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: **January 18, 2023** | *Time*: **9:30 a.m.**
This agenda is subject to change.

Meeting name	**Prescription Drug Affordability Board**
Meeting location	Virtual
Zoom link	Click here to 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; Yasu Tanaka, data analyst, Melissa Stiles, administrative specialist; Joanna Tucker Davis, 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	5 minutes
☐ Presentation by: Oregon State Pharmacy Association Questions from board members	Brian Mayo and Kevin Russell	25 minutes
☐ Legislative bills and session discussion	Jesse O'Brien	15 minutes
☐ PDAB Policies and Procedures Board approval of amended Public Comment Policy	Cortnee Whitlock	5 minutes
☐ Board approval of 2023 work plan Affordability review criteria and fee development	Cortnee Whitlock	5 minutes
☐ Board discussion on rulemaking Fee structure and affordability reviews	Cortnee Whitlock	30 minutes
☐ Announcements	Staff	5 minutes
☐ Public comment	Chair Patterson	10 minutes
☐ Adjournment	Chair Patterson	2 minutes

Next meeting

February 15, 2023, at 9:30 a.m.

Accessibility

The meeting is accessible to persons with disabilities. A request for hearing impaired assistance and accommodations for persons with disabilities may be made to Melissa Stiles by email at pdab@dcbs.oregon.gov or by phone at 971-374-3724, at least 48 hours in 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 Meeting
Wednesday, December 14, 2022
Draft Minutes

Call to order and roll call
Chair Akil Patterson called the meeting to order at 9:34 a.m. and asked for the roll call.

Board Members present: Vice Chair Shelley Bailey, Dr. Richard Bruno, Dr. Amy Burns, Dr. Daniel Hartung, Chair Akil Patterson, Robert Judge (alternate), John Murray (alternate).
Board members absent: Dr. Rebecca Spain (alternate)
Chair appointed John Murray, alternate, to vote in today's meeting if necessary.

Approval of the minutes
Chair Akil Patterson asked if board members had any changes to the Nov. 16, 2022, minutes on Pages 3-7 in the agenda packet: https://dfr.oregon.gov/pdab/Documents/20221214-PDAB-document-package.pdf. **Richard Bruno** moved to approve and **Vice Chair Shelley Bailey** provided a second.

MOTION by Richard Bruno to approve the November 16, 2022, minutes.
Board Voice Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, John Murray, Shelley Bailey, Akil Patterson.
Nay: None.
Motion passed.

Program update: Executive Director Ralph Magrish said the Drug Price Transparency (DPT) program held its annual hearing Dec. 1 to review findings and recommendations for the Oregon Legislature. They heard stories from Oregonians about financial hardships in seeking affordable drugs and extraordinary efforts to access medication, and the role of the community pharmacist in supporting them. The DPT hosted two panels, one on insulin pricing with representatives from the National Academy for State Health Policy (NASHP), Regence Blue Cross Blue Shield of Oregon, OSPIRG, and Civica Rx. The second panel on the pharmaceutical supply chain and pharmacy benefit manager (PBM) rebates included representatives from Pharmaceutical Care Management Association (PCMA), PhRMA, Healthcare Distribution Alliance (wholesaler trade association), and Oregon State Pharmacy Association (OSPA). Sen. Deb Patterson, Rep. Rob Nosse, and Rep. Ron Noble were moderators. The hearing and report are available on the DPT website: https://dfr.oregon.gov/drugtransparency/Pages/annual-reports.aspx. DPT is the program that will provide the board with a quarterly list of drugs and insulin products beginning next quarter for board affordability reviews.

In January, staff will post a research analyst position. Staff is working on a December newsletter. Staff will ask representatives at PORTAL to do a board presentation about affordability reviews soon. PORTAL is the Program on Regulation, Therapeutics, and Law, within the Division of Pharmacoepidemiology and Pharmacoeconomics at the Harvard Medical School and Brigham and Women's Hospital. Staff is exploring a contract with PORTAL for technical assistance with affordability review criteria and reviews. PORTAL currently supports the Colorado program and is a national leader in this area. Staff is also updating the PDAB web page and will begin posting all written public comments submitted to the board. Staff now has access to the state All Payer All Claims (APAC) data base housed at Oregon Health Authority for use in fee development work, consistent with board statutory requirements. The board will hear more about this at the January meeting when it kicks off the affordability review process.

Board approval of final reports: **Cortnee Whitlock**, policy analyst, thanked the board for their contributions, guidance, and support, saying the board's experience and insight have been extremely valuable during the development of the annual reports. The unedited version of the report is located on Pages 8-57 in the agenda document: https://dfr.oregon.gov/pdab/Documents/20221214-PDAB-document-package.pdf. She displayed on the screen for board members a report version with edit notes and scrolled through to show board members changes incorporated as a result of their feedback during the Nov. 16 meeting. In the generic report, staff added language about biologicals and biosimilars on Page 15. Robert Judge said price inflation on brand drugs has really affected the ratio. Cortnee Whitlock said staff can update it and also incorporate those ideas into the next generic drug report due in June 2023. She continued scrolling through the document to point out an addition about generic co-pays on Page 15 and high-cost brands on Page 20. On Page 25, staff added information about the prescription drug supply chain for Medicare Part D. On Page 31, staff added a graph about fee-for-service. Daniel Hartung recommended changing the label "encounter" and Amy Burns suggested the word CCO instead. Amy Burns suggested using "pharmacy claim" instead of "encounter" in other parts of the report. On Page 39, staff changed the title to "health inequities in diverse communities." The conclusion on Page 47 shows the recommendations approved by the board Nov. 16. John Murray said he appreciates the depths of the reports. Chair Patterson asked for a motion and a second. John Murray made a motion to approve the Rx Generic Drug Report and Rx Distribution Payment System Report as amended. Richard Bruno provided the second.

MOTION by John Murray to approve final reports as amended.
Board Vote:
Yea: Richard Bruno, Amy Burns, Daniel Hartung, John Murray, Shelley Bailey, Akil Patterson.
Nay: None
Motion passed.

Chair Patterson thanked board members, staff for their work on the reports, knowing it has been a heavy lift.

2023 presentations to the board: Ralph Magrish, executive director, congratulated and thanked the board for the final report approval, a sentinel accomplishment. He and Chair Patterson worked on a model for board presentations, beginning today with asking each member to identify groups they would like to hear from in 2023. The focus will be on issues-based solutions to drug affordability, which means presenting issues that are important to the speaker, with solutions. There will be one, 15-minute presentation per meeting, with 10 more minutes for board questions. The purpose of the presentations will be providing board members information to better understand issues, especially as the board prepares for affordability reviews. Presenters will be asked to submit slides 10 days before the meeting so the board can meet its statutory obligation of posting materials one week before the meeting. Chair Patterson will prepare a letter about the process for other organizations wishing to present. Organizations identified by the board today will take priority in scheduling. If Harvard Medical School's PORTAL and other similar groups are available, they will get priority scheduling as well. He asked members to share requests.

Vice Chair Shelley Bailey recommends pharmacy services administrative organizations (PSAO), companies that contract with PBMs on innovative solutions. She would like to invite Eyad Farah, president of Health Mart Atlas, the nation's largest PSAO for small chain and community pharmacies.

John Murray would like to hear from the Oregon State Pharmacy Association on their recent report and from the Secretary of State's office when they complete the audit on PBMs. He would also like to hear from an insurer group about how prescription medication costs travel through their system, from beginning to end, where the money goes and how they ensure the patient is getting the best benefit possible.

Chair Akil Patterson would like to hear from PhRMA about how they would benefit and reach out to low, socio-economic communities, and how marketing dollars have been spent in relation to actual drug creation costs.

Dr. Richard Bruno would like to hear from primary care providers at federally-qualified health centers, or with 340B pharmacies, or advocacy groups such as Oregon Primary Care Association, or a group representing 340B pharmacies. He would like to hear from Insulin for All or other patient advocacy groups.

Dr. Daniel Hartung recommends Institute for Clinical and Economic Review (ICER) to learn about systematic and cost-effective analysis of price changes and unjustified price increases, about their process and what they are doing to support payers, public, and private agencies through products they generate.

Robert Judge recommends generic manufacturers, Civica or CostPlus Drug Company, so the board can better understand the influences on the supply chain and payer costs.

Vice Chair Shelley Bailey would like to hear from CostPlus Drugs. She recommends 3AxisAdvisors join the Oregon State Pharmacy Association (OSPA) presentation for their work on the report. For 340B stakeholders, she recommends 340B Coalition. She also recommends Matt DiLoreto from the trade group Healthcare Distribution Alliance, to hear about wholesaler innovative solutions.

Dr. Amy Burns recommends someone from the Health Evidence Review Commission, HERC, which prioritizes efficient treatments for disease stages for Medicaid. She also recommends hearing from PEBB, OEEB or other state employee systems with drug programs that drive a lot of cost, or other large groups with accessible information that make difficult decisions on pharmacy coverage. Amy Burns said HERC is a 13-member, governor-appointed committee made up of health professionals and consumers, overseeing various committees. Their mandate is to research literature, clinical practice guidelines, and standard of care for health conditions for Oregonians, providing a guidance document called the Prioritized List of Health Services, partly based on cost. That list governs what is covered and not covered for Oregon Medicaid, which serves 1.5 million people in Oregon. Originally, it was meant to be a guide for all Oregonians, she said. **John Murray** said he is curious how to dovetail that into the board's work and wonders how the board best finds affordable medications, making suggestions to achieve those therapeutic ends with the medications available. He said new diabetes medications are $400 per month but are far better than some older ones. How does the board dovetail that into affordability for those medications and access for people who need it most? **Amy Burns** said HERC looks at the system as a whole, not primarily at medications. She agrees about diabetes medications and said new diabetes drugs can be as much as $1,200 per month, expensive but with significant outcomes. If the board wanted to hear specifically about Medicaid, that would be the State Pharmacy and Therapeutics Committee, which takes cost into consideration, but with privileged information. Ralph Magrish agreed the rebate information is not publicly available. He said about one in four Oregonians receive that coverage and it is important for the board to hear solutions for all.

Vice Chair Shelley Bailey agrees with John Murray about hearing from the Secretary of State's office once their CCO PBM performance audit is complete.

Robert Judge recommends hearing from Myers and Stauffer about acquisition-based cost pricing for prescription drugs.

Ralph Magrish thanked the board for their recommendations and said staff will schedule presentations throughout the year.

2023 roadmap: Cortnee Whitlock, policy analyst, reviewed the roadmap for board work in 2023 shown on Pages 58-61 of the agenda packet: https://dfr.oregon.gov/pdab/Documents/20221214-PDAB-document-package.pdf. Beginning in January, the board's primary focus will be around rule development and affordability review criteria. They will hold rulemaking advisory committees to engage stakeholders and the public. During rulemaking hearings, no more than two board members can attend due to Oregon public meeting laws. Staff will provide an update about the hearings at board meetings. On June 1, the generic drug report is due to the Legislature. The report will be similar to this year's report with updates or additional information. Rules must be completed by July 1. Beginning in August, the board will look at implementation of fee structures and the affordability criteria for the nine drugs and insulin product. In September, the board will also begin studies for Section 5 criteria around price trends and affordability and recommendations. Staff will use the same process as this year, providing outlines and requesting draft sections from board members. Amy Burns asked if the generic report would include biosimilars. Ralph Magrish said it could be part of the conversation next year to include biosimilars in the drug list. Robert Judge agreed biosimilars need to be part of the conversation, especially with the most expensive drug having a biosimilar coming to market next year. Cortnee Whitlock said the annual report will be due by Dec. 31, 2023.

Public comment: The chair allocated three minutes for public comment. He called on the person who signed up in advance to speak, Tonia Sorrell-Neal, Pharmaceutical Care Management Association, who provided testimony to the board.

Adjournment: The meeting was adjourned at 10:47 a.m. **Richard Bruno** made the motion, and **John Murray** provided the second.

MOTION by Richard Bruno to adjourn the meeting.
Board Voice Vote
Yea: Richard Bruno, Daniel Hartung, Robert Judge, John Murray, Shelley Bailey, Akil Patterson.
Nay: None.
Motion passed.

The Current State of Community Pharmacy Pricing in Oregon

Findings of the Report: Understanding Pharmacy Reimbursement Trends in Oregon by 3 Axis Advisors

Brian Mayo, Executive Director, Oregon State Pharmacy Association

Kevin Russell RPh, Central Oregon Director, Oregon State Pharmacy Association

What OSPA is hearing from pharmacists, public, and insurers

- **Chain pharmacists**: work conditions in chain pharmacies are horrible and unsafe due to cutbacks in labor (assumed to be due to low reimbursements)
- **Public**: service in chain pharmacies has deteriorated to the point that it can take days to get prescriptions and pharmacies will not answer phones or provide help when needed
- **Independent pharmacists**: total reimbursements are too low to run a sustainable business and we will have to close if this continues (Bi-Mart)
- **Insurers**: community pharmacies are too expensive, and we need members to use mail order pharmacies to save money

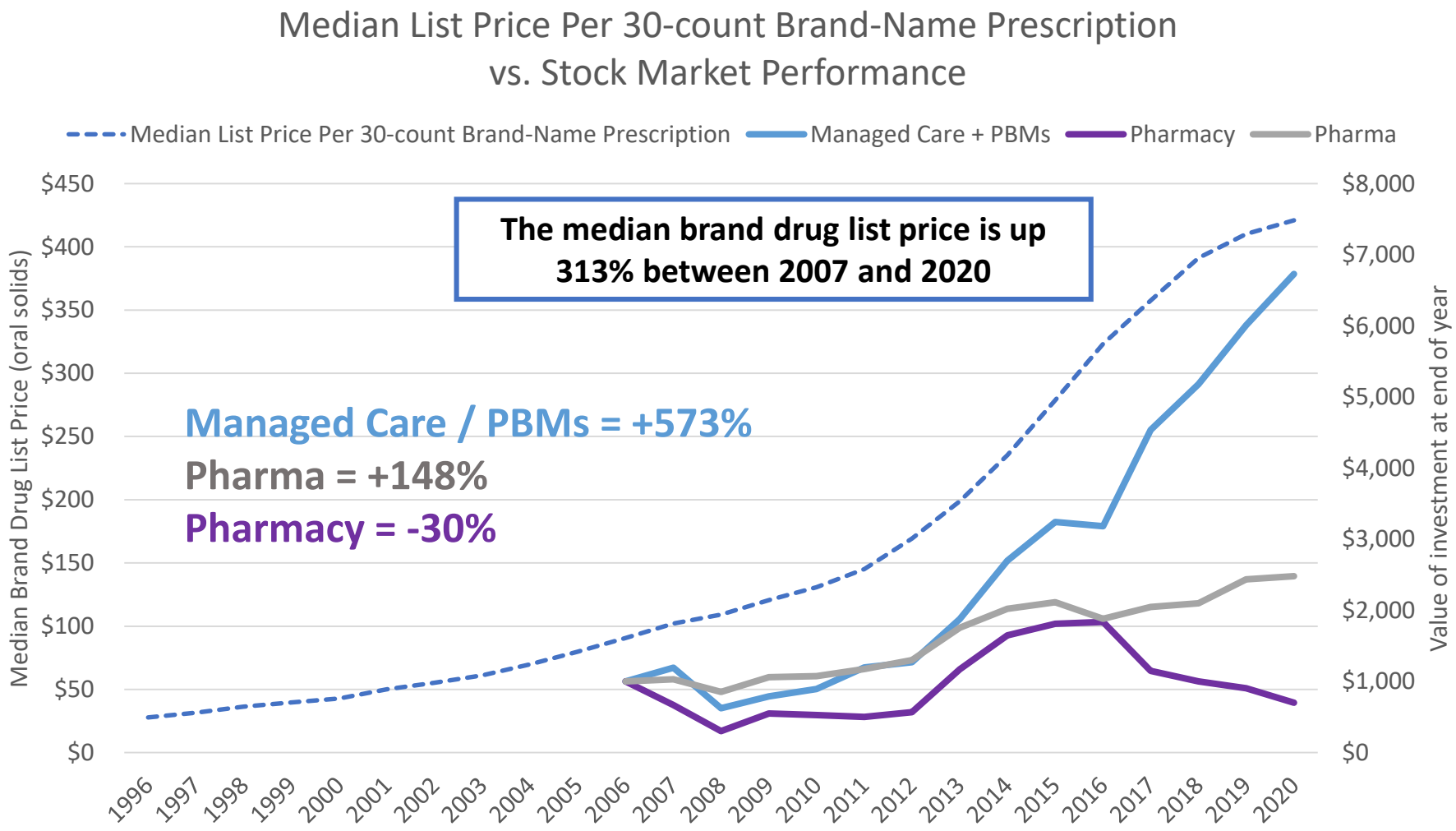
OSPA: Let's study what is really happening

OSPA commissioned a study by 3-Axis Advisors

- 86 of Oregon's estimated 534 retail community pharmacies (16.1%) participated
- Examined prescription claims and reimbursement data for 3 years (2019-2021)
- Medicaid reimbursements to pharmacies from CCO PBMs were compared to reimbursements reported to the Oregon Medicaid program as reflected in the State Drug Utilization Database

Understanding Pharmacy Reimbursement Trends in Oregon can be accessed at Oregon State Pharmacy Association (oregonpharmacy.org)

Who is really benefiting from higher U.S. drug list prices?



Source: MediSpan Price Rx, Yahoo Finance, 3 Axis Advisors

Managed Care / PBMs = Cigna, CVS, United Healthcare, Centene, Molina, Anthem, Humana
Pharma = Pfizer, Bristol Myers Squibb, Viatris, Teva, Merck, J&J, AstraZeneca, Novartis, GSK, Sanofi
Pharmacy = Walgreens, Rite Aid
NOTE: 2020 stock prices are through Dec 10, 2020

Pharmacy Cost to Dispense

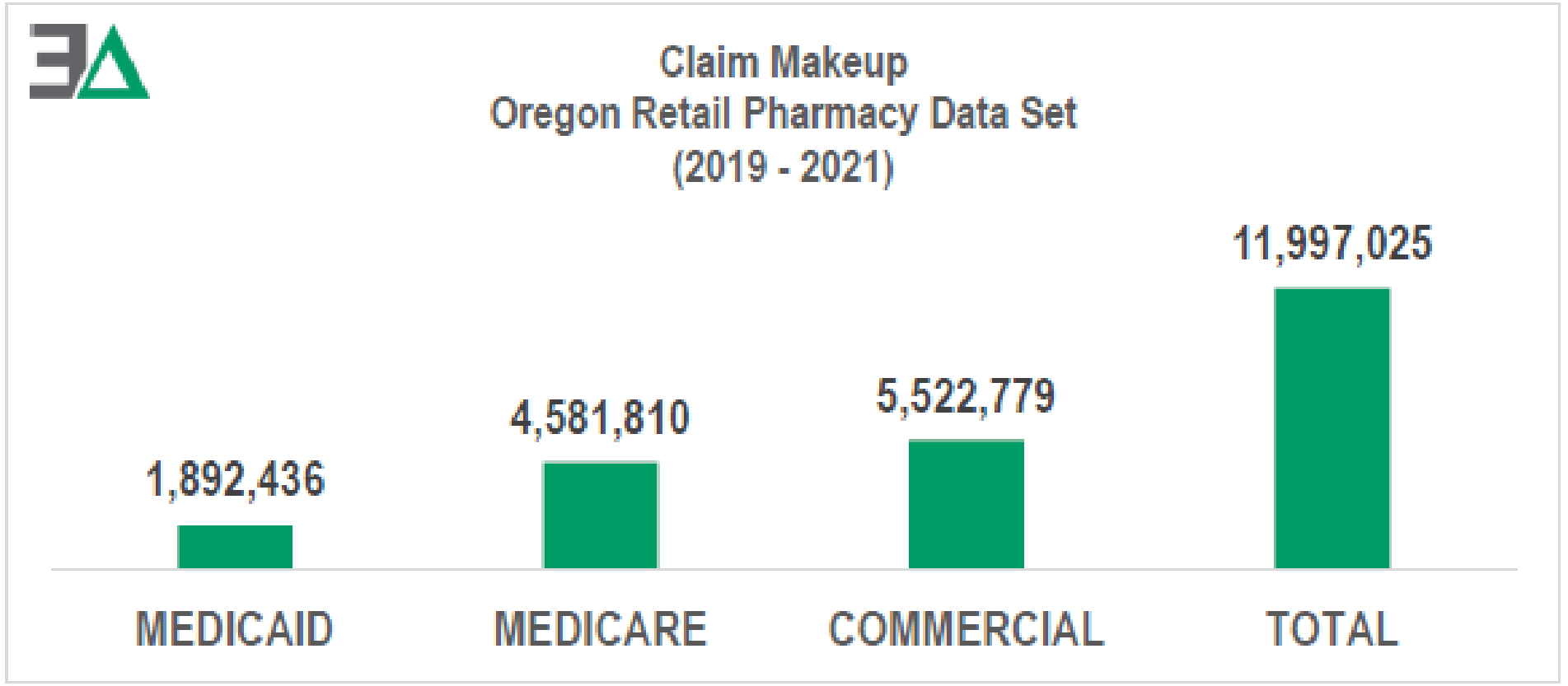
- $12.40 = a pharmacy's cost to dispense a prescription in 2018
  This was based on an extensive national study with 24% of US pharmacies participating. This factors in all non-drug costs pharmacies incur as part of doing business and does not include profit.

- $15.00 = a reasonable 2023 estimate of a pharmacy's cost to dispense a prescription
  Payment below this level is not sustainable to provide good healthcare and service and to open new pharmacies in areas where they are needed.

- $7.00 = Average margin being paid to Oregon pharmacies per our reimbursement report

https://www.nacds.org/pdfs/pharmacy/2020/NACDS-NASP-NCPA-COD-Report-01-31-2020-Final.pdf

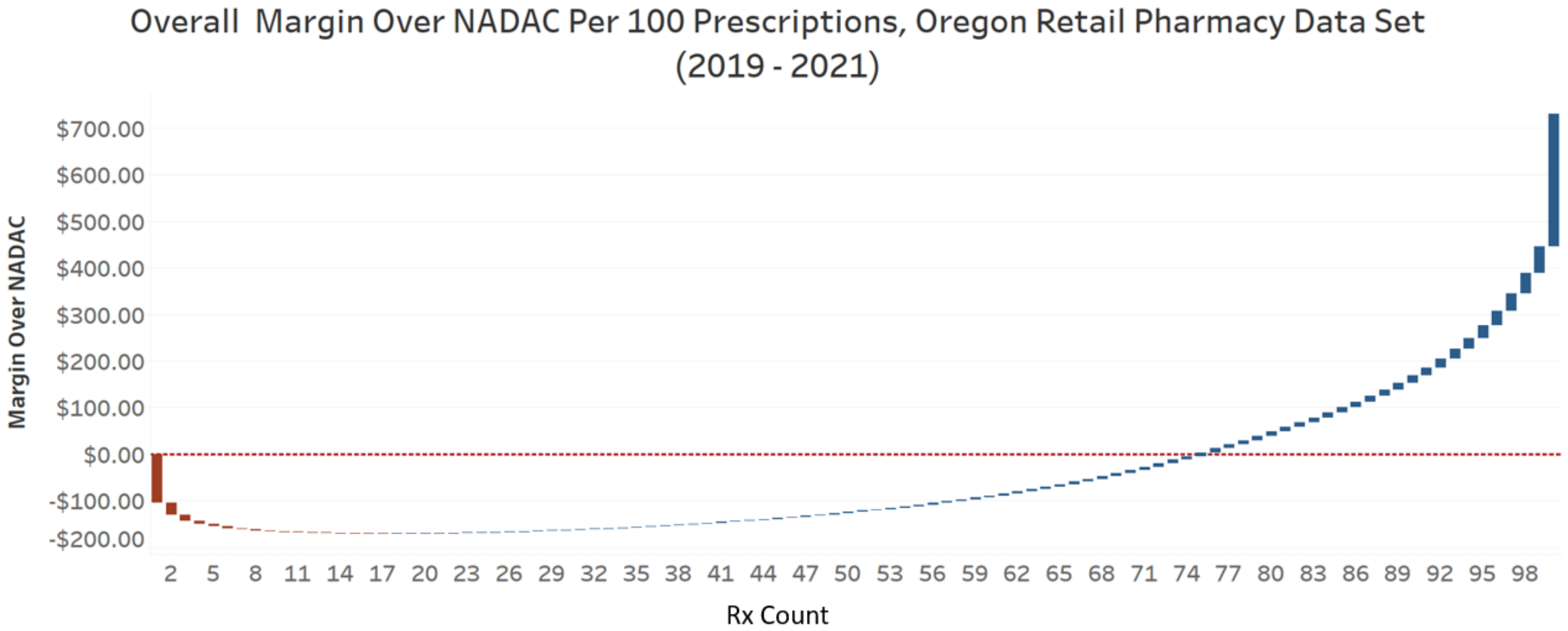
The Understanding Pharmacy Reimbursement Trends in Oregon report looked at almost 12 million claims!



Source: 86 Oregon retail pharmacies in study

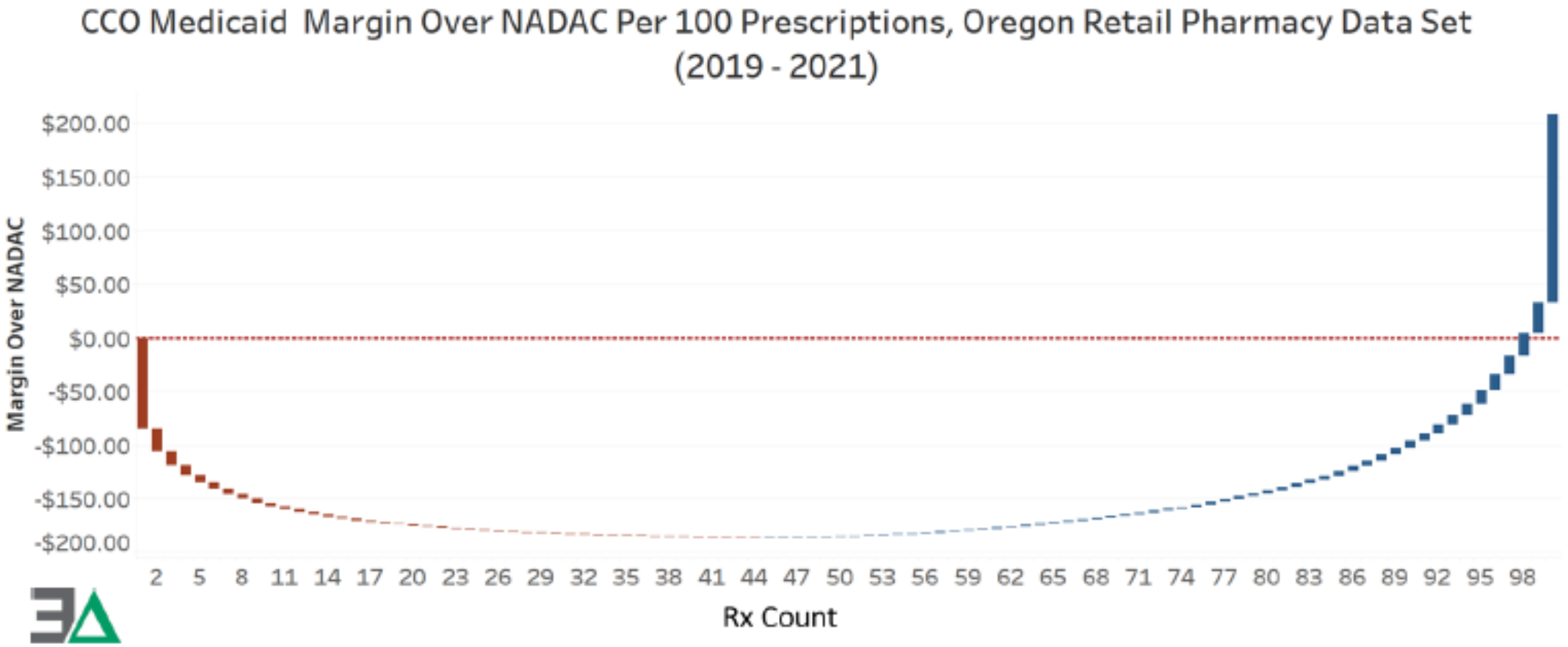
Overall Pharmacy Payment

Average margin is $7
19/100 reimbursements are below cost
75/100 prescriptions are needed to break even on drug cost
Top 3% of prescriptions account for 50% of margin- not equitable between pharmacies



CCO Medicaid Payment

Average margin is $2
44/100 reimbursements are below cost
97/100 prescriptions are needed to break even on drug costs
Top 2% of prescriptions are the entire margin



Sources: 86 Oregon retail pharmacies in study, CMS NADAC, 3 Axis Advisors, LLC

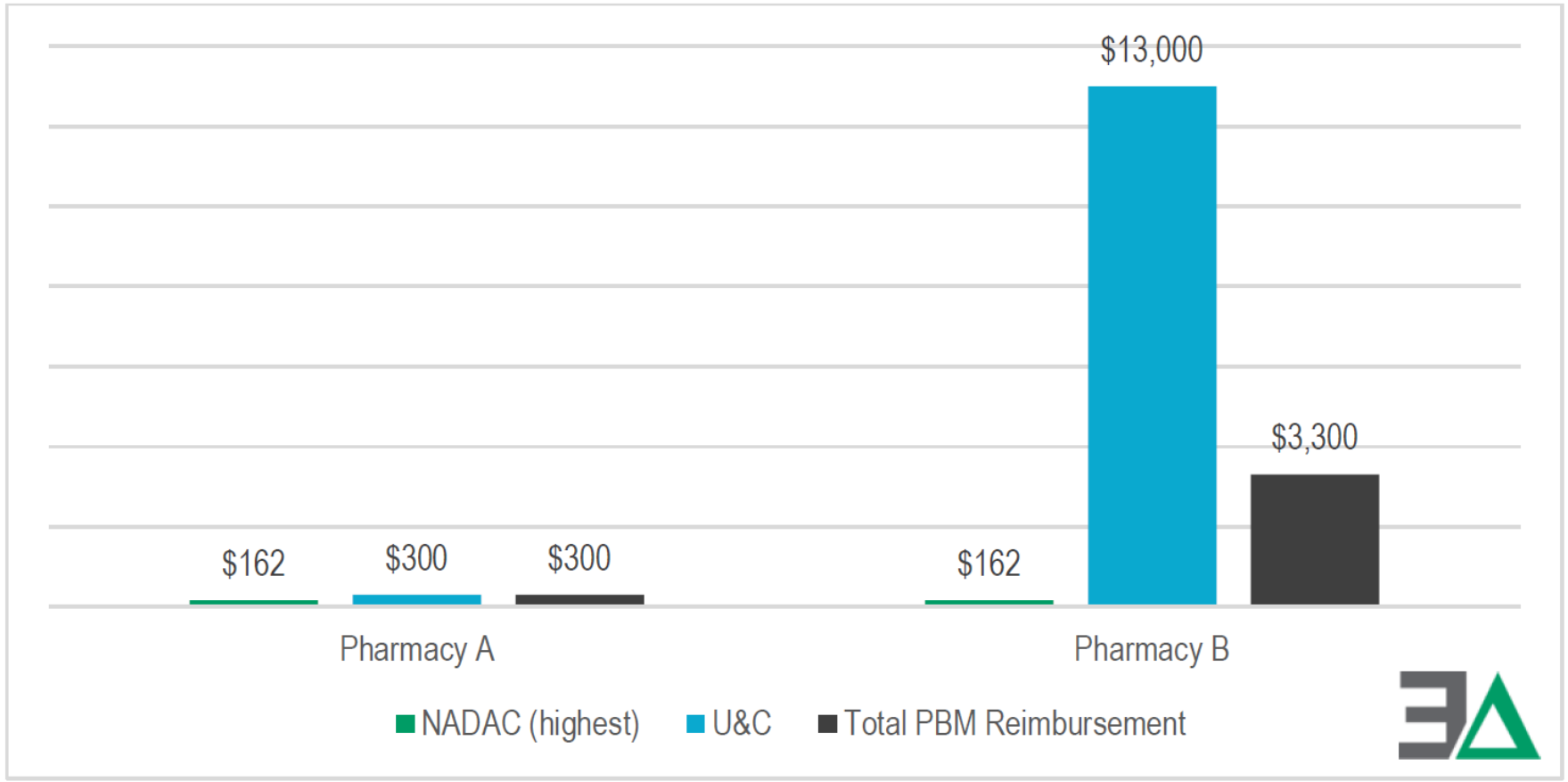
Medicaid pays lower margin % to pharmacies in areas with lower household income

Figure 53: Gross Pharmacy Margin % in Overall Oregon Medicaid Relative to Median Household Income in Geographic Area (Street Address of Pharmacy)

Sources: 72 Oregon retail pharmacies in study, CMS NADAC, Medi-Span, US Census Bureau, 3 Axis Advisors, LLC

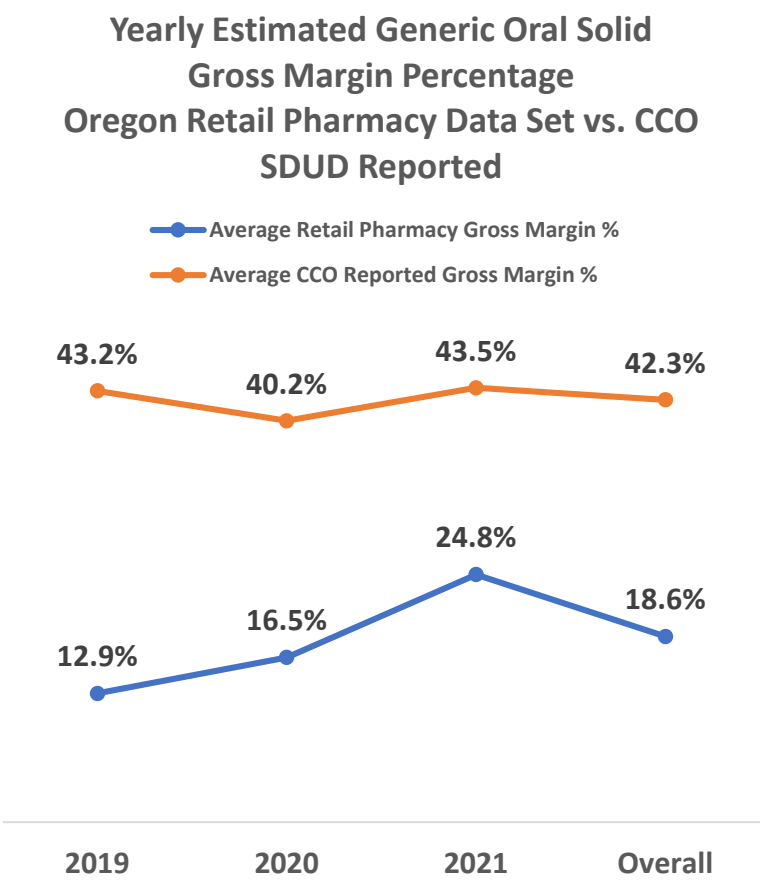
Pharmacies charge high prices to survive as they must capture top 1% margin claims and they do not know which claims those will be

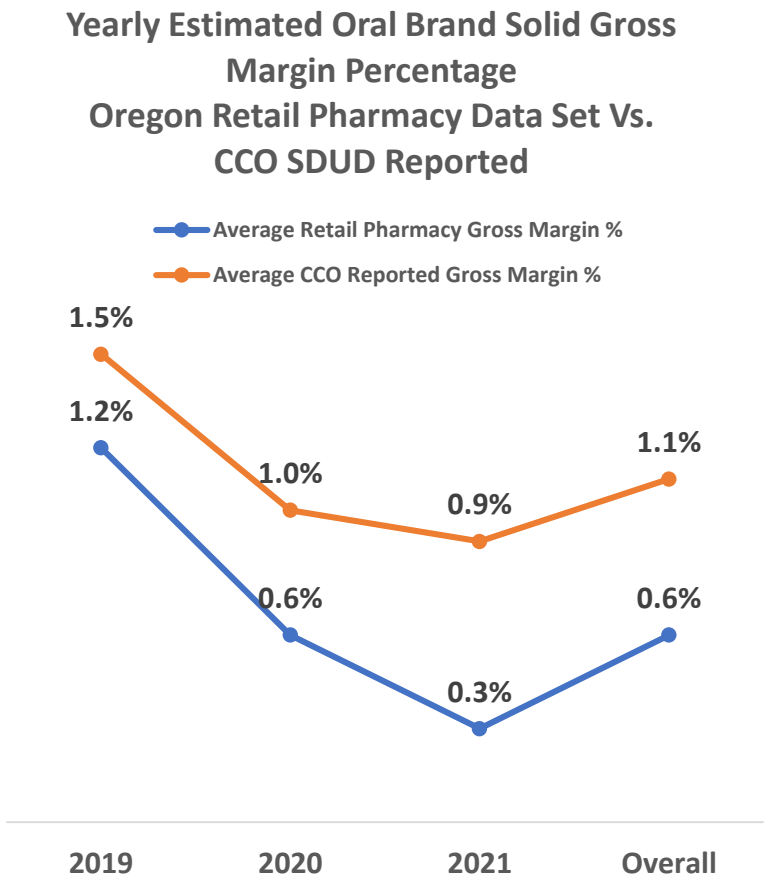
Figure 64: Same Plan Analysis of Imatinib Mesylate 400 mg Reimbursement Across Two Different Pharmacies (2021)



Sources: 86 Oregon retail pharmacies in study, CMS NADAC, 3 Axis Advisors, LLC

Data suggests PBMs are capturing spread in pricing or paying affiliated pharmacies a higher margin



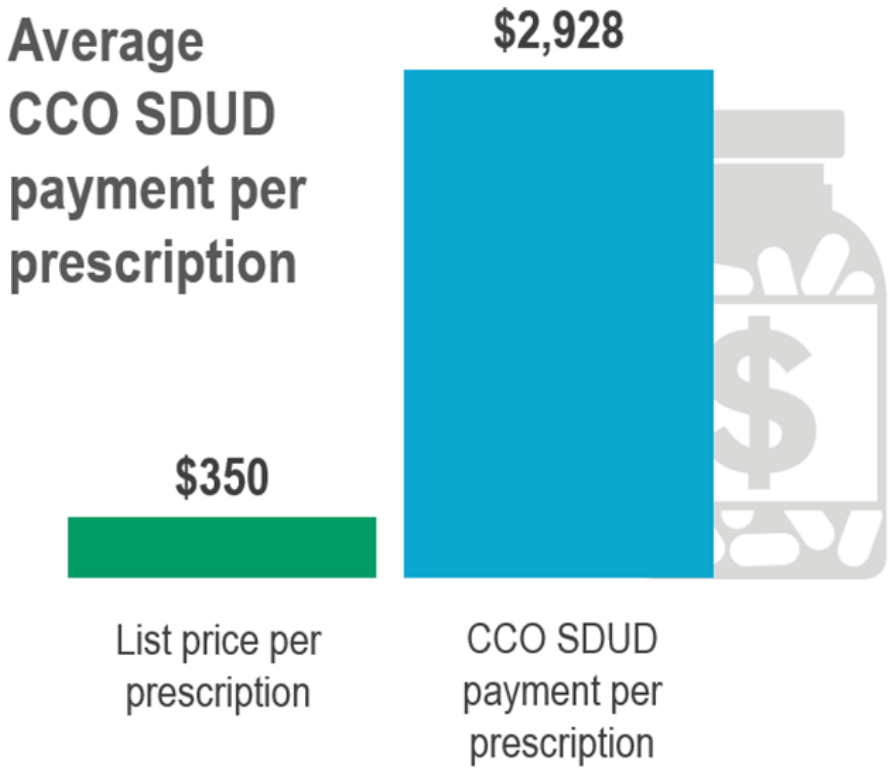


The PBM boondoggle on dimethyl fumarate

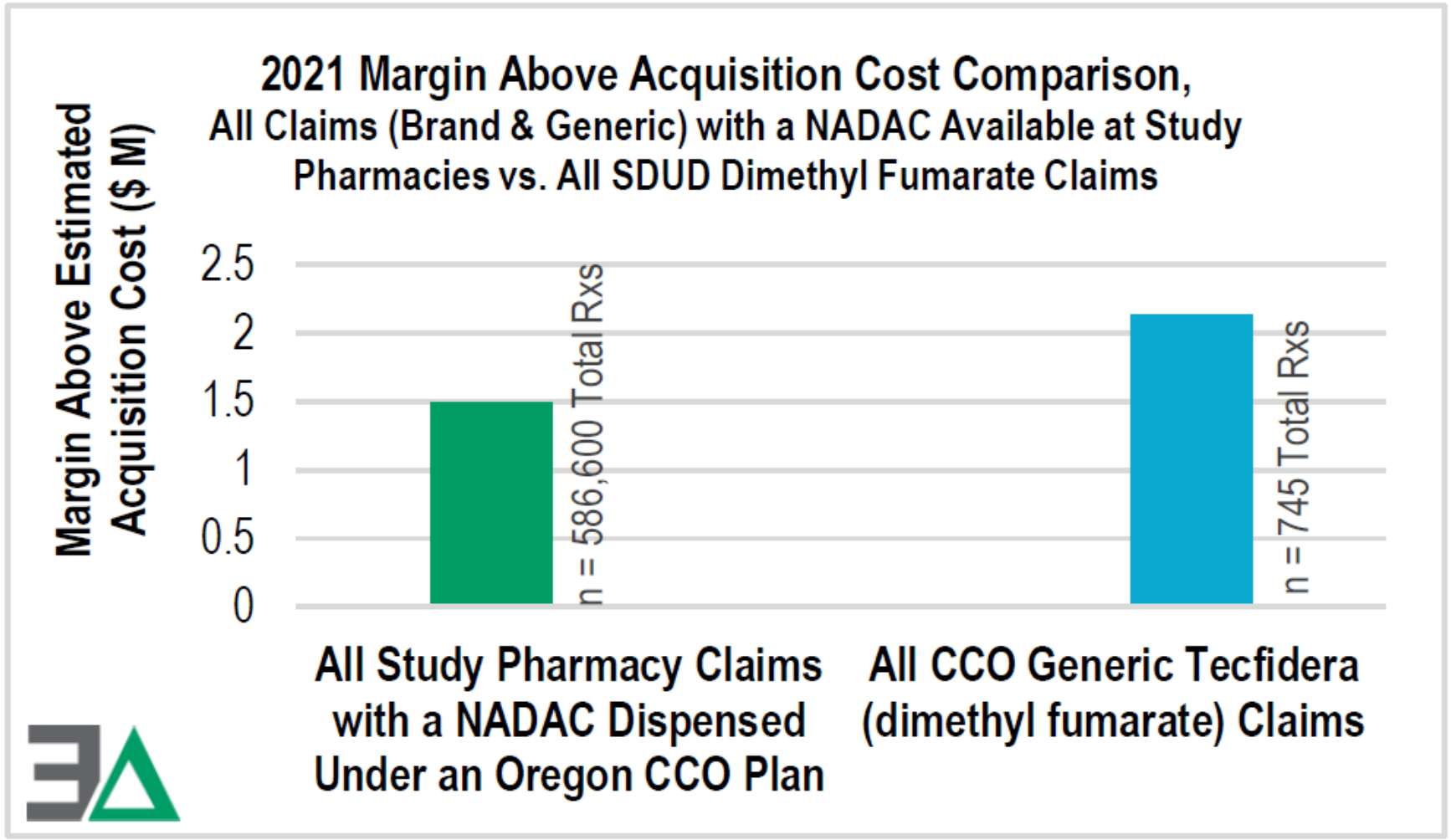
PBMs can steer prescriptions to their own affiliated pharmacies and decide what to pay themselves

In 2020 the drug Tecfidera™ went generic (dimethyl fumarate). By January 2021, the pharmacy acquisition price of the generic had dropped from the $8,275 brand price to $350 (WAC). There were no study pharmacy claims for this drug in 2021 indicating it was restricted and likely filled at a PBM affiliated pharmacy.

Per SDUD, Oregon Medicaid was charged an average of $2,578 in margin over WAC for each claim, totaling $1,920,889!



CCO PBMs paid their affiliated pharmacies more margin for one drug than they paid all study pharmacies for all drugs combined!



OSPA Conclusions

- PBMs are steering patients to their own affiliated pharmacies for their own profit and this has resulted in increases to the cost of care.
- PBMs are likely engaging in profit taking from spread pricing, inflating the cost of community pharmacies to payors.
- Current pharmacy payment models provide the wrong incentives for pharmacies to maintain high prices and limit access to patients with low paying prescriptions.
- Margins paid by third parties to Oregon community pharmacies are too low to sustain a business or provide adequate public access to prescriptions and healthcare.
- Adequate pharmacy margins are available without increasing total cost of drugs or care, they are just being distributed inequitably.

Recommended solutions

Cost + fee reimbursement solves many problems

2023 HB 3013 requires pharmacy payment no less than “Oregon Average Acquisition Cost” + the pharmacy dispensing fee established by the Oregon Health Authority.

- Provides state control and transparency over drug cost and fee calculations- establishes “one price”.
- State and private payors will know what community pharmacies are getting paid and can audit pharmacy charges from their PBM. This also allows fair comparison of mail order or specialty pharmacy charges.
- Pharmacies will no longer have an incentive to charge high usual and customary prices or to turn away patients with “below cost” prescriptions.
- Pharmacies can depend on consistent reimbursement to manage their businesses and bring back pharmacies in under served areas. + allows improved access and service

Move to administrative fee only model for paying PBMs

In this model PBMs would be paid a fee for their services disassociated from rebate percentages and drug cost percentages. No spread would be allowed on drug or rebate transactions. Goals would be:

- Remove all incentives for PBMs to benefit from high prices of drugs
- Remove PBM rebate market pressures that leads to escalating drug list prices
- Create "duties of care" to provide patients access to drugs and pharmacist care in their communities
- Prohibit conflict of interest of directing members to PBM owned or affiliated pharmacies
- Prohibit fees or other profit taking strategies from network pharmacies
- Create auditable transparencies of fees and drug costs
- Align incentives to achieve cost-effective drug therapy to improve patient outcomes

See California 2022 SB 1361 as example legislation

Your local pharmacists care, let them provide care.

This is not just about the price of a drug. Patients need access to a local pharmacist who can help them use medication optimally, safely, and cares about making them better. Patients need a local pharmacy to solve problems and provide urgent access when needed. This service has value and pharmacies need to be paid for this value to continue to exist.

Bill #	Relating Clause	Bill Summary
HB 2630	Relating to exemption of prescription drug sales; prescribing an effective date.	Exempts receipts from sales of prescription drugs by a pharmacy from commercial activity subject to corporate activity tax.
HB 2715	Relating to insurance coverage of prescription drugs.	Prohibits health insurers and pharmacy benefit managers from restricting coverage of physician-administered prescription drugs that are obtained by nonparticipating pharmacies.
HB 2716	Relating to reimbursing the cost of prescription drugs.	Prohibits specified practices by insurers and pharmacy benefit managers in reimbursing cost of prescription drugs.
HB 2725	Relating to pharmacy benefit managers; declaring an emergency.	Prohibits pharmacy benefit manager from imposing fees on rural pharmacies after point of sale.
HB 2742	Relating to health care costs.	Excludes certain costs from consideration as total health expenditures for purposes of Health Care Cost Growth Target program.
HB 2762	Relating to prescription drug costs.	Requires insurers offering health benefit plans and pharmacy benefit managers to provide specified information regarding prescribed drug covered by plan or administered by manager, at time drug is prescribed.
HB 3012	Relating to pharmacy benefit managers.	Requires pharmacy benefit managers to annually report specified information to Department of Consumer and Business Services, including costs and rebates of prescription drugs for enrollees.
HB 3013	Relating to pharmacy benefits; declaring an emergency.	Requires pharmacy benefit managers to be licensed by Department of Consumer and Business Services beginning January 1, 2024, and imposes new requirements on pharmacy benefit managers.
HB 3015	Relating to pharmacy benefit managers.	Prohibits pharmacy benefit manager, after adjudication of and payment on claim for reimbursement of prescription drug, from recouping reimbursement paid except as part of routine audit, or from imposing retroactive fee on basis that was not determined when claim was adjudicated.
SB 565	Relating to the cost of health care.	Requires insurer, pharmacy benefit manager, Public Employees' Benefit Board, Oregon Educators Benefit Board and health care service contractor to count payments made by or on behalf of enrollee for costs of certain prescription drugs when calculating enrollee's contribution to out-of-pocket maximum, deductible, copayment, coinsurance or other cost-sharing for drugs.
SB 608	Relating to prescription drugs; prescribing an effective date.	Prohibits insurers offering policies or certificates of health insurance and pharmacy benefit managers from requiring claim for reimbursement of prescription drug to include modifier or other indicator that drug is 340B drug.

Prescription Drug Affordability Board
Policy Number: 04 - **Amendment**
Title: Public Comment Policy and Procedures
Date Issued: August 3, 2022
Dates Reviewed: August 3, 2022; August 17, 2022
Date Adopted: August 17, 2022
Date Amended:

1. Purpose

The opportunity for public comment will be provided at each Prescription Drug Affordability Board meeting.

2. Policy Statement

The Prescription Drug Affordability Board welcomes public comment during Board meetings. Board members generally will not respond to public comments during a meeting. Public comments may be submitted in writing or given orally during the designated time by completing the PDAB Public Comment form provided on the PDAB website.

The PDAB Public Comment form's purpose is 1) to sign up to provide comments, 2) to assist board staff with time allotments for meeting agenda items, and 3) to disclose interest or affiliation.

Having an interest or affiliation does not prevent written or oral comments from being provided, but is included on the form for transparency purposes. Prior to the public comment, the Board Chair will state whether the form has been completed and any interest or affiliation of the speaker.

Written Comments
The Board will receive written public comments and the PDAB Public Comment form through the Prescription Drug Affordability Board at pdab@dcbs.oregon.gov. The form includes fields for the name, organization and topic item for persons submitting written testimony. Written public comments submitted less than 72 hours before a board meeting will be considered at the following meeting. Beginning January 1, 2023, all written public comments will be posted to the PDAB website. Board staff will post these comments online in advance of the meeting date, following submission requirements.

Oral Comments
Persons interested in providing oral public comments may sign up by completing the PDAB Public Comment form and emailing it to pdab@dcbs.oregon.gov no later than 24 hours before the meeting. Anyone who did not sign up before the deadline will have the opportunity to speak at the next meeting after completing the PDAB Public Comment form. Speakers will be called to speak in the order in which they sign up. The Board Chair will ask the speakers to introduce themselves with their name and affiliation if any.

The amount of time allocated for oral public comment will be determined by the Board Chair in consultation with Board staff. When there are multiple requests to comment on a particular topic, the Board Chair may limit or expand the total time for comment or reduce the time allotted for each speaker. Any changes will be announced at the beginning of the public comment agenda item.

Oregon Prescription Drug
Affordability Board

Prescription Drug Affordability Board

2023 Roadmap

PDAB ROADMAP for 2023

Rules
- Rulemaking for Fee Structure
- Rulemaking for Affordability Criteria
- Schedule Rulemaking Advisory Committee (RAC) meetings

Annual Reports
- Generic Drug

Rules
- Implement Fee Structure
- Implement Affordability Criteria

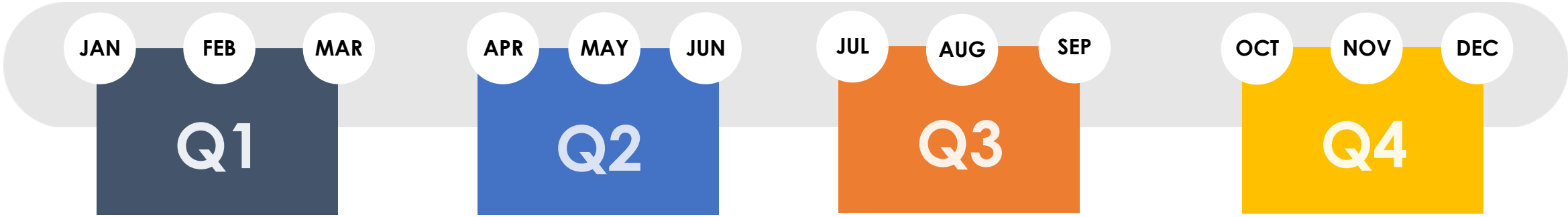
Studies
- Price trends for list of Rx
- Affordability of Rx
- Recommendations from Rx list

Report from DPT

Rx list of Carriers

Identify 9 Rx & Insulin
- Review list for 2024 review

Annual Reports
- Price trends for list of Rx
- Report of Affordability Reviews conducted by the Board
- Recommendations from Rx list



Oregon Prescription Drug Affordability Board

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2023 Board Meetings and Topics

TOPICS	Jan. 18 PDAB Meeting	Feb. 15 PDAB Meeting	March 15 PDAB Meeting	April 19 PDAB Meeting	May 17 PDAB Meeting	June 21 PDAB Meeting	Report Due Date
Work Plan	**Board approval**						
Affordability rulemaking	**Rule development**					**Approval of rule**	
Fee structure rulemaking	**Rule development**					**Approval of rule**	
				RAC meetings and hearing			
Generic Drug Report*	**Presentation of outline to board**		**Presentation of report draft to board**		**Presentation of report draft edits to board**	**Board approval of final draft**	**06/01/23**

*Annually by June 1, the board conducts a study of the operation of the US market for generic drugs, both drugs dispensed by pharmacists and drugs administered by physicians, including:

1. The prices of generic drugs on a year-to-year basis
2. The degree to which generic drug prices affect insurance premiums
3. Annual changes in health insurance cost-sharing for generic drugs
4. The potential for and history of generic drug shortages
5. The degree to which generic drug prices affect annual spending in the state medical assistance program
6. Any other topic the board considers relevant to the cost of generic drugs

2023 Board Meetings and Topics

TOPICS	July 19 PDAB Meeting	Aug. 23 PDAB Meeting	Sept. 20 PDAB Meeting	Oct. 18 PDAB Meeting	Nov. 15 PDAB Meeting	Dec. 13 PDAB Meeting	Report Due Date
Identify list of drugs & insulin	**Identify list of drugs & insulin**						
SB 844, Section 5 Report and Recommendations (1, 2 & 3)			**Presentation of outline to board**	**Presentation of report draft to board**	**Presentation of report draft edits to board**	**Board approval of final draft**	**12/31/23**

(1) Price trends for the list of prescription drugs provided to the board by the DCBS

(2) The prescription drugs that were reviewed under section 2 of SB 844

(3) Recommendations, if any, for legislative changes necessary to make prescription drug products more affordable in Oregon.

Oregon Prescription Drug
Affordability Board

Prescription Drug Affordability Board

Discussion for fee structure and affability review rulemaking

Fee Structure

SB 844, Section 3

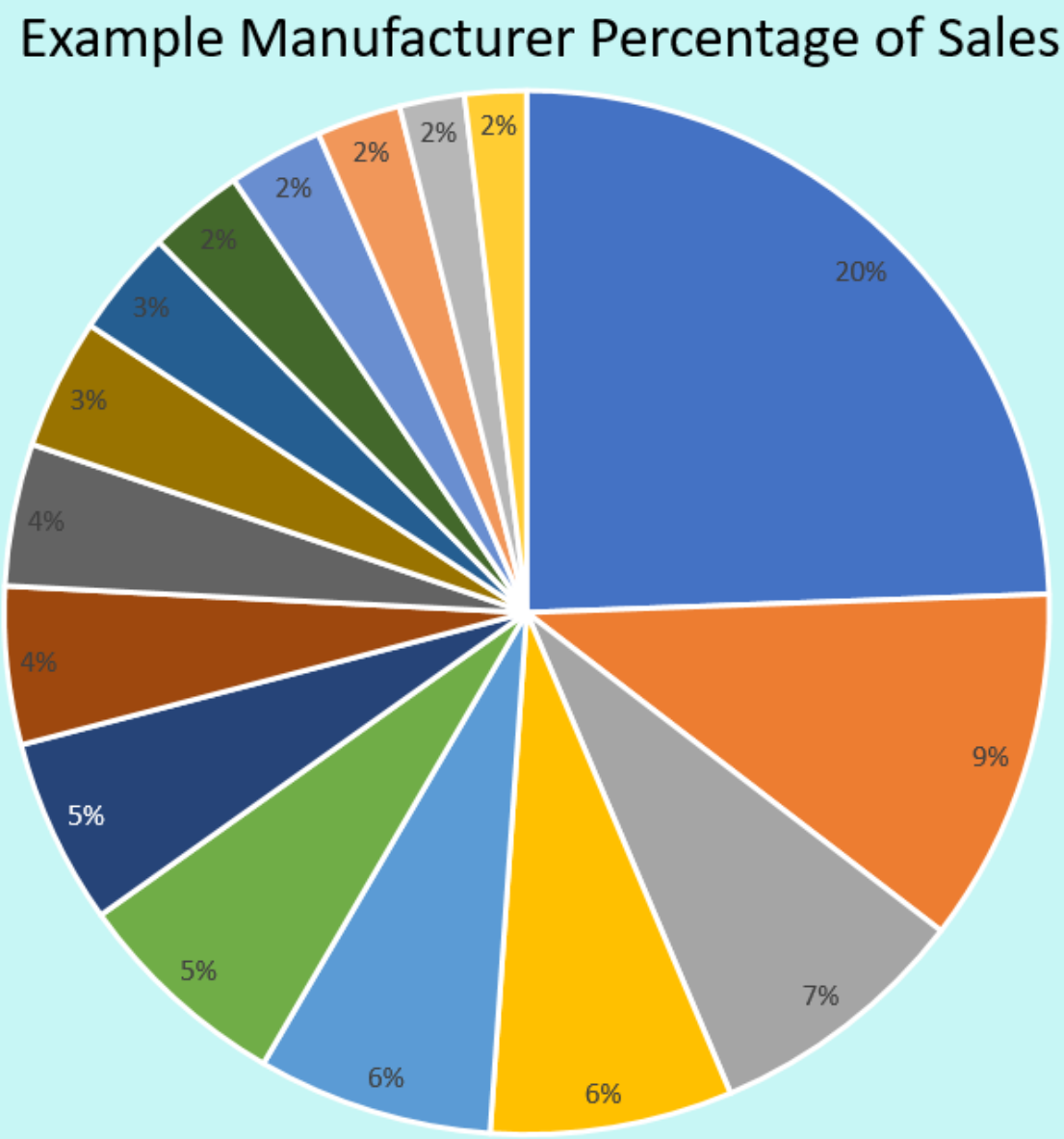
(1) DCBS shall adopt by rule, in consultation with PDAB, annual fees to be paid by manufacturers that sell prescription drugs in this state. The fees shall be established in amounts necessary to meet the costs of the department and the board in administering sections 1 to 3. The fees shall be imposed 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 section 4.

Concept 1

Starting with certified 2021 data, match the Oregon All Payer All Claims (APAC) database's prescription drug information with Medi-Span pricing data.

Fees shall be imposed based on a manufacturer's share of gross revenue from sales of prescription drugs in Oregon.



Oregon Prescription Drug Affordability Board

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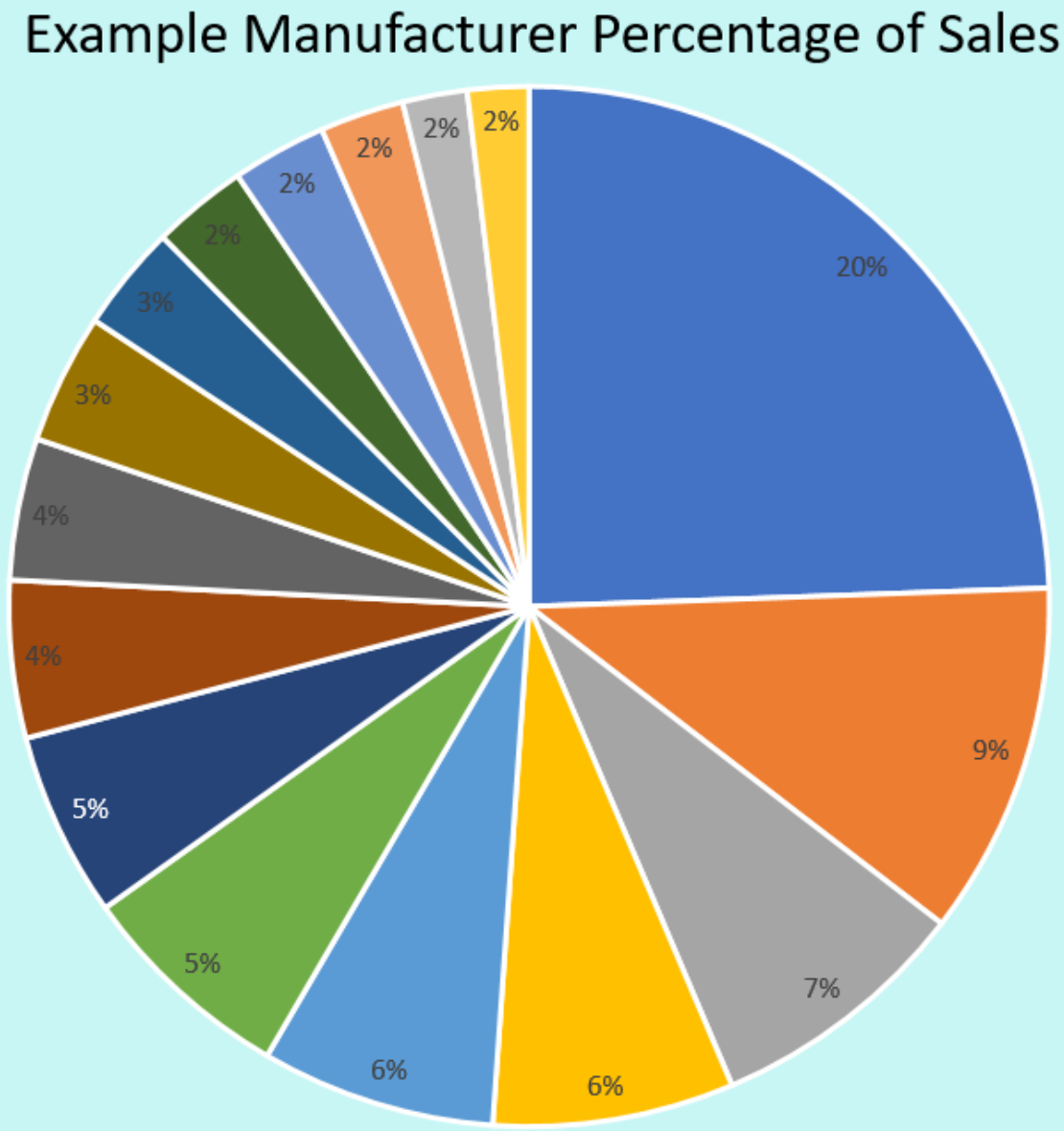
Concept 2

Starting with certified 2021 data, match the Oregon All Payer All Claims (APAC) database's prescription drug information with Medi-Span pricing data.

Implementing a base fee with an additional fee based on a manufacturer's placement of a tiered fee structure from sales of prescription drugs in Oregon.



Oregon Prescription Drug Affordability Board

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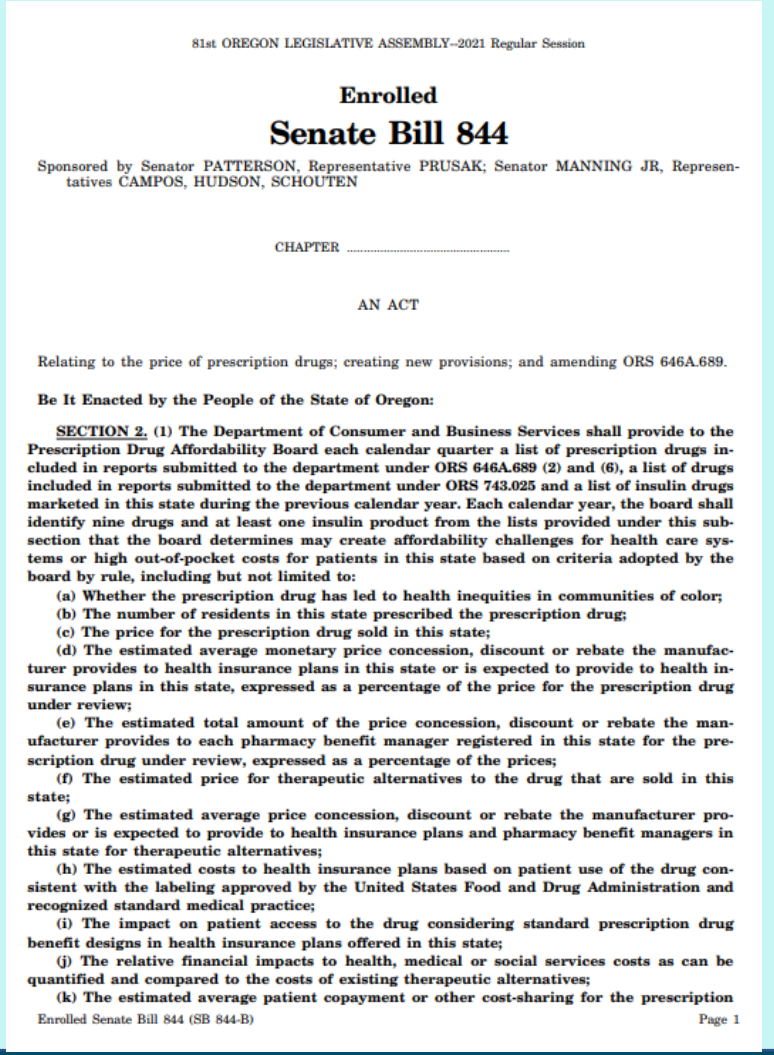
Affordability Review Criteria

SB 844, Section 2

(1) DCBS shall provide to PDAB each calendar quarter a list of prescription drugs included:

- ❖ Reports submitted to the department under ORS 646A.689 (2) & (6),
- ❖ a list of drugs included in reports submitted to the department under ORS 743.025, and
- ❖ a list of insulin drugs marketed in this state during the previous calendar year.

Each calendar year, the board shall identify nine drugs and at least one insulin product from the lists provided under this subsection that the board determines may create affordability challenges for health care systems or high out-of-pocket costs for patients in this state based on criteria adopted by the board by rule.



81st OREGON LEGISLATIVE ASSEMBLY--2021 Regular Session

Enrolled

Senate Bill 844

Sponsored by Senator PATTERSON, Representative PRUSAK; Senator MANNING JR, Representatives CAMPOS, HUDSON, SCHOUTEN

CHAPTER .....

AN ACT

Relating to the price of prescription drugs; creating new provisions; and amending ORS 646A.689.

Be It Enacted by the People of the State of Oregon:

SECTION 2. (1) The Department of Consumer and Business Services shall provide to the Prescription Drug Affordability Board each calendar quarter a list of prescription drugs included in reports submitted to the department under ORS 646A.689 (2) and (6), a list of drugs included in reports submitted to the department under ORS 743.025 and a list of insulin drugs marketed in this state during the previous calendar year. Each calendar year, the board shall identify nine drugs and at least one insulin product from the lists provided under this subsection that the board determines may create affordability challenges for health care systems or high out-of-pocket costs for patients in this state based on criteria adopted by the board by rule, including but not limited to:

(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

Enrolled Senate Bill 844 (SB 844-B) Page 1

Oregon Prescription Drug Affordability Board

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Criteria including but not limited to:

(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;

Criteria including but not limited to (continued):

(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;

(L) Any information a manufacturer chooses to provide; and

(m) Any other factors as determined by the board in rules adopted by the board.

Section 2, sub-sections 2 & 3

(2) A drug that is designated by the Secretary of the United States Food and Drug Administration, under 21 U.S.C. 360bb, as a drug for a rare disease or condition is not subject to review under subsection (1) of this section.

(3) The board shall accept testimony from patients and caregivers affected by a condition or disease that is treated by a prescription drug under review by the board and from individuals with scientific or medical training with respect to the disease or condition.

Section 2, sub-sections 4

(4)(a) If the board considers the cost-effectiveness of a prescription drug in criteria adopted by the board under subsection (1) of this section, the board may not use quality-adjusted life-years, or similar formulas that take into account a patient's age or severity of illness or disability, to identify subpopulations for which a prescription drug would be less cost-effective. For any prescription drug that extends life, the board's analysis of cost-effectiveness must weigh the value of the quality of life equally for all patients, regardless of the patients' age or severity of illness or disability.

(b) As used in this subsection:

- (A) "Health utility" means a measure of the degree to which having a particular form of disease or disability or having particular functional limitations negatively impacts the quality of life as compared to a state of perfect health, expressed as a number between zero and one.
- (B) "Quality-adjusted life-year" is the product of a health utility multiplied by the extra months or years of life that a patient might gain as a result of a treatment.

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Section 2, sub-sections 5

5) To the extent practicable, the board shall access pricing information for prescription drugs by:

(a) Accessing pricing information collected by the department under ORS 646A.689 and 743.025;

(b) Accessing data reported to the Oregon Health Authority under ORS 442.373;

(c) Entering into a memorandum of understanding with another state to which manufacturers already report pricing information; and

(d) Accessing other publicly available pricing information.

Section 2, sub-sections 6 & 7

(6) The information used to conduct an affordability review may include any document and research related to the introductory price or price increase of a prescription drug, including life cycle management, net average price in this state, market competition and context, projected revenue and the estimated value or cost-effectiveness of the prescription drug.

(7) The department and the board shall keep strictly confidential any information collected, used or relied upon for the review conducted under this section if the information is:

(a) Information submitted to the department by a manufacturer under ORS 646A.689; and

(b) Confidential, proprietary or a trade secret as defined in ORS 192.345.