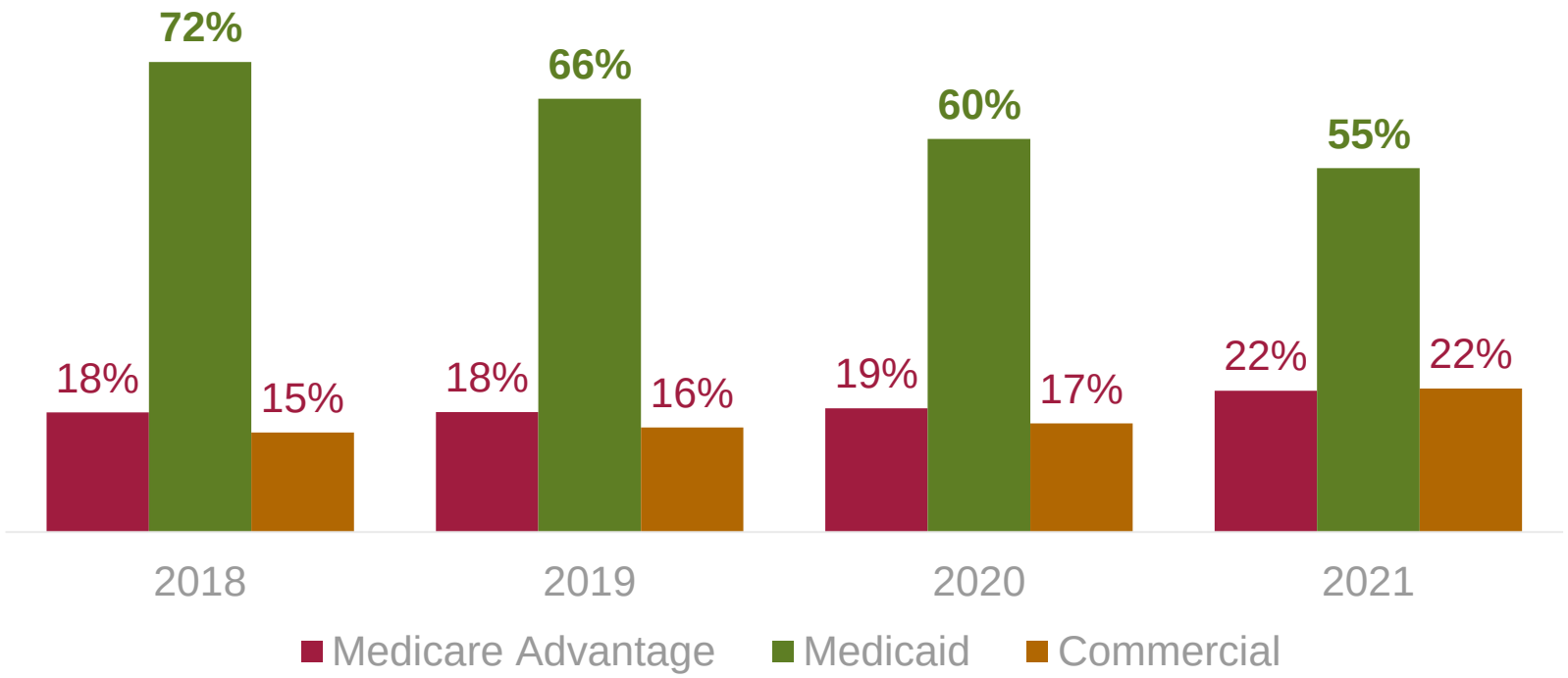
Statewide, more than a fifth of spending for retail pharmacy was returned to payers and PBMs through rebates each year

Pharmacy rebates as a percent of gross retail pharmacy spending, 2018-2021

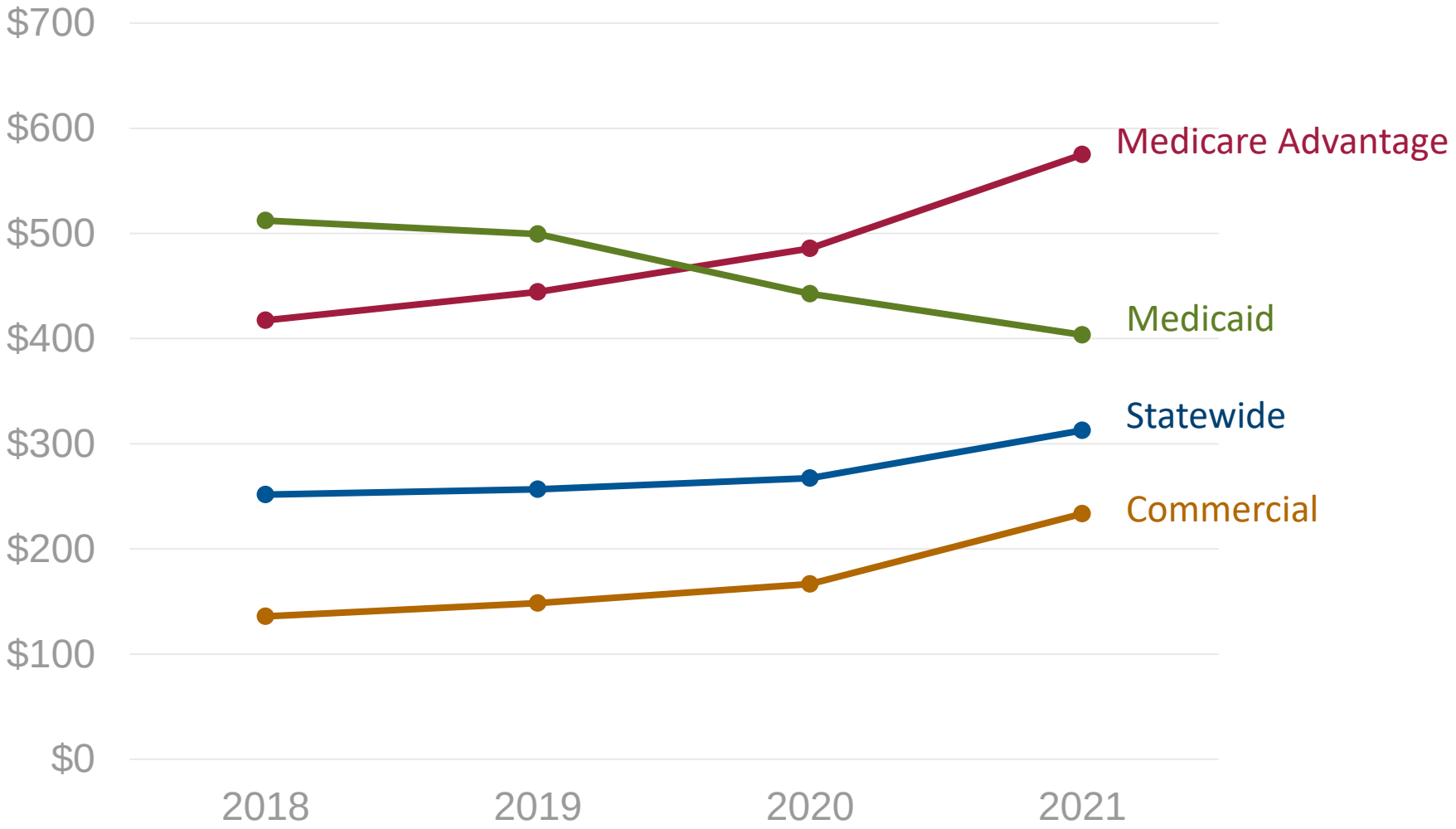


Most of the rebates are recouped by Medicaid, due to federal and state policies

Pharmacy rebates as a percent of gross retail pharmacy spending, by market
2018-2021



Pharmacy rebates, per person per year, by market



Questions?

For More Information

Cost Growth Target Advisory Committee

https://www.oregon.gov/oha/HPA/HP/Pages/cost-growth-target-advisory-committee.aspx

Cost Growth Target Reports

https://www.oregon.gov/oha/HPA/HP/Pages/cost-growth-target-reports.aspx

Contact Us:

HealthCare.CostTarget@oha.Oregon.gov

Oregon Health Authority

HEALTH CARE COST GROWTH TARGET

Oregon Health Authority | HEALTH CARE COST GROWTH TARGET

Save the Dates!

Oregon's 2023 health care cost growth target public hearings

May 17th

Part 1 – Health care cost trends in Oregon 2020-2021

9 AM – Noon | Virtual

Sept 14th

Part 2 – Perspectives on 2020-2021 cost growth trends

9 AM – Noon | TBD

For more information visit
https://www.oregon.gov/oha/HPA/HP/Pages/cost-growth-target-public-hearings.aspx

Oregon Prescription Drug
Affordability Board

Senate Bill 192

Ralph Magrish, executive director
Oregon Prescription Drug Affordability Board
& Drug Price Transparency Program

Senate Bill 192 achieves 4 things:

- ❑ **PBMs**: New annual report from pharmacy benefit managers
- ❑ **UPLs**: PDAB will develop a plan to establish upper payment limits, or cost controls, for some of the most unaffordable prescription drugs in Oregon.
- ❑ **Fee structure**: Allows a combined fee structure for PDAB and DPT.
- ❑ **Members**: Makes alternates full board members.

2

What Senate Bill 192 achieves:

❑ PBMs:

SECTION 2. (1) As used in this section:

(a) "Carrier" has the meaning given that term in ORS 743B.005.

(b) "Manufacturer" has the meaning given that term in ORS 646A.689.

(c) "Prescription drug" has the meaning given that term in ORS 646A.689.

(2) Not later than June 1 of each calendar year, a pharmacy benefit manager registered under ORS 735.532 shall file a report with the Department of Consumer and Business Services. The report must contain, for the immediately preceding calendar year, the aggregated dollar amount of rebates, fees, price protection payments and any other payments the pharmacy benefit manager received from manufacturers:

(a) Related to managing the pharmacy benefits for carriers issuing health benefit plans in this state; and

(b) That were:

(A) Passed on to carriers issuing health benefit plans in this state or enrollees at the point of sale of a prescription drug in this state; or

(B) Retained as revenue by the pharmacy benefit manager.

3

What Senate Bill 192 achieves:

(continued)

❑ PBMs:

SECTION 2. (3) The report described in subsection (2) of this section may not disclose:

(a) The identity of a carrier or an enrollee;

(b) The price charged for a specific prescription drug or class of drugs; or

(c) The amount of any rebate or fee provided for a specific prescription drug or class of prescription drugs.

(4) Information submitted to the department under this section is confidential and not subject to disclosure except as provided in subsection (5) of this section and ORS 705.137.

(5) Not later than October 1 of each calendar year, the department shall publish on the department's website the aggregated data from all reports filed by pharmacy benefit managers under this section for the preceding calendar year. The department shall publish the data in a manner that does not disclose confidential information of pharmacy benefit managers.

What Senate Bill 192 achieves:

❑ UPLs:

SECTION 3. (1) The Prescription Drug Affordability Board established in ORS 646A.693 shall develop a plan for establishing upper payment limits on drugs sold in this state that are subject to affordability reviews under ORS 646A.694. The plan shall include:

(a) A methodology for establishing upper payment limits;

(b) An analysis of the resources needed by the board to implement the plan;

(c) An analysis of how upper payment limits would be enforced; and

(d) An analysis of how upper payment limits could be implemented with respect to:

(A) Plans administered by the Public Employees' Benefit Board;

(B) Plans administered by the Oregon Educators Benefit Board;

(C) Other state-administered health benefits;

(D) Health benefit plans, as defined in ORS 743B.005; and

(E) Other forms of insurance that provide pharmaceutical benefits, to the extent permitted by federal law.

(2) No later than September 15, 2024, the Prescription Drug Affordability Board shall report to the interim committees of the Legislative Assembly related to health, in the manner provided in ORS 192.245, the following information:

5

What Senate Bill 192 achieves:

❑ Fee structure:

SECTION 4. ORS 705.146 is amended to read:
705.146. The Prescription Drug Affordability Account is established as a subaccount in the Consumer and Business Services Fund created in ORS 705.145, consisting of moneys collected under ORS 646A.695 and moneys that may be appropriated for deposit into the Prescription Drug Affordability Account by the Legislative Assembly. Interest earned on the account shall be credited to the account. Moneys in the account are continuously appropriated to the [*Prescription Drug Affordability Board*] **Department of Consumer and Business Services** to carry out ORS 646A.693 to 646A.695.

Key:
Italic words in *[brackets]* means removed language
Bold words means added language

6

What Senate Bill 192 achieves:

(continued)

❑ Fee structure:

SECTION 9. ORS 646A.695 is amended to read:

(1) The Department of Consumer and Business Services shall adopt by rule, in consultation with the Prescription Drug Affordability Board, annual fees to be paid by manufacturers [*that sell*] **of** prescription drugs **that are sold** in this state. The fees shall be established in amounts necessary to meet the costs of the department [*and the board*] in administering ORS 646A.693 to 646A.695. [*The fees shall be imposed based on a manufacturer's share of gross revenue from sales of prescription drugs in this state.*]

(2) Fees collected under this section shall be deposited in the Prescription Drug Affordability Account established in ORS 705.146.

Key:
Italic words in *[brackets]* means removed language
Bold words means added language

7

What Senate Bill 192 achieves:

❑ Members:

SECTION 6. ORS 646A.693 is amended to read:

646A.693. (1) The Prescription Drug Affordability Board is established in the Department of Consumer and Business Services to protect residents of this state, state and local governments, commercial health plans, health care providers, pharmacies licensed in this state and other stakeholders within the health care system in this state from the high costs of prescription drugs.

(2) The board consists of [*five*] **eight** members [*and three alternates*] appointed by the Governor.

Key:
Italic words in *[brackets]* means removed language
Bold words means added language

Oregon Prescription Drug
Affordability Board

Board Discussion and Approval

- Health insurer data template review
- PDAB hearing update
- Affordability review rule updates and approval

Cortnee Whitlock, policy analyst
Amanda Claycomb, research analyst

Insurer data call and affordability review timeline

- ❑ ~~Finalize~~ Review template and timeline with board. July 19
- ❑ Board begins affordability review, looks at list of candidate drugs to provide DCBS for data call. August 23
- ❑ DCBS distributes data call template to insurers. ~~July 28~~ August 28
- ❑ Data returned from insurers to DCBS. ~~August 31~~ September 29
- ❑ Data review and processing begins. ~~September 1~~ October 2
- ❑ Board to review consolidated insurer data. ~~October 18~~ November 15

Affordability review rule hearing update

- Hearing held on June 22, 2023
- Received 1 oral comment and 2 written comments
- The hearing officer report will be available at the end of July when the final rule is filed
- Reminder that ORS 646A.694 sets the criteria for affordability determination for identifying drugs and insulin products, addressing criteria for and limitations on determination, ensuring confidentiality, and developing rules

3

Manufacturer feedback on affordability rule

- Define affordability more holistically to include value to the healthcare system generated by innovative therapies. This definition should account for savings resulting from reduced hospitalizations, acute care episodes, and other medical costs.
- Rules must explicitly exclude rare disease drugs from consideration per the statute.
- Consider the impact of regulations and policies on innovation for rare disease treatments. Carefully consider utility of information about accelerated approval drugs to protect investments in treatments for rare diseases.
- Consider other affordability solutions: controlling PBMs through banning of spread pricing; allowing patients to spread their out-of-pocket costs throughout the benefit year; accumulator adjustment and maximizer program bans; banning AFPs.
- Accurately define out-of-pocket costs, co-insurance, cost-sharing, copayment, and other terms.

Manufacturer feedback on affordability rule

- Modify the therapeutic alternative definition to match the U.S. Department of Health & Human Services.
- The board is placing too much emphasis on attempting cost effectiveness review rather than focusing on the ability of a patient to afford necessary medicines and cost sharing requirements imposed by insurance plans.
- Remove the cost effectiveness metric, given that the statutory provision regarding insulin appears to be a moot issue.
- Adopt more robust confidentiality protections for proprietary and trade secret information. Have a means to ensure it is free from disclosure and include organizations contracted by the board.
- Data from 340B covered entities should reflect how they are using the discounts and the charity care they are providing.

Manufacturer feedback on affordability rule

- **Clear and meaningful standards for how the drug selection and affordability review processes will be conducted.** Provide a specific methodology to be used in the drug selection and affordability review processes.
- **Procedures for evaluating the reliability of information.** Adopt specific procedures for reviewing and evaluating accuracy and completeness of the information the board will consider.
- **Procedures for stakeholder feedback.** Adopt greater procedural protections to allow impacted stakeholders to provide feedback on board processes and decision.
- **Protections against the use of QALYs.** Adopt this prohibition in the regulations and provide clear safeguards to restrict the board from directly or indirectly considering QALYs and similar measures.
- **Clear standards on how the board will maintain confidentiality of manufacturer data.** The proposed rules do not address how the board will ensure the confidentiality of the materials it reviews in accordance with applicable law, including those in the PDAB statute.

Affordability review rule updates and approval

- Review edits of the affordability review rule
- Discuss updates to the definition of therapeutic alternative from feedback provided from hearing

Affordability review rule updates and approval

Added to section (1)(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.

Added to section (2)(n) In addition to the criteria in subparagraph (1)(m): A prescription drug approved by the FDA for other indications, in addition to a rare disease or condition, is not exempt from an affordability review for those other indications.

Affordability review rule updates and approval

The current definition being used in rule for **therapeutic alternative** is "to mean a drug product that contains a different chemical structure than the drug prescribed but is in the same pharmacologic or therapeutic class and can be expected to have a similar therapeutic effect and adverse reaction profile when administered to patients in a therapeutically equivalent dosage."

BIO believes the following definition should be based upon US government [or Department of Health and Human Services] or medical society guidelines and recommends modifying this definition to the following:

- *Therapeutic alternative is to mean a drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved for the same indication with the same pharmacological or therapeutic class and has been shown through peer-reviewed studies to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose or has been recommended as consistent with standard medical practice by medical professional association guidelines.*

Department of Consumer and Business Services

Division of Financial Regulation

Data Call for Health Insurance Companies in Oregon

Instructions for completing this report. Due Date: MMMM DD, YYYY

DCBS is collecting this information under authorities granted in ORS 731.296 and ORS 646A.693 through ORS 646A.693.697 in support of the Prescription Drug Affordability Board.
The purpose of this Excel sheet is for health insurance plans to report on required data for prescription drugs under both pharmacy and medical benefits for policies or certificates issued in Oregon during **2022**.

Health insurance plans should fill out the information on each of the tabs listed below. The tabs to complete are colored light blue.

Company Information

Click here to go to the Company Information tab
Enter the information for your company on this tab.
Note: Data entered into the company information tab will auto populate at the top of other tabs.

Company Name and NAIC Code:
Enter your company's name. *Format: alphabetic characters*
Enter your company's NAIC code. *Format: numeric value*

Primary Contact:
Enter the name, phone number, and email address of your company's primary contact for this data request.
Ensure the primary contact is an individual; do not list a shared email box in place of a real person.

Secondary Contact:
If there is an additional contact or shared email/phone number you would like to include, please list that information under the secondary contact field.

Authorizing Authority:
Enter the name, phone number, and email address of the supervisor or manager approving the data provided for this data request.

Technical Contact:
Enter the name, phone number, and email address of the person who helped pull the data provided for this request.

Market Type:
Select the market from the drop-down box in cell B13. Please note, if the market type of "other" is selected, enter a description of that other market type in B14.
If your company serves more than one market type, save and fill out a separate version of this workbook for each market your company serves. Example: A company that has both small and large group markets sends two files. File 1 - "Company Name Data Call YYYY-MM-DD - Small Group" and File 2 - "Company Name Data Call YYYY-MM-DD - Large Group"

Department of Consumer and Business Services

Department of Consumer and Business Services

Division of Financial Regulation

Data Call for Health Insurance Companies in Oregon

Data Limitations and Notes

Click here to go to the Data Limitations and Notes tab

Use this tab to list any limitations or quality concerns regarding the data you are supplying or the methodology used to obtain the information provided. This tab can be skipped if there are no data limitations or quality concerns.
Company information at the top should auto populate with the data entered on the "Company Information" tab.
To list any data concerns, select the tab name from the drop-down list in column A. Select "All" when noting data limitations and quality concerns that impact all data. The "other" option in the drop-down box is for data limitation or quality concerns that apply to multiple tabs but not all tabs; when selecting "other" note the impacted tab(s) in column C.
Format: alphabetic characters in drop-down selection box .

If the data limitation and concerns apply to a specific data point (example: number of prescriptions), select the impacted data point from the drop-down in column B. There are also options to select "all" or "other" from this drop-down field for notes about the data or methodology that are not limited to a single data point.
Format: alphabetic characters in drop-down selection box.
List any additional data limitations, concerns, or notes in a new row as needed. *Format: alphabetic characters*

Cost Data

Click here to go to the Cost Data tab

Use this tab to list the cost information, number of prescriptions, number of enrollees, and other cost details for each of the listed prescription drugs.
Note: If there were no claims for a listed NDC, enter 0 for all required fields on that drug's row.

Company information at the top should auto populate with the data entered on the "Company Information" tab.

Prescription Drug Name and **Therapy Class:** No action should be needed, as these fields should have the drug information listed based on the drugs identified by the Prescription Drug Affordability Board for review.

National Drug Code(s):
For your convenience, any 11 Digit NDCs associated with the drug found in our records have been listed. If your company's records show any NDCs associated with the drug in question not listed in the main table, please use the "Additional NDCs Not Listed Above" section at the bottom of the page to note any and all NDCs not listed in the main table. *Format:11-digit numeric value .*

Covered Under Pharmacy Benefit, Medical Benefit, or Both:
Select from the drop-down box whether the prescription drug was prescribed under the pharmacy benefit, medical benefit, or both. *Format: alphabetic characters in drop-down selection box .*

Number of Prescriptions:
The number of claims received for the prescription drug in the reporting year. *Format: numeric value*

Number of Enrollees:
The number of enrollees who filed claims for the prescription drug in the reporting year. *Format is numeric value*

Total Annual Plan Spending 2022 (Allowed Dollar Amount):
The total payments made under the policy to health care providers on behalf of covered members, including payments made by issuers and member cost sharing. *Format: dollar amount*

Total Annual Deductible Costs for Enrollees:
The total deductible costs for enrollees for the listed drug in 2022. *Format: dollar amount .*

Total Annual Co-Pay Costs for Enrollees:
The total co-pay costs for enrollees to receive the listed drug in 2022. *Format: dollar amount .*

Total Annual Coinsurance Cost for Enrollees:
The total coinsurance cost for enrollees to receive the listed drug in 2022. *Format: dollar amount.*

Total Other Enrollee Costs:
Use this field to enter the total dollar amount of any additional costs or fees charged to enrollees in 2022 that were associated with the listed drug that do not fall under deductibles, co-pay, or coinsurance. If no additional fees applied, leave this field blank or enter "0". *Format: dollar amount.*

Notes Regarding Other Enrollee Costs:
If other enrollee costs were listed, enter a brief description or explanation of the nature and type of additional fees.
Format: alphabetic characters

Total Annual Out of Pocket Costs for Enrollees:
No action required for this field. This field should automatically generate the total amount of the enrollee cost fields.
Format: dollar amount

Claim Status

Click here to go to the Claim Status tab

Use this tab to list the aggregate claims data (i.e. number of claims approved, denied, etc.) for each listed drug.

Note: If there are no claims for a listed NDC, enter 0 for all required fields on that drug's row.

Company information at the top should auto populate with the data entered on the "Company Information" tab.

Prescription Drug Name and **Therapy Class:** No action should be needed, as these fields should have the drug information listed based on the drugs identified by the Prescription Drug Affordability Board for review.

National Drug Code(s):
For your convenience, any 11 Digit NDCs associated with the drug found in our records have been listed. If your company records show any NDCs associated with the drug in question not listed in the main table, please use the "Additional NDCs Not Listed Above" section at the bottom of the page to note any and all NDCs not listed in the main table. *Format:11-digit numeric value.*

Covered Under Pharmacy Benefit, Medical Benefit, or Both:
Specify whether the prescription drug was prescribed under the pharmacy benefit, medical benefit, or both.
Format: alphabetic characters in drop-down selection box.

Approved Claims:
Enter the total number of 2022 claims for the listed drug that were approved. *Format: numeric value*

Denied Claims:
Enter the total number of 2022 claims for the listed drug that were denied. *Format: numeric value*

Total Number of Claims:
No action required for this field. This field should automatically generate the total number of claims based on the data entered into the approved and denied fields. *Format: numeric value*

Appeals Filed:
Enter the total number of appeals filed in 2022 for denied claims. *Format: numeric value*

Denied Claims Overturned Upon Appeal:
Enter the total number of claims that were initially denied but then the denial was overturned upon appeal in 2022.
Format: numeric value

Claim Notes:
(Optional field) Use this field to list any relevant notes your company wishes to share regarding the claim numbers.

Prior Authorization and Approval Process

Click here to go to the Prior Auth and Approval Process tab

Use this tab to list prior authorizations and approval process for each listed drug.

Please note, data on this tab may be considered proprietary information. To help protect the confidentiality of this data, data from individual companies will not be shared. Data supplied here will only be used in an aggregate form.

Prescription Drug Name and Drug Class: No action required, as these fields should have the information listed based on the drugs identified by the Prescription Drug Affordability Board for review.

Formulary status (Preferred, non-preferred, or excluded)
Indicate whether the drug class is preferred, non-preferred, or excluded on the formulary drug list. *Format: alphabetic characters in drop-down selection box.*

Co-pay formulary status (fixed fee or percentage)
Indicate whether the drug class has a co-payment formulary status that is fixed fee or percentage of cost. *Format: alphabetic characters in drop-down selection box.*

Note: When the Co-Pay formulary status is selected, the adjacent columns will highlight the needed information.

Fixed fee rate of co-pay
Required if co-pay formulary status is fixed fee. Indicate the fixed fee amount of the drug class. *Format: numeric value*

Percentage of coinsurance:
Required if co-pay formulary status is percentage. Specify the percentage for the prior authorization tier for the prescription

Step therapy required:
Indicate whether the drug class requires step therapy in the prior authorization process. *Format: alphabetic characters in drop-down selection box.*

Prior authorization required:
Select "yes" if prior authorization is required for the drug, or "no" if prior authorization is not required for the drug. Format: alphabetic characters in drop-down selection box.

Is third party payment allowed for the drug:
Please answer yes or no. *Format: alphabetic characters in drop-down selection box.*

Rebates

Click here to go to the Rebates tab

Use this tab to enter the aggregate rebate data for each listed drug.

Please note, data on this tab may be considered proprietary information. To help protect the confidentiality of this data, data from individual companies will not be shared. Data supplied here will only be used in an aggregate form. You may use the "Data Limitations and Notes" tab to make any notes you wish regarding the sensitivity of data reported in the "Rebates" tab.

Company information at the top should auto populate with the data entered on the "Company Information" tab.

Prescription Drug Name and Therapy Class: No action required, as these fields should have the information listed based on the drugs identified by the Prescription Drug Affordability Board for review.

Covered Under Pharmacy Benefit, Medical Benefit, or Both:
Specify whether the prescription drug was prescribed under the pharmacy benefit, medical benefit, or both.
Format: alphabetic characters in drop-down selection box.

Total Number of Claims:
Enter the total number of 2022 claims for the prescription drug. *Format: numeric value.*

Number of Claims with Rebates or Discounts Applied:
Enter the number of 2022 claims for the prescription drug in which a discount or rebate was applied.
Format: numeric value

Total Cost of the Drug Before Discounts and Rebates
Enter the total dollars paid for prescription drug claims in the pharmacy and medical benefits *before* rebates and price concessions were applied. *Format: dollar amount*

Rebates and Discounts from Manufacturer:
Enter the total dollar amount of all rebates and discounts received from the manufacturer for the prescription drug in 2022. *Format: dollar amount*

Rebates and Discounts from PBM:
Enter the total dollar amount of all rebates and discounts received from the Pharmacy Benefit Manager (PBM) for the prescription drug in 2022. *Format: dollar amount*

Other Discounts and Rebates:
(Optional) List the total dollar amount of any other rebates or discounts for the prescription drug in 2022. *Format: dollar amount*

Notes About Other Discounts and Rebates:
If a dollar amount was listed for other discounts and rebates, enter a brief description or explanation of those rebates / discounts in this field. *Format: alphabetic characters*

Total Rebates:
No action required for this field. This field should automatically generate the total amount of the rebate and discount fields. *Format: dollar amount*

Rebate Percentage:
No action required for this field. This field should automatically generate by calculating the total sum of rebates and discounts divided by the total cost before rebates and discounts. *Format: percentage*

Company Information - Provide the following information (required fields will highlight yellow until the requested data is entered)

Note: Yellow highlighted cells = required data. Once the data is entered the highlight will disappear.

Company					
Company Name	ABC Company Name				
NAIC Code	12345656744332				
Contact Information					
Contact Type:	Name	Job Title	Phone Number	Email	Notes
Primary Contact (required)	Bob Smith	Vice President of gathering data stuff	503-123-4567	bob.smith@ABCcompany.com	Enter any notes about contacting the person here. Example: prefers phone to email.
Secondary Contact (optional)	John Jacob Jingleheimer-Schmidt	Administrative Assistant	1-800-000-0000	john.jacob.jingleheimerschmidt@abc.company.com	
Authorizing Authority (required)	Dr. Joan Jacob Jingleheimer-Smythe	Chief Operational Officer (COO)	654-123-4567	dr.joan.jacob.jingleheimerschmidt@abc.company.com	
Technical Contact (required)	Captain Planet	Data and Research Development Analyst	665-466-5466 ext. 54		
Market Type Information					
Market Type	Small Group				

*Note: the Primary Contact *must* be an actual person. Do not list a shared email or phone number for the Primary contact. Shared phone numbers or emails can be included under the secondary contact information if applicable.

Company Information:

Company:	ABC Company Name
NAIC Code:	12345656744332
Market:	Small Group

Click here to enter or correct Company Information

Section	Data Point	Data Quality or Limitation Notes
All		

Company Information:

Company:	ABC Company Name
NAIC Code:	12345656744332
Market:	Small Group

Click here to enter or correct Company Information

Note: Yellow highlighted cells = required data. Once the data is entered the highlight will disappear.

Prescription Drug Name	Therapy Class	National Drug Code	Covered Under Pharmacy Benefit, Medical Benefit, or Both	Number of Prescriptions	Number of Enrollees	Total Annual Plan Spending 2022 (Allowed Dollar Amount)	Total Annual Deductible Costs for Enrollees	Total Annual Co-Pay Costs for Enrollees	Total Annual Coinsurance Cost for Enrollees	Total Other Enrollee Costs	Notes Regarding Other Enrollee Costs	Total Annual Out of Pocket Costs for Enrollees
Drug Name 1	Antivirals	00012345678								$ -		$ -
Drug Name 1	Antivirals	12345678901								$ -		$ -
Drug Name 1	Antivirals	23456789012								$ -		$ -
Drug Name 2	Dermatologicals	13579246801								$ -		$ -
Drug Name 2	Dermatologicals	10864297531								$ -		$ -
Drug Name 2	Dermatologicals	98765432101								$ -		$ -
Drug Name 2	Dermatologicals	98765432102								$ -		$ -
Drug Name 3	Analgesics - Anti-Inflammatory	87654321091								$ -		$ -
Drug Name 3	Analgesics - Anti-Inflammatory	76543210912								$ -		$ -

Additional NDCs Not Listed Above: Use the space below to list the requested data for any NDCs of the drug of interest that are not listed above.

Prescription Drug Name	Therapy Class	National Drug Code	Covered Under Pharmacy Benefit, Medical Benefit, or Both	Number of Prescriptions	Number of Enrollees	Total Annual Plan Spending 2022 (Allowed Dollar Amount)	Total Annual Deductible Costs for Enrollees	Total Annual Co-Pay Costs for Enrollees	Total Annual Coinsurance Cost for Enrollees	Total Other Enrollee Costs	Notes Regarding Other Enrollee Costs	Total Annual Out of Pocket Costs for Enrollees
												$ -
												$ -
												$ -

Company Information:

Company:	ABC Company Name
NAIC Code:	12345656744332
Market:	Small Group

Click here to enter or correct Company Information

Note: Yellow highlighted cells = required data. Once the data is entered the highlight will disappear.

Prescription Drug Name	Therapy Class	National Drug Code	Covered Under Pharmacy Benefit, Medical Benefit, or Both	Approved Claims	Denied Claims	Total Number of Claims	Appeals Filed	Denied Claims Overturned Upon Appeal	Claim Notes
Drug Name 1	Antivirals	00012345678				0			
Drug Name 1	Antivirals	12345678901				0			
Drug Name 1	Antivirals	23456789012				0			
Drug Name 2	Dermatologicals	13579246801				0			
Drug Name 2	Dermatologicals	10864297531				0			
Drug Name 2	Dermatologicals	98765432101				0			
Drug Name 2	Dermatologicals	98765432102				0			
Drug Name 3	Analgesics - Anti-Inflammatory	87654321091				0			
Drug Name 3	Analgesics - Anti-Inflammatory	76543210912				0			

Additional NDCs Not Listed Above: Use the space below to list the requested data for any NDCs of the drug of interest that are not listed above.

Company Information:

Company:	ABC Company Name
NAIC Code:	12345656744332
Market:	Small Group

Click here to enter or correct Company Information

Note: Yellow highlighted cells = required data. Once the data is entered the highlight will disappear.

Prescription Drug Name	Drug Class	Formulary status	Co-pay formulary status	Fixed fee rate of co-pay	Percentage of coinsurance	Step therapy required	Prior auth required	Is 3rd Party Payment Allowed for the drug?	Notes
Drug Name 1	Antivirals								
Drug Name 2	Dermatologicals								
Drug Name 3	Analgesics - Anti-Inflammatory								
Drug Name 4	Gastrointestinal Agents								
Drug Name 5	Hematological Agents								
Drug Name 6	Analgesics - Anti-Inflammatory								
Drug Name 7	Analgesics - Anti-Inflammatory								
Drug Name 8	Gastrointestinal Agents								
Drug Name 9	Antidiabetics								
Drug Name 10	Antineoplastics and Adjunctive Therapies								
Drug Name 11	Psychotherapeutic and Neurological Agents								
Drug Name 12	Antineoplastics and Adjunctive Therapies								
Drug Name 13	Antidiabetics								
Drug Name 14	Antineoplastics and Adjunctive Therapies								
Drug Name 15	Miscellaneous Therapeutic Classes								
Drug Name 16	Antidiabetics								

Company Information:

Company:	ABC Company Name
NAIC Code:	12345656744332
Market:	Small Group

Click here to enter or correct Company Information

Note: Yellow highlighted cells = required data. Once the data is entered the highlight will disappear.

Prescription Drug Name	Drug Class	Covered Under Pharmacy Benefit, Medical Benefit, or Both	Total Number of Claims	Number of Claims with Rebates or Discounts Applied	Total Cost of the Drug Before Discounts and Rebates	Rebates and Discounts from Manufacturer	Rebates and Discounts from PBM	Other Discounts and Rebates (including PAPs)	Notes about other discounts and rebates	Total Rebates	Rebate Percentage
Drug Name 1	Antivirals									$ -	
Drug Name 2	Dermatologicals									$ -	
Drug Name 3	Analgesics - Anti-Inflammatory									$ -	
Drug Name 4	Gastrointestinal Agents									$ -	
Drug Name 5	Hematological Agents									$ -	
Drug Name 6	Analgesics - Anti-Inflammatory									$ -	
Drug Name 7	Analgesics - Anti-Inflammatory									$ -	
Drug Name 8	Gastrointestinal Agents									$ -	
Drug Name 9	Antidiabetics									$ -	
Drug Name 10	Antineoplastics and Adjunctive Therapies									$ -	
Drug Name 11	Psychotherapeutic and Neurological Agents									$ -	
Drug Name 12	Antineoplastics and Adjunctive Therapies									$ -	
Drug Name 13	Antidiabetics									$ -	
Drug Name 14	Antineoplastics and Adjunctive Therapies									$ -	
Drug Name 15	Miscellaneous Therapeutic Classes									$ -	
Drug Name 16	Antidiabetics									$ -	
Drug Name 17	Dermatologicals									$ -	

PhRMA
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950 F STREET, NW, SUITE 300 • WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

June 23, 2023

Department of Consumer and Business Services
Karen Winkel, Rules Coordinator
350 Winter Street NE
Salem, OR 97309-0405
Karen.j.winkel@dcbs.oregon.gov, with a copy to DFR.Rules@oregon.gov

Re: Oregon Prescription Drug Affordability Board – Proposed Rules 925-200-0010, 925-200-0020

Dear Ms. Winkel:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the Notice of Proposed Rulemaking filed by the Prescription Drug Affordability Board on May 23, 2023. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. PhRMA had previously commented on our concerns with the PDAB's proposed methodology to select prescription drugs for affordability review (OAR 925-200-0010) and process to conduct affordability review on specific selected specific drugs (OAR 925-200-0200) (the "Proposed Rules").[1] PhRMA continues to have concerns about the lack of meaningful standards for and adequate detail on how the Board will use and consider information, as the lack of meaningful, binding procedures in the Proposed Rules raises concerns about arbitrary and inconsistent decision-making in violation of the Oregon Administrative Procedure Act ("APA").[2]

As currently drafted, PhRMA believes the Proposed Rules provide insufficient binding standards to implement the drug selection and affordability review procedures for which the Board is responsible under the PDAB statute.[3] We specifically highlight the following concerns: [4]

- Clear and meaningful standards for how the drug selection and affordability review processes will be conducted. As PhRMA has explained in detail in its Prior Comments, the Board has not, in the Proposed Rules or elsewhere, set forth a principled and specific methodology for selecting eligible drugs and conducting affordability reviews. In lieu of establishing these methodologies, the

[1] *See* Letter from Pharmaceutical Research and Manufacturers of America ("PhRMA") to Or. Prescription Drug Affordability Board ("Board") (Feb. 11, 2023); Letter from PhRMA to Board (Mar. 12, 2023); Letter from PhRMA to Board (Apr. 16, 2023); Letter from PhRMA to Board (May 14, 2023) (collectively, the "Prior Comments"). PhRMA incorporates by reference all comments, concerns, and objections that it has previously raised about the proposed drug selection and affordability review processes.

[2] As noted in our Prior Comments, a central tenet of the APA is that "decisions by administrative agencies be rational, principled, and fair, rather than ad hoc and arbitrary." *Gordon v. Bd. of Parole & Post Prison Supervision*, 343 Or. 618, 633 (2007).

[3] 2021 Or. Laws ch. 598 (enacted under Senate Bill 844). PhRMA also notes revisions in proposed OAR 925-200-0020(2)(c) to the definition for "therapeutic alternative" from the version originally included in the Board's May 17, 2023 meeting materials. *See* Letter form PhRMA to Board (May 14, 2023), at 3. We refer the Board to our discussion of that issue in the Prior Comments. *See* Letter form PhRMA to Board (Feb. 11, 2023), at 5; Letter from PhRMA to Board (Apr. 16, 2023), at 5; Letter from PhRMA to Board (May 14, 2023), at 3.

[4] PhRMA also continues to have concerns about the Board's Temporary Procedural Rule OAR 925-100-0003, as described in our letter to the PDAB, and about the constitutionality of the Oregon PDAB statute more generally. *See* Letter from PhRMA to Board (Oct. 19, 2022). PhRMA reserves all of its legal arguments with regard to those issues.

Proposed Rules provide only a laundry list of possible data that the Board may consider when selecting eligible drugs for affordability reviews without providing concrete standards for how the Board will obtain these various data or how they will be weighed, compared, and considered both independently and relative to other information and factors.

The Proposed Rules' approach fails to give stakeholders necessary transparency into whether, how, and under what circumstances the Board will use various categories of information as part of the drug selection and affordability review processes. It is also inconsistent with the requirements of the APA, which requires the Board to render decisions in a manner that is "rational, principled, and fair, rather than ad hoc and arbitrary."[5] Standardless, ad hoc evaluations and decisions are contrary to this basic requirement of administrative law and contravene the Board's obligation to ensure that it "make[s] policies for even application" across regulated entities and products.[6]

PhRMA urges the Board not to adopt the Proposed Rules as currently written and to revise the Proposed Rules to provide a specific methodology to be used in the drug selection and affordability review processes.

- Procedures for evaluating the reliability of information. PhRMA's Prior Comments raise several specific questions regarding how the Board intends to obtain and evaluate the information it proposes to use in the drug selection and affordability review processes.[7] We ask that the Board revise the Proposed Rules to adopt specific procedures for reviewing and evaluating the accuracy and completeness of the information it will consider.

- Procedures for stakeholder feedback. PhRMA urges the Board to adopt greater procedural protections to allow impacted stakeholders to provide feedback on the Board's processes and decisions. Because of the voluminous and complex nature of the data considered by the Board and the variety of sources it is drawn from, the Board should give impacted stakeholders, including manufacturers, a reasonable opportunity to review and provide written responses to and relevant additional information for contemplated drug selection and affordability review determinations (including the data and other information relied upon by the Board in reaching those determinations) before they are finalized.[8]

- Protections against the use of QALYs. The PDAB statute expressly bars use of QALYs or "similar formulas that take into account a patient's age or severity of illness or disability" for purposes of evaluating a drug's cost-effectiveness.[9] We strongly urge the Board to expressly adopt this

[5] *Gordon*, 343 Or. at 633.
[6] *Sun Ray Drive-In Dairy, Inc. v. Or. Liquor Control Comm'n*, 16 Or. App. 63, 72 (1973).
[7] *See, e.g.*, Letter from PhRMA to Board (Feb. 11, 2023), at 3; Letter from PhRMA to Board (Apr. 16, 2023), at 2.
[8] We note, for example, that the Colorado PDAB recently removed over one hundred and fifty drugs from its initial published list of brand-name prescription drugs and biologics eligible for affordability review, likely due to errors in its earlier determinations. *Compare* Colo. PDAB, 2023 Colorado PDAB Eligible Prescription Drug List (May 8, 2023) (showing 735 eligible brand-name prescription drugs and biologics) *with* the June 6, 2023 version of the same document (showing only 582). Stakeholder feedback on potential errors or discrepancies in the Board's calculations provides an important opportunity to identify and correct any such issues before they may be incorporated into the Board's determinations.
[9] ORS § 646A.694(4).

prohibition in its regulations and provide clear safeguards that restrict it from directly or indirectly considering QALYs and similar measures.[10]

- Clear standards on how the Board will maintain confidentiality of manufacturer data. PhRMA reiterates its concerns that the Proposed Rules do not address how the Board will ensure the confidentiality of the materials it reviews in accordance with applicable law, including those in the PDAB Statute.[11] State and federal law protect manufacturers' confidential, proprietary, and trade secret information from disclosure; such information cannot be publicly disclosed without violating prohibitions against the misappropriation of trade secrets.[12] In addition, the Fifth Amendment's prohibition against taking private property without just compensation similarly prohibits the uncompensated disclosure of trade secrets.[13] Courts have made clear that "when disclosure [of pricing information] is compelled by the government," even the "failure to provide adequate protection to assure its confidentiality ... can amount to an unconstitutional 'taking' of property."[14] Consistent with these state and federal requirements, the Legislature incorporated into the PDAB Statute an independent obligation on the PDAB to "keep strictly confidential any information" that is "[c]onfidential, proprietary or a trade secret," including "[i]nformation submitted to the department by a manufacturer under ORS 646A.689."[15] In order to effectuate these requirements and sufficiently protect against disclosure of this information, the Board should revise its Proposed Rules to incorporate clear standards addressing how it will maintain the confidentiality of relevant information consistent with state and federal law.

PhRMA and its member companies appreciate the opportunity to comment on these proposed rules and thank you for your consideration of our feedback. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

Dharia McGrew, PhD
Director, State Policy

Merlin Brittenham
Assistant General Counsel, Law

[10] *See* further discussion regarding the PDAB Statute's restriction on the use of QALYs, evLYGs, or similar measures in Letter from PhRMA to Board (April 16, 2023), at 7-8.
[11] Or. Rev. Stat. § 646A.694(7) (enacted as § 2(7) of the PDAB Statute). We also reiterate our concerns regarding potential disclosure of sensitive information related to the federal 340B program. *See* Apr. 16, 2023 PhRMA Letter, at 7.
[12] See 18 U.S.C. § 1839(5)(B)(ii)(II) (defining "misappropriation" under the federal Defend Trade Secrets Act); Oregon Uniform Trade Secrets Act, ORS 646.461 to .475.
[13] See, e.g., *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002–04 (1984). The Fifth Amendment's Taking Clause applies against the states under the Fourteenth Amendment.
[14] *St. Michael's Convalescent Hosp. v. California*, 643 F.3d 1369, 1374 (9th Cir. 1981) (brackets and quotation marks omitted).
[15] Or. Rev. Stat. § 646A.694(7).

Biotechnology Innovation Organization
1201 New York Avenue NW
Suite 1300
Washington, DC, 20005
202-962-9200

VIA Electronic Delivery

June 29, 2023

Ms. Karen Winkel
Rules Coordinator
Division of Financial Regulation
350 Winter Street NE
Salem, OR 97301

Re: PRESCRIPTION DRUG AFFORDABILITY REVIEW

Dear Ms. Winkel:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Oregon Prescription Drug Affordability Board's (PDAB or Board) proposed regulations regarding the Prescription Drug Affordability Review.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, delay their onset, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

BIO has serious concerns regarding the impact that these regulations would have on access to medicines, particularly transformative therapies, including gene therapies and those approved through the accelerated approval process (AAP), which is an important approval pathway for treatments for diseases with no or very few therapies available. Our detailed comments follow.

General Comments

We are deeply concerned that the proposed rules go beyond the statute.[1] The statute includes an explicit exemption for drugs approved for rare disease patients. However, there is no exemption for these essential medicines in the proposed regulations. Indeed, because the proposed regulations include a reference to expedited pathways, including accelerated approval—a key pathway to accelerate access to innovative medicines for patients with serious conditions with unmet needs—the draft rules capture these drugs in the possible list

[1] SB 744 (2021). Accessed: June 28, 2023.
https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/SB844/Enrolled

of drugs it could consider for affordability review. **We believe the rules must explicitly exclude rare disease drugs from consideration per the statute.**[2]

We also have serious concerns regarding the lack of specificity on how the board will determine whether the use of the drug has led to an affordability issue. The term "affordability" is vague, leading to a great deal of subjectivity. For example, for whom is the PDAB examining affordability? Do the rules refer to affordability for the uninsured, commercially insured, and those with public insurance, or is it meant to address affordability for those with chronic illness? Also, with respect to patient and caregiver input, BIO believes the draft rules should outline how the information will be weighed and how much emphasis will be placed upon their input.

We also stress that any affordability reviews must be taken into context with factors of the entire supply chain. The supply chain, while similar, can be different for various medicinal therapies. The PDAB must weigh the fact that other entities in the supply chain, such as wholesalers, PBMs, health plans, and pharmacies (specialty or otherwise) add costs to the system— and these costs are not under the manufacturers' control. **We believe affordability should be defined more holistically to include value to the healthcare system generated by innovative therapies. This definition should account for savings resulting from reduced hospitalizations, acute care episodes, and other medical costs.** (Please see the appendix included with this letter.)

Accelerated Approval Drugs

The draft regulations indicate the PDAB will consider whether the drug or biologic was approved through the AAP, without any explanation as to how that information will be used. The AAP has been an essential regulatory tool to expedite patients' access to safe, effective, and innovative FDA-approved products that address high unmet needs for conditions that have few or no other treatments. This pathway has tackled some of the most pressing public health needs and saved countless patients' lives, including many patients living with rare disease. Using the same well established evidentiary standard as for traditional approvals, the pathway has facilitated approval of treatments for many severe diseases, such as a variety of cancers (including rare cancers), Human Immunodeficiency Virus (HIV), various bacterial infections, Multiple Sclerosis, Sickle Cell Disease, rare diseases, and others that may fall into this same severe disease category.

The Board must consider the impact any draft regulations and policies it enacts on innovation for rare disease treatments. There are more than 7,000[3] known rare diseases – 95% of which have no approved therapies[4]— and approximately 1 in 10 Oregon residents may have one. Additionally, treatments approved through the AAP frequently address conditions for which there are no other treatments. Hundreds of new drugs or biologics to treat serious or life-threatening diseases or conditions with high unmet medical need have been approved through the AAP extending and, in certain cases, saving patients' lives by providing earlier access to novel therapies than would have been possible using the traditional approval pathway. Through AAP, HIV has gone from a death sentence to a manageable chronic condition, while cancer mortality rates due to improved medications

[2] Ibid.
[3] https://www.fda.gov/patients/rare-diseases-fda
[4] Kaufman, Petra, et al., "From Scientific Discovery to Treatments for Rare Diseases—A View from the National Center for Advancing Translational Sciences—Office of Rare Diseases Research," Orphanet Journal of Rare Diseases, November 6, 2018. https://ojrd.biomedcentral.com/articles/10.1186/s13023-018-0936-x

and other treatments have decreased by 33%.[5] As of June 30, 2021, 67% of drugs approved through the AAP were for oncology indications.[6]

The utility of information regarding AAP drugs must be carefully considered, otherwise there is risk of disincentivizing investment in these critical areas. This would have disproportionate effect on patients with rare diseases not only in Oregon, but in other states as well, many of whom spend an average of 4.8 years and more than 7 specialist visits to receive an accurate diagnosis,[7] which can take far longer for patients within racial or ethnic minorities. For many of these patients, development of a treatment can only be accomplished through the accelerated approval pathway due to factors such as extremely small patient populations and uncertain endpoints for study due to the heterogenous nature of many rare diseases.

Out-of-Pocket Costs

The draft regulations frequently reference as criteria the patient's copay and out-of-pocket costs (OOP). We agree that these are some of the biggest factors regarding affordability but note that manufacturers do not set copayment or cost-sharing amounts, health plans do. According to the Oregon Health Authority (OHA), 95% of all Oregonians have health insurance. We also believe it is important to note the impact of prescription drug costs on health insurance premiums in California – which has collected this type of data since 2017—between 2017 and 2021, ranged between 12.9% and 14.1%.[8] The Oregon Department of Consumer and Business Services estimates that prescription drug spending accounts for 13.9% of all health care spending.[9] The impact on overall health insurance premiums has been consistent over the last several years, however, health insurers and pharmaceutical benefit managers (PBMs) have progressively found ways to increase out-of-pocket costs on their members.

Unfortunately, in most cases savings from manufacturers in the forms of rebates and discounts paid to PBMs and plan sponsors are not used to lower patient out-of-pocket costs. These savings are not passed onto the patient or beneficiary. Further, regarding how OOP costs will be measured, it is unclear whether the Board will consider actual amounts paid (i.e., whether a patient's OOP costs were off-set by a manufacturer assistance program) or what the OOP obligation is under a patient's plans. In many cases, "PBMs may also have an incentive to favor high-priced drugs over drugs that are more cost-effective. Because they often receive rebates that are calculated as a percentage of the manufacturer's list price, PBMs receive a larger rebate for expensive drugs than they do for ones that may provide better

[5] https://www.cancercenter.com/community/blog/2023/01/cancer-survival-rates-are-improving#:~:text=Overall%2C%20the%20rate%20dropped%20from,currently%20sits%20at%2068%20percent.
[6] https://www.fda.gov/drugs/nda-and-bla-approvals/accelerated-approvals
[7] "The Diagnostic Journey for Rare-Disease Patients: Scaling Sustainable Solutions," Avalere, June 2021. https://avalere.com/wp-content/uploads/2021/07/Diagnostic_Journey_for_RD_Patients-June-2021.pdf (Accessed: May 2, 2023)
[8] "Impact of Prescription Drugs on Health Insurance Premiums: California Department of Insurance, Report for Calendar Year 2021 Experience," California Department of Insurance, January 2023. Accessed: June 26, 2023. https://www.insurance.ca.gov/01-consumers/110-health/60-resources/upload/CDI-2022-SB-17-Prescription-Drug-Cost-Report-Final-Accessible.pdf
[9] "Prescription Drug Price Transparency: Results and Recommendations – 2022," Department of Consumer and Business Affairs, November 30, 2022. Accessed: June 27, 2023. https://dfr.oregon.gov/drugtransparency/Documents/Prescription-Drug-Price-Transparency-Annual-Report-2022.pdf

value at lower cost. As a result, people who have a high-deductible plan or have copays based on a drug's list price may incur higher out-of-pocket costs."[10]

A patient copay for a cell or gene therapy (that may not be for a rare disease), particularly a coinsurance, will be high and the draft regulations do not appear to recognize that there is an OOP cap most plans must follow. Manufacturers often provide assistance to help patients with these OOP costs. However, PBMs have developed accumulator and maximizer programs to prevent manufacturer cost-sharing assistance from accruing toward patient deductibles and annual OOP maximums. The proliferation of these programs impedes the goal of increasing patient affordability. As a result, patients may struggle to afford and adhere to their medications as insurers and PBMs seek to shift more cost-sharing responsibility to patients.

In another alarming trend, employers have greatly accelerated use of alternative funding programs (AFPs) in recent years.[11] Employers establish AFPs with vendors such as ImpaxRX, Paydhealth, SHARx, PayerMatrix and Script Sourcing get payers to exclude specialty drugs, gene therapies, or other treatments from the employer's health benefit. These treatments are then excluded from the plan's formulary or excluded entirely, resulting in a patient having no coverage. The vendors then direct patients towards charitable foundations or manufacturer patient assistance programs.[12] In some cases, the plan will cover the drug if the patient assistance program does not cover the medicine, which is more likely for higher income individuals. In other cases, where the foundation pays, this diverts limited patient assistance funds towards patients that are not truly needy and subverts the charitable intention of the needs-based assistance from charitable organizations or manufacturers. In still other cases where neither party pays, patients can be without access to essential treatments.

Therefore, we encourage the Board and the State of Oregon to consider additional levers available to reduce out-of-pocket costs for patients, such as controlling PBMs through banning of spread pricing and allowing patients to spread their OOP costs throughout the benefit year, which will now be allowed in Medicare under the *Inflation Reduction Act*. The cost of the drug is but one of many parts of the overall healthcare costs for patients, and for the state, and thus, thinking beyond just the price of the drug is critical to helping achieve the goal of reduced OOP costs for patients. We also encourage the Board to consider other affordability solutions such as, accumulator adjustment and maximizer program bans, or banning AFPs, as a more effective and meaningful way to help ensure patients are able to afford their medicines rather than additional regulation on biopharmaceutical manufacturers that would have little to no impact on OOP.

Definitions

Out-of-Pocket Costs and Other Cost-Sharing Data

Further, given the various schemes under which PBMs and health plans utilize cost-sharing in benefit design to cut costs, it is important to ensure that the terms in the draft

[10] "Pharmacy Benefit Managers and Their Role in Drug Spending," The Commonwealth Fund, April 22, 2019. https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending (Accessed: May 1, 2023)
[11] Adam Fein, "The Shady Business of Specialty Carve-Outs," August 2, 2022, https://www.drugchannels.net/2022/08/the-shady-business-of-specialty-carve.html
[12] Ibid.

regulations such as, out-of-pocket (OOP) costs, co-insurance, cost-sharing, and copayment, are accurately defined, in addition to references to "other cost sharing data."

Therapeutic Alternatives

The draft regulations define the term "**therapeutic alternative,**" "to mean a drug product that contains a different chemical structure than the drug prescribed but is in the same pharmacologic or therapeutic class and can be expected to have a similar therapeutic effect and adverse reaction profile when administered to patients in a therapeutically equivalent dosage." We believe this definition should be based upon US government [or Department of Health and Human Services] or medical society guidelines. As such, we recommend modifying this definition to the following:

- *Therapeutic alternative is to mean a drug product that contains a different therapeutic agent than the drug in question, but is* ***FDA-approved for the same indication with*** *the same pharmacological or therapeutic class and has been shown through peer-reviewed studies to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose or has been recommended as consistent with standard medical practice by medical professional association guidelines.*

Affordability Review Process

We are deeply concerned that the Board is placing too much emphasis on attempting cost effectiveness review rather than focusing on the ability of a patient to afford necessary medicines and the cost sharing requirements imposed by plans as described above. While the statute permits the PDAB to consider cost-effectiveness, it does not require it. If anything, the statute places certain guardrails surrounding the ability of the PDAB to engage in certain types of cost-effectiveness analyses.[13]

In addition, the draft regulations propose including "[f]or insulin drugs marketed in the U.S. and available in Oregon," as being eligible for an affordability review. While we understand the statute[14] references an insulin that may create affordability challenges, considering an entire class of drugs as a "metric" seems inappropriate, because it assumes that the entire class could create "affordability challenges" which is inconsistent with the current statute. Specific to insulin, all three major insulin manufacturers that control approximately 90% of the U.S insulin market recently announced significant decreases to the list price of their insulins effective at the beginning of 2024, meaning that many insulins are currently - or will soon be available - for $35, the same level as in Medicare. By including insulin as a metric, the Board and the State seems to assume that $35 will "create affordability challenges. We recommend the Board remove this metric, given that the statutory provision regarding insulin appears to be a moot issue.

Affordability Review Process should consider more appropriate factors.

It is unclear from the proposed regulation how FDA approval criteria, such as the use of an expedited pathway such as accelerated approval, will inform drug selection. As noted

[13] SB 744 (2021).
[14] Ibid.

earlier, this appears to raise the risk that Board policy will disincentivize use of these pathways which are typically geared towards providing access when there is high unmet need and none or few other therapeutic alternatives. Moreover, affordability must be viewed more globally as many innovative therapies have the potential to generate significant savings to the overall healthcare system because of reduced hospitalizations, acute care episodes, and other medical costs. Some therapies can offer a lifetime of savings, especially innovative durable therapies.

For drugs selected for an affordability review, the draft regulations would allow the Board to request broad disclosures from manufacturers, much of which is proprietary and confidential trade secret information.

Much of the information listed is amongst a manufacturer's most sensitive proprietary and confidential trade secret information. While the statute[15] clearly states the PDAB must keep this information confidential, there were no provisions in the draft regulations that identified the procedures the PDAB would undertake to identify and protect this information, especially with respect to open meetings. We request the Board establish a process that manufacturers can identify their confidential proprietary and trade secret information pursuant to State and Federal law. We strongly urge the Board to adopt more robust confidentiality protections for this data and request that the Board more clearly define how they will use it, and how it will impact their analysis.

Lastly, the PDAB's report should also never disclose any confidential, proprietary and trade secret information. The Board should have a means to ensure that this confidential information is free from disclosure.

The protection of this information guarantees the innovative, healthcare ecosystem can thrive. We also urge the Board to include confidentiality procedures for third-party organizations it might contract with to carry out any functions.

Data from 340B Covered Entities Should Reflect How they are Using the Discounts and the Charity Care they are Providing.

Finally, the statute[16] directs the PDAB to consider data from safety net hospitals that receive discounts under the 340B Drug Discount Program. We understand the reasons why the PDAB may want to know data from safety net providers, however the proposed regulations are missing key data points that have an important effect on affordability—how the safety net provider is using these discounts, and whether these safety net providers pass along discounts to patients or are expanding charity care to indigent patients.

A 2022 study by IQVIA suggests only 1.4% of patients are receiving discounts on 340B drugs at contract pharmacies.[17] This is because while 340B-eligible providers may pass along the discounts to patients, most are not required to do so. Indeed, most disproportionate share (DSH) hospitals do not, and the 340B statute does not require them to, pass along drug discounts to patients. DSH hospitals now account for more than 80% of

[15] SB 744 (2021)

[16] SB 744 (2021).

[17] Martin, Rory, Ph.D., and Illich, Kepler, MA, "Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?", White Paper, IQVIA, September 2022. https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/are-discounts-in-the-340b-drug-discount-program-being-shared-with-patients-at-contract-pharmacies.pdf (Accessed April 23, 2023)

340B sales,[18] while children's and DSH hospitals account for more than 70% of contract pharmacy arrangements.

According to a report by the U.S. Government Accountability Office (GAO), only 12 hospitals that responded to a GAO survey indicated that they provide some or all of the discounts to patients at contract pharmacies.[19]

Further, trends by DSH hospitals in the 340B program are exacerbating health inequity. Physicians are leaving private practice for hospital employment, and hospitals are acquiring community-based physician practices, especially in oncology—often in wealthier locations. Hospitals convert these facilities to outpatient departments so they can participate in the 340B Program. This provides lucrative financial benefits for the hospital.[20,21] As of August 12, 2021, there were 1,129 340B-enrolled DSH hospitals, which had 21,841 registered off-site clinics, only 29% of which were in medically underserved areas.[22] This results in patients having reduced access to private physician offices and fewer community clinics, particularly in areas where they lack public transportation to travel to wealthier areas, which is often the case in poorer, medically underserved areas. This can exacerbate health inequities.

These arrangements do not produce better outcomes for patients. According to a study funded by the U.S. Agency for Healthcare Research and Quality (AHRQ), financial gains for 340B DSH hospitals have not been associated with clear evidence of expanded care or lower mortality among low-income patients.[23]

- In one example, as highlighted in the *New York Times*, Ben Secours Mercy Health (Mercy) in Richmond, Virginia opened new clinics in more affluent areas with the 340B profits from Richmond Community Hospital, which serves a predominantly Black neighborhood. Mercy had slashed services at Richmond Community Hospital, leaving it with a radiology unit in disrepair and closing its intensive care unit. The hospital exists today with a mere emergency room and a psychiatric ward, and no maternity ward. Services have been cutback in an underserved community that sorely needs it, while Mercy has opened nine off-site clinics in wealthier parts of Richmond since 2013. Richmond Community Hospital now has the highest profit margins of any hospital in Virginia generating as much $100 million per year because of its 340B purchases.[24]

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[18] MedPAC, *Overview of the 340B Drug Pricing Program*, May 2015. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf (Accessed: April 25, 2023)
[19] "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement," US GAO, June 2018. https://www.gao.gov/assets/gao-18-480.pdf (Accessed: May 9, 2023)
[20] Desai, Sunita, Ph.D., and McWilliams, J. Michael, M.D., Ph.D., "Consequences of the 340B Drug Pricing Program," New England Journal of Medicine, February 8, 2018. https://www.nejm.org/doi/full/10.1056/nejmsa1706475 (Accessed: April 25, 2023)
[21] Conti, Rena M., and Bach, Peter B., "The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities," *Health Affairs*, October 2014. https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0540 (Accessed: May 23, 2023)
[22] 340B and Health Equity: a missed opportunity in medically underserved areas," Xcenda, 2021. https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_issue_brief_340b_muas_nov2021.pdf (Accessed: April 25, 2023)
[23] *Consequences of 340B*, NEJM, February 8, 2018.
[24] Thomas, Katie, and Silver-Greenberg, Jessica, "Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits," *New York Times*, September 27, 2022. https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html?smid=tw-share (Accessed: April 25, 2023)

- In another example, the Cleveland Clinic, adopted the 340B program in April 2020. While the hospital's main campus is in a medically underserved area, it has hundreds of off-site clinics in wealthier areas with more private health insurance, instead of expanding services in its own backyard. The hospital's 340B profits for the 3-quarters it participated in 2020 were a staggering $136 million.[25]

Finally, studies show DSH hospitals use for-profit pharmacies to expand their reach into more affluent areas, while their use of contract pharmacies in low-income medically underserved areas declined.[26,27] Between 2011 and 2019, the share of 340B retail pharmacies in socioeconomically disadvantaged and primarily non-Hispanic Black and Hispanic/Latino neighborhoods declined by 3.6% and 1.9%, respectively. The percentage of 340B pharmacies in the lowest income neighborhoods declined by 5.6%. However, the number of 340B pharmacies in the highest income neighborhoods increased by 5%.[28]

In another alarming trend associated with DSH hospitals in the 340B program, the expansion of off-site clinics and provider consolidation, especially in oncology, is making care more expensive for the most vulnerable patients. This is because there are fewer community clinics, so patients must seek care at more expensive hospital outpatient departments.[29] According to a study in the *Journal of Health Services Research*, "[t]he probability of a patient receiving cancer drug administration in hospital outpatient departments (HOPDs) versus physician offices increased 7.8 percentage points more in new 340B markets than in markets with no 340B hospital. Per-patient spending on other cancer care increased $1,162 in new 340B markets than in markets with no 340B hospital."[30] Further, according to a study by the Community Oncology Alliance (COA), "340B hospitals' own self-reported pricing data reveals that they price the top oncology drugs at 4.9 times their 340B acquisition costs, assuming a 34.7 percent discount, which is a conservative estimate based on 340B hospital survey data collected by the Centers for Medicare & Medicaid Services (CMS)."[31]

Further, the GAO found, "on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other hospitals in GAO's analysis. For example, in 2012, average per beneficiary spending at 340B DSH hospitals was $144, compared to approximately $60 at non-340B hospitals. The differences

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[25] Mathews, Anna Wilde, et al., "Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients.," *Wall Street Journal*, December 20, 2022. https://www.wsj.com/articles/340b-drug-discounts-hospitals-low-income-federal-program-11671553899 (Accessed: April 26, 2023)
[26] Nikpay, Sayeh, Ph.D., MPH, and Gracia, Gabriela Ph.D., "Association of 340B Contract Pharmacy Growth with County-Level Characteristics, American Journal of Managed Care, March 2022. https://www.ajmc.com/view/association-of-340b-contract-pharmacy-growth-with-county-level-characteristics (Accessed: May 9, 2023)
[27] Lin, John, MD, MSHP, et al., "Assessment of US Pharmacies Contracted with Health Care institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics," *JAMA Health Forum*, June 17, 2022. file:///C:/Users/jgeisser/Downloads/lin_2022_ld_220014_1655237074.69207.pdf (Accessed: May 23, 2023)
[28] Ibid.
[29] Jung, Jeah, Ph.D., Xu, Wendy Y., Ph.D., and Kalidindi, Yamini, M.H.A., "Impact of the 340B drug Pricing Program on Cancer Care Site and Spending in Medicare," *Journal of Health Services Research*, January 22, 2018.
[30] Ibid.
[31] "Examining Hospital Price Transparency, Drug Profits, and the 340B Program 2022," Community Oncology Alliance, September 12, 2022. https://mycoa.communityoncology.org/education-publications/studies/examining-hospital-price-transparency-drug-profits-and-the-340b-program-2022 (Accessed: May 3, 2023)

did not appear to be explained by the hospital characteristics GAO examined or patients' health status."[32]

In one real example, a retiree with neuroendocrine cancer, after receiving treatment from a community oncology clinic for years, was told by her Medicare insurance that she now had to receive her treatment at the local hospital. She was told it was meant to reduce expenses. At her previous clinic, the charge was $4,000 per month, $3,000 per month was paid by Medicare. Yet, for the same medication, she was charged $9,500, of which Medicare only pays $3,800.[33] In this case and many like it, the increase in out-of-pocket costs results because patient cost-sharing is based on the amount the off-site clinic and hospital are reimbursed for the drug, not the amount they paid. This is supported by additional study results that indicate that hospital 340B participation increases cost-sharing amounts billed to Medicare beneficiaries by 16.79%.[34]

Further, in another threat to affordability, hospitals operating as non-profits are providing less charity care, despite the dramatic uptick in 340B sales.[35] Studies show the majority of 340B DSH hospitals (63%) provide charity care at a level less than the national average of all hospitals.[36] Further "nearly one-third (29%) of 340B DSH hospitals provide charity care that represents less than 1% of their total patient costs."[37] This reduces access to free and discounted drugs and services that safety net providers were meant to help.

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BIO appreciates the opportunity to provide feedback regarding the Oregon Prescription Drug Affordability Review Board proposed rules. We look forward to continuing to work with the Board to ensure Oregonians can access medicines in an efficient, affordable, and timely manner. Should you have any questions, please do not hesitate to contact me at 202-962-9200 or at jgeisser@bio.org.

Sincerely,

/s/

Jack Geisser
Senior Director, Healthcare Policy, Medicaid, and State Initiatives

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[32] "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals" U.S. Government Accountability Office, June 2015. https://www.gao.gov/assets/gao-15-442.pdf (Accessed: April 25, 2023)

[33] "The 340B Drug Discount Program in Review: How Abuse of the 340B Program is Hurting Patients," Community Oncology Alliance, September 2017.

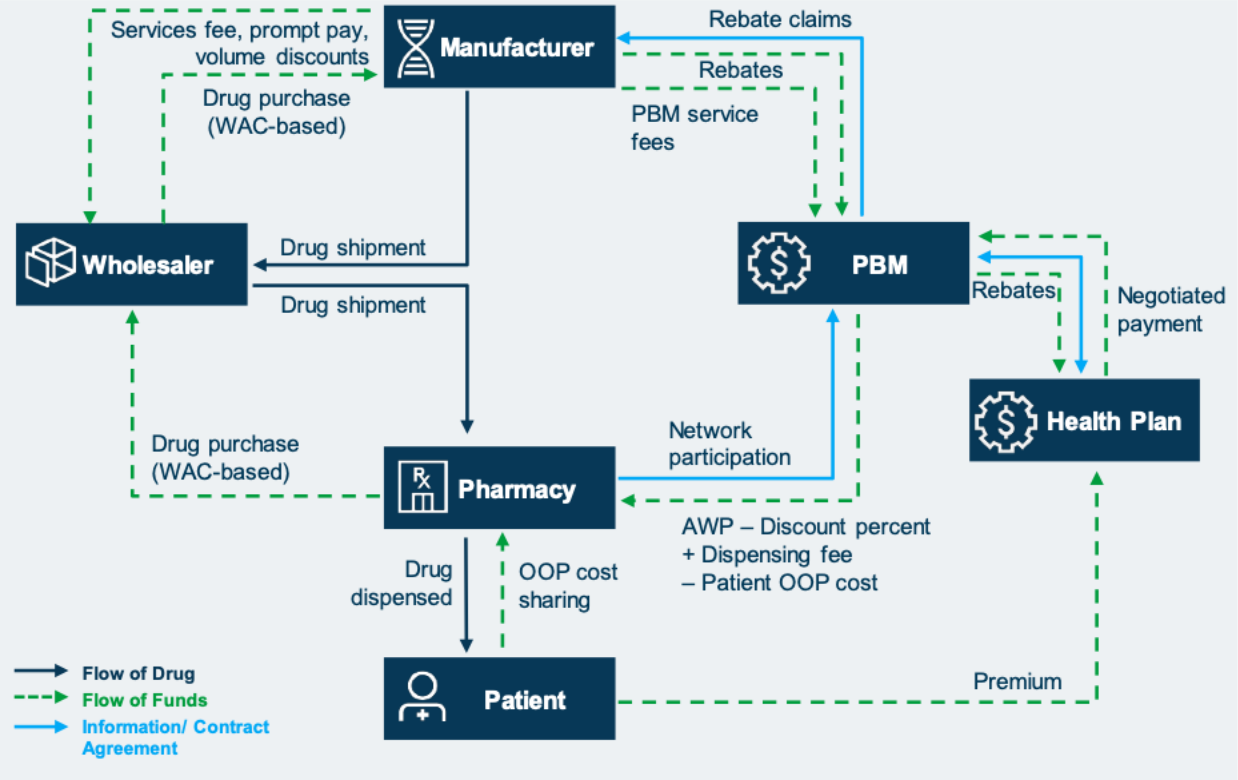
[34] Nikpay, Sayeh, et al., "The Incidence of Hospital Drug Price Subsidies: 340B, Drug Utilization, and Subsidized Medical Care," Conference Study Paper, American Society of Health Economists Conference, American Society of Health Economists. June 26, 2019. https://ashecon.confex.com/ashecon/2019/webprogram/Paper8192.html (Accessed: May 3, 2023)

[35] MedPAC. Overview of the 340B Drug Pricing Program. May 2015. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf (Accessed: April 25, 2023)

[36] "Left Behind: An Analysis of Charity Care Provided by hospitals enrolled in the 340B Discount Program," Air340B, November 2019. https://340breform.org/wp-content/uploads/2021/04/AIR340_LeftBehind-v6.pdf (Accessed: April 25, 2023)

[37] Ibid.

Appendix:
Understanding the Prescription Drug Supply Chain: Note that manufacturers rarely, if ever, sell prescription drugs directly to consumers. Rather, manufacturers work with an array of wholesalers, pharmacies, and pharmacy benefit managers to distribute drugs.



Source: Avalere: Follow the Pill: Understanding the Prescription Drug Supply Chain – May 20,2020

OAR 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 breakthrough therapy designation. For brand-name drugs and biological products, whether there are any approved and marketed generic drugs or biosimilar drugs for the specific brand-name drug or biological product.

(5) Where there are therapeutic alternatives, the cost and availability of potential alternatives.

(6) Whether the prescription drugs have a patent expiration or data exclusivity expiration within 18 months.

(7) For insulin drugs marketed in the U.S. and available in Oregon, criteria for selection may include, but not limited to, those products with the highest insurer reported:

(a) Overall spend;

(b) Per-patient spend; and

(c) Patient out-of-pocket cost.

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.

(2) PDAB will conduct an affordability review by considering, to the extent practicable, the additional following factors:

(a) In addition to the criteria in subparagraph (1)(a): Whether the pricing of the prescription drug results in or has contributed to health inequities:

(A) Under resourced communities; or

(B) Regions with limited pharmacy access.

(b) In addition to the criteria in subparagraph (1)(b): Include off label use of prescription drugs used to treat other conditions.

(c) In addition to the criteria in subparagraph (1)(f): Consider the estimated net price. Cost and availability of therapeutic alternatives to the prescription drug in the state, including any relevant data regarding costs, expenditures, availability, and utilization related to the prescription drug and its therapeutic alternatives. Therapeutic alternative is to mean, "A drug product that contains a different chemical structure than the drug prescribed, but is in the same pharmacologic or therapeutic class and can be expected to have a similar therapeutic effect and adverse reaction profile when administered to patients in a therapeutically equivalent dosage."

(d) In addition to the criteria in subparagraph (1)(d), (1)(e), and (1)(g): Consider information submitted by manufacturers related to patient assistant programs and coupons.

(e) Current wholesale acquisition cost of the prescription drug and changes in the prescription drug's net cost over time.

(f) Analysis to consider acquisition cost for pharmacies.

(g) Effect of price on consumers' access to the prescription drug by reviewing changes in pricing, expenditure, and utilization over time.

(h) Potential market for prescription drug for labeled and off-label indications and budget impact on various payors in the state.

(i) In addition to the criteria in subparagraph (1)(j):

(A) To the extent such information can be quantified, the relative financial effects of the prescription drug on broader health, medical, or social services costs, compared with therapeutic alternatives or no treatment.

(B) To the extent such information can be quantified, the total cost of the disease and the drug price offset.

(j) In addition to the criteria in subparagraph (1)(k): Patient copayment or other cost sharing data, across different health benefit plan designs, including:

(A) Copayment and coinsurance impacts from:

(i) Patient assistance programs; and

(ii) Copay coupons;

(B) Deductible;

(C) Patient out-of-pocket costs; and

(D) Any other cost sharing data.

(k) Input from Specified Stakeholders:

(A) Patients and Caregivers

(i) Seek input from patients and caregivers affected by a condition or disease that is treated by the prescription drug under review by gathering information related to:

(I) The impact of the disease;

(II) Patient treatment preferences;

(III) Patient perspective on the benefits and disadvantages of using the prescription drug;

(IV) Caregiver perspective on the benefits and disadvantages of using the prescription drug; and

(V) Available patient assistance in purchasing the prescription drug.

(ii) In seeking additional information, attempt to gather a diversity of experience among patients from different socioeconomic backgrounds.

(B) Individuals with Scientific or Medical Training: Seek input from individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review, including:

(i) The impact of the disease;

(ii) Perspectives on benefits and disadvantages of the prescription drug, including comparisons with therapeutic alternatives if any exist; and

(iii) Input regarding the prescription drug utilization in standard medical practice, as well as input regarding off label usage.

(C) Safety Net Providers: heath care providers that care for uninsured patients and patients with low income and receive discounted prices on prescription drugs through section 340B of the federal Public Health Service Act (42 U.S.C. 256b):

(i) The utilization of the prescription drug by the safety net provider

patients;

(ii) Whether safety net providers receive a 340B discount for the prescription drug;

(iii) Where safety net providers do not receive a discount, whether access to the prescription drug is impeded; and

(iv) Any other topics identified by safety net provider stakeholders.

(D) Payers

(i) Total cost of care for disease(s);

(ii) Cost of the prescription drug to the payer;

(iii) The availability of therapeutic alternatives on the formulary;

(iv) Coverage mandates and impacts to per member per month or premiums;

(v) Affordability concerns of the prescription drug, from employer groups and other plan sponsors; and

(vi) Other costs to consider.

(L) Rebates, Discounts, and Price Concessions:

(A) To the extent practicable, estimated manufacturer net-sales or estimated net-cost amounts (including rebates, discounts, and price concessions) for the prescription drug and therapeutic alternatives; and

(B) Financial assistance the manufacturer provides to pharmacies, providers, consumers, and other entities.

(m) Information from the Oregon Health Authority (OHA), Health Evidence Review Commission (HERC), and Pharmacy and Therapeutics Committee (P&T) that is relevant to the prescription drug or therapeutic alternative under review.

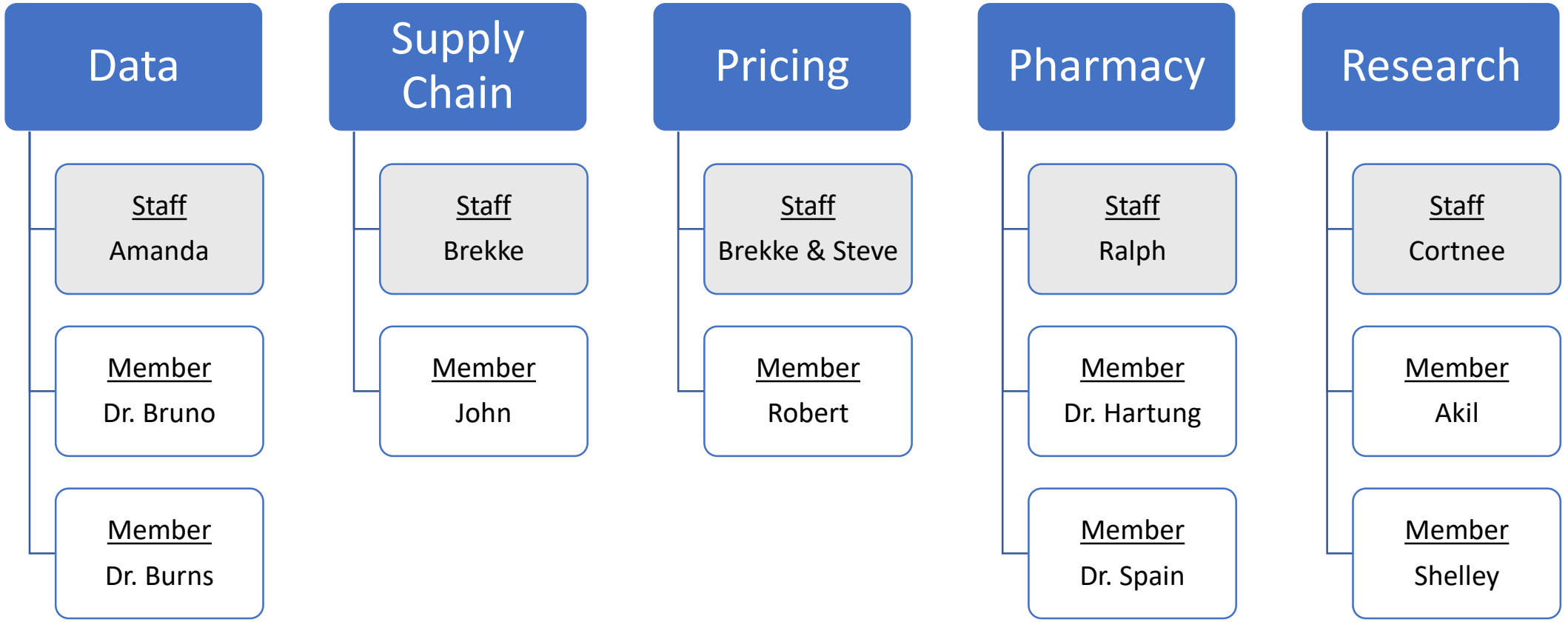
(n) In addition to the criteria in subparagraph (1)(m): A prescription drug approved by the FDA for other indications, in addition to a rare disease or condition, is not exempt from an affordability review for those other indications.

Oregon Prescription Drug
Affordability Board

Member Staff Touch Bases

Cortnee Whitlock

program & policy analyst


Data
Staff
Amanda
Member
Dr. Bruno
Member
Dr. Burns
Supply Chain
Staff
Brekke
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John
Pricing
Staff
Brekke & Steve
Member
Robert
Pharmacy
Staff
Ralph
Member
Dr. Hartung
Member
Dr. Spain
Research
Staff
Cortnee
Member
Akil
Member
Shelley

Data:

- Six data sections under OAR 925-200-0020
- Manufacturing, health insurance plans, and insulin data provided by the Drug Price Transparency program

Research:

- Seven data sections under OAR 925-200-0020
- Health inequities, pharmacy access, and stakeholder feedback

Supply Chain:

- Five data sections under OAR 925-200-0020
- Examine how manufacturers, pharmacy benefit managers, and health insurance plans impact the unaffordability of prescription drugs

Pricing:

- Ten data sections under OAR 925-200-0020
- Examine WAC, rebates, PAP, discounts, price concessions, cost over time, acquisition costs, and any other pricing or costs impacting affordability

Pharmacy:

- Thirteen data sections under OAR 925-200-0020
- Rx drug uses, disease treatment, therapeutic alternatives, labeled and off-label indications, and any other criteria associated with pharmacy costs.

Overlap:

- Five data sections under OAR 925-200-0020 that overlap.