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

This is a regular meeting. *Date*: **April 17, 2024** | *Time*: **9:30 a.m.**
This is a draft agenda and subject to change.

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

Board Members: Chair Shelley Bailey; Vice Chair Amy Burns; Daniel Hartung; Robert Judge; Christopher Laman; John Murray; Akil Patterson

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

Purpose	Subject	Presenter	Estimated Time Allotted
Informational and vote	Call to order, roll call, approval of **02/21/2024 minutes**	Chair Shelley Bailey	5 minutes
Informational	Executive session pursuant to ORS 192.660(2)(f) to consider information or records that are exempt by law from public inspection.	Chair Shelley Bailey	20 minutes
Informational and roll call	Return to open session: roll call	Chair Shelley Bailey	5 minutes
Informational	Executive director's program update	Ralph Magrish	5 minutes
Discussion	Board discussion of a **new timeline and template** for the affordability reviews.	Ralph Magrish and Cortnee Whitlock	30 minutes
Discussion	Board review of **draft generic drug report**	Cortnee Whitlock	30 minutes
Discussion	**Senate Bill 192 upper payment limit planning** update and board discussion	Ralph Magrish	30 minutes
Informational	Announcements	Staff	5 minutes
Informational	General public comment *Comments will be limited to 3 minutes per person or organization. Written comments are reviewed by the board prior to the meeting.*	Chair Shelley Bailey	10 minutes
Informational	Adjournment	Chair Shelley Bailey	2 minutes

Next meeting

May 15, 2024, 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 provide testimony to the board

The Prescription Drug Affordability Board welcomes people to provide testimony. Testimony is when a person sends a letter to the board or signs up to speak during a board meeting. There are two types of testimony: general testimony is about any topic not related to the affordability review; affordability review testimony is about the drugs the board will consider during the affordability review process taking place between May and November 2024. There are two ways to provide testimony: oral or written. Oral testimony is speaking to the board during the public comment portion of the agenda. Written testimony is sending comments in writing to the board. Written comments will be posted to the PDAB website.

General testimony

- **Oral:** To speak during a board meeting about any topic not related to the affordability review, please submit the PDAB public comment form no later than 24 hours before the PDAB meeting.
- **Written:** to provide written comments about any topic not related to the affordability review, please submit the PDAB public comment form with attachments no later than 72 hours before the PDAB meeting.

Drug affordability review testimony

- **Oral:** To speak during a board meeting about a drug under reviewed by the board, please submit the PDAB public comment form no later than 24 hours before the PDAB meeting.
- **Written:** to provide written comments about a drug under review by the board, please submit the PDAB public comment form with attachments by the deadlines posted on the affordability review web page. Written comments specific to drugs under review and submitted by the deadlines below will be included in the affordability review drug reports that are posted one week before the meeting. However, written comments specific to drugs under review may be submitted up until 72 hours before the November board meeting.

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) Regular Meeting
Wednesday, February 21, 2024
Draft Minutes

Web link to the meeting video: https://youtu.be/0jfiYKppbLo
Web link to the meeting materials: https://dfr.oregon.gov/pdab/Documents/20240221-PDAB-document-package.pdf

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Call to order and roll call: Acting Chair Shelley Bailey called the meeting to order at 9:36 am and roll was called.
Board members present: Acting Chair Shelley Bailey, Amy Burns, Daniel Hartung, Robert Judge, Christopher Laman, John Murray, and Akil Patterson (arrived at 9:52 am)
Absent: None

Declaration of potential conflict of interest: John Murray declared a potential conflict of interest as an owner of Murray Drugs and under advisement from the Ethics Commission because of his contracts to provide pharmacy services to public and private insurance companies.

Welcome new board member: Ralph Magrish welcomed new board member Christopher Laman. View the meeting video at minute 00:01:50.

Election of Officers: After the resignation from the chair position by Akil Patterson on Jan. 26, board members needed to elect a new chair. Robert Judge nominated Shelley Bailey, with a second by Amy Burns. View the election of officers in the meeting video at minute 00:03:26.

MOTION to appoint Shelley Bailey as board chair.
Board Vote:
Yes: Amy Burns, Daniel Hartung, Robert Judge, Christopher Laman, John Murray, Chair Shelley Bailey.
No: None
Absent for the vote: Akil Patterson
Motion passed 6-0

With the election of Shelley Bailey to chair, board members needed to elect a new vice chair. Amy Burns nominated Robert Judge but he declined due to other obligations. Robert Judge nominated Amy Burns and John Murray provided the second.

MOTION to appoint Amy Burns as board vice chair.
Board Vote:
Yes: Amy Burns, Daniel Hartung, Robert Judge, Christopher Laman, John Murray, Chair Shelley Bailey.
No: None
Absent for the vote: Akil Patterson
Motion passed 6-0

Approval of minutes: John Murray made the motion and Robert Judge provided a second to approve the minutes on Pages 3-5 in the agenda packet. View the approval in the meeting video at minute 00:10:07.

MOTION to approve the minutes.
Board Vote:
Yes: Amy Burns, Daniel Hartung, Robert Judge, John Murray, Chair Shelley Bailey.
No: None
Abstain: Christopher Laman
Absent for the vote: Akil Patterson
Motion passed 5-0

Program update by Executive Director Ralph Magrish. View the executive director's report in the meeting video at minute 00:02:15.

Legislature update by Numi Rehfield-Griffith, senior policy advisory. View the Legislative update on Pages 70-77 of the agenda packet and view the update in the meeting video at minute 00:14:12.

Board affordability review of Ozempic: The chair led the board in the affordability review of Ozempic, which included drug-specific public comment on Pages 23-29, board discussion, and potential motion to include Ozempic on the list of prescription drugs that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon. The board reviewed the information in the affordability review report on Pages 5-29 of the agenda packet. Amy Burns made the motion and Robert Judge provided the second to include Ozempic. View the video of the board discussion at minute 00:36:16.

MOTION to include Ozempic on the list of prescription drugs that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon.
Board Vote:
Yes: Amy Burns, Robert Judge, John Murray, Christopher Laman, Chair Shelley Bailey.
No: None
Abstain: Akil Patterson
Absent for the vote: Daniel Hartung
Motion passed 5-0

Board affordability review of Trulicity: The chair led the board in the affordability review of Trulicity, which included drug-specific public comment on Pages 47-49, board discussion, and potential motion to include Trulicity on the list of prescription drugs that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon. The board reviewed the information in the affordability review report on Pages 30-49 of the agenda packet. Robert Judge made the motion and John Murray provided the second to include Trulicity. View the video of the board discussion at minute 01:00:46.

MOTION to include Trulicity on the list of prescription drugs that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon.
Board Vote:
Yes: Amy Burns, Robert Judge, John Murray, Christopher Laman, Chair Shelley Bailey.
No: None
Abstain: Akil Patterson
Absent for the vote: Daniel Hartung
Motion passed 5-0

Board affordability review of Shingrix: The chair led the board in the affordability review of Shingrix, which included drug-specific public comment on Pages 62-69, board discussion, and a potential motion to include Shingrix on the list of prescription drugs that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon. The board reviewed the information in the affordability review report on Pages 50-69 of the agenda packet. Board members did not make a motion. View the video of the board discussion at minute 01:24:32. View the public comment speakers at minute 01:24:59.

Public comment: Chair Bailey called on those who signed up to speak to the board. There were two requests to provide oral testimony and two written comments, which are posted to the PDAB website. View the public comments from Susan Schwarz, Global Coalition on Aging, and Dharia McGrew, PhRMA, in the meeting video at minute 01:40:50.

Adjournment: John Murray made a motion to adjourn and Amy Burns provided a second. Chair Bailey adjourned the meeting at 11:17 am and announced the next board meeting on March 20, 2024 at 9:30 am. View adjournment at minute 01:46:27.

Oregon Prescription Drug
Affordability Board

New affordability review timeline and template updates

Ralph Magrish and Cortnee Whitlock

April 17, 2024

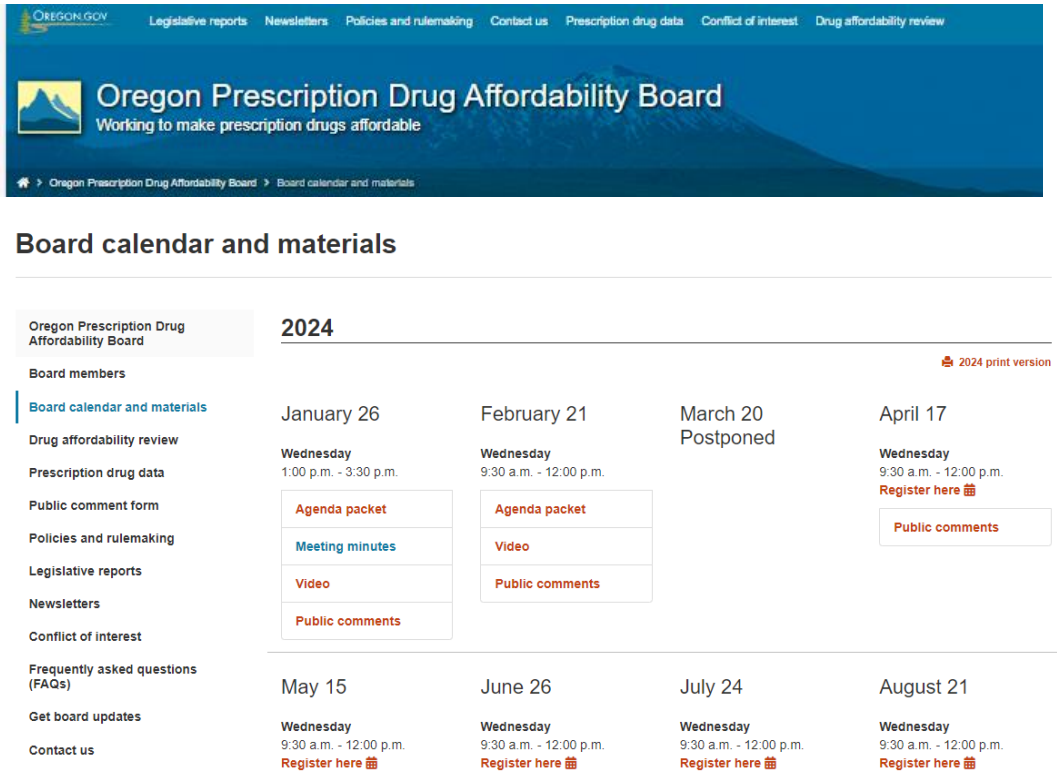
Consumer participation at future board meetings

PDAB Meeting Date	Prescription drugs	Main Treatment
May 15	Ozempic	Type 2 diabetes
May 15	Trulicity	Type 2 diabetes
June 26	Shingrix	Reduces the incidence of shingles
June 26	Ocrevus	Multiple sclerosis (MS)
July 24	Entyvio	Ulcerative colitis & Crohn's
July 24	Inflectra	Rheumatoid arthritis, Crohn's, ulcerative colitis
Aug. 21	Cosentyx	Plaque psoriasis, psoriatic arthritis
Aug. 21	Skyrizi	Plaque psoriasis & Crohn's
Sept. 18	Tremfya	Plaque psoriasis (similar to Humira and Stelara)
Sept. 18	Vyvanse	ADAD & eating disorder (neurological)
Oct. 16	Genvoya	HIV
Oct. 16	Triumeq	HIV
Nov. 20	The board will have the final review of drugs and make Legislative recommendations.	

How to attend online board meetings:

Go to https://dfr.oregon.gov/pdab

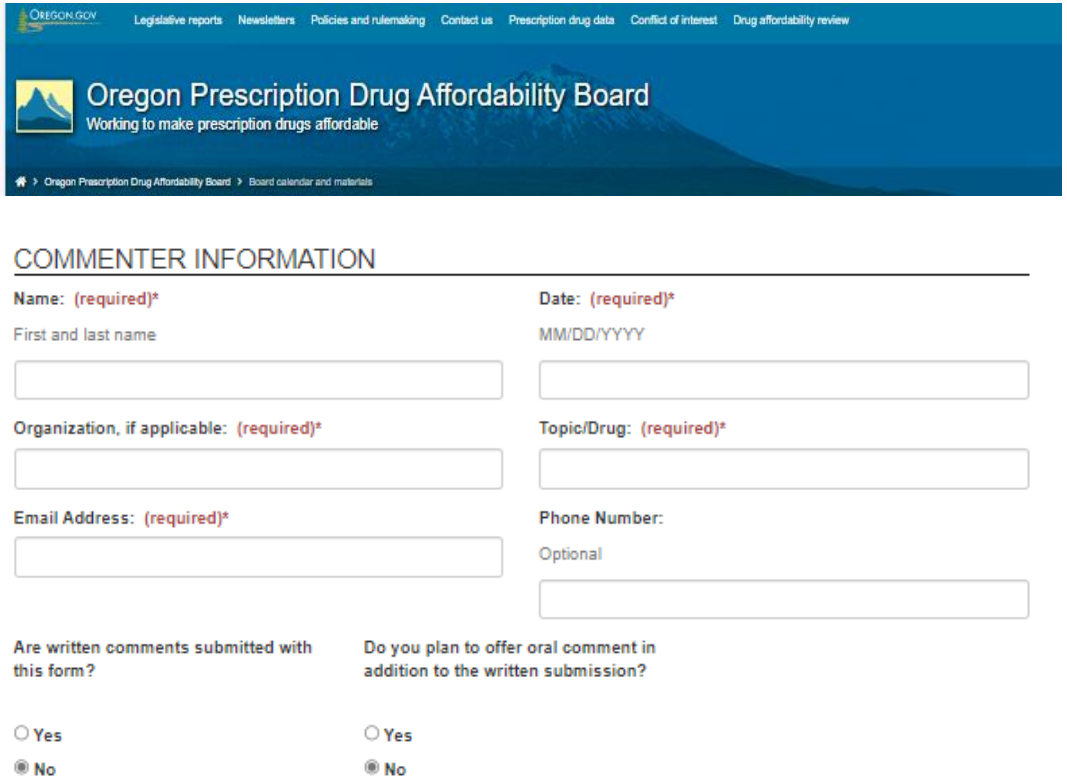
- Click on board calendar and materials
- Scroll to the meeting date
- Click on ***Register here***
- Sign up for the Zoom meeting
- If you need assistance, email to pdab@dcbs.oregon.gov or call 971-374-3724



How to submit public comment for board meetings:

Go to https://dfr.oregon.gov/pdab

- Click on the public comment form
- Complete and submit the form
- Register for the Zoom meeting
- If you need assistance, email pdab@dcbs.oregon.gov or call 971-374-3724



Register for the board meetings or submit public comment:

https://dfr.oregon.gov/pdab/

Contact us

pdab@dcbs.oregon.gov

971-374-3724

Oregon Prescription Drug **Affordability Board**

Oregon Prescription Drug
Affordability Board

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

«M_01_Drug_Name»[1] Affordability Review

DRAFT: REVISED MARCH 19, 2024

[*IMAGE OF DRUG*]

[1] [image source]

Table of Contents

Review Summary

Price history

[drugName] initially began marketing on **«M_38_Date_of_first_FDA_approval»**. Over the past five years, [drugName]'s wholesale acquisition cost (WAC) has increased by **«M_5_year_YoY_WAC_change»** YoY[2] on average. This increase outpaced inflation in **[insert appropriate years]**.[3]

Therapeutic alternatives

A clinical review found **[#]** therapeutic alternatives for «M_01_Drug_Name». **[copy from TA paragraph]**

Cost to the healthcare system

In 2022, total gross spend for **«M_01_Drug_Name»** in Oregon was **$«A03_APAC_Spend»** across **«A01_APAC_Total_Enrollees» enrollees,** with a gross per patient spend of **$«A04_APAC_Spend__enrollee»**.[4] Net spend for private insurers was estimated to be **<amount of net spend PEPY>** per enrollee per year.[5]

Cost to patients

On average, patient out-of-pocket costs was **«Avg_OoP»**[6] for «M_01_Drug_Name» in 2022 across deductibles, copays, and coinsurance.

[2] Based on data from Medi-Span.
[3] Inflation rates obtained from the US Bureau of Labor Statistics website. Accessed from page https://www.bls.gov/cpi/tables/supplemental-files/ on 1/11/24.
[4] Based on Oregon's 2022 All Payer All Claims (APAC) data across commercial insurers, Medicaid, and Medicare. APAC cost information are prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.
[5] Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon's commercial insurance carriers. Cost information from the data call is the cost of the drug after price concessions.
[6] Ibid

Review Background

Senate Bill 844 (2021) created the Prescription Drug Affordability Board (PDAB) to evaluate the cost of prescription drugs and protect residents of this state, state and local governments, commercial health plans, health care providers, pharmacies licensed in Oregon and other stakeholders within the health care system from the high costs of prescription drugs.

In accordance with OAR 925-200-0020, PDAB will conduct an affordability review on the prioritized subset of prescription drugs, selected under OAR 925-200-0010, and 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.

This review addresses the affordability review criteria in OAR 925-200-0020, to the extent practicable. Therefore, due to limitations in scope and resources, some criteria will have minimal or no consideration in this review.

In addition to information provided by the Department of Consumer and Business Services (DCBS) pursuant to ORS 646A.694, this review reflects information from various sources, including Oregon's APAC database, state licensed insurance carriers responding to a DCBS data call, Medi-Span, and resources from the U.S. Food and Drug Administration (FDA) such as the Orange Book (small molecule drugs) and the Purple Book (biologics).

Drug Information

Drug proprietary name(s): **«M_01_Drug_Name»**

Non-proprietary name: **«M_02_Nonproprietary_name»**

Manufacturer: **[drugManufacturer]**

FDA approval

«M_01_Drug_Name» was first approved by the FDA on **«M_38_Date_of_first_FDA_approval»**.[7]

The drug qualified for the following expedited forms of approval: **«M_39_Expedited_approvals_for_the_drug»**

At time of the review, the drug had no approved indications with designations under the Orphan Drug Act.

[7] FDA approval date based on the earliest occurring approval dates in the FDA Orange/Purple Book. For drugs with multiple forms/applications, the earliest approval date across all related FDA applications was used.

Health Inequities

ORS 646A.694(1)(a) and OAR 925-200-0020 (1)(a) & (2)(a)(A-B). Limitations in scope and resources available for this statute requirement. Possible data source through APAC.

[Does the Rx lead to inequities in communities of color

Does the Rx lead to inequities in under resourced communities **or** regions with limited pharmacy access.]

Residents prescribed

ORS 646A.694(1)(b) and OAR 925-200-0020(1)(b) & (2)(b). Data source from APAC.

Based on APAC claims, **<number of scripts filled>** Oregonians filled a prescription for <drug name> in 2022.[8]

Price for the Drug

ORS 646A.694(1)(c) and OAR 925-200-0020(1)(c) & (2)(e), (f), & (g). Data source from Medi-Span, APAC, and carrier data call.

Price History

The package wholesale acquisition cost (WAC) for **«M_01_Drug_Name»** (NDC **«NDC_for_WAC», [drug package dosage information]** was **$«M_40_Package_WAC»** as of 12/31/2023.[9]

The WAC for the drug was evaluated using Medi-Span's price history tables for the package WAC from 2019 to 2023. From 2019-2023 the average year-over-year change to the package WAC was calculated and determined to be **«M_5_year_YoY_WAC_change»%**. As of January 1, 2024, the WAC price increased another **[xxx]%** to **$[latest WAC pull]**. The historical change in the package WAC is displayed in Figure 1 and the year over year change in WAC for «M_01_Drug_Name» compared to inflation rates[10] is displayed in Figure 2.

[8] Number of 2022 enrollees in APAC database across commercial insurers, Medicaid, and Medicare. For more information regarding APAC data visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.

[9] To determine which NDC to use for the WAC price history, the available 2022 utilization data was analyzed and the NDC with the highest volume of claims in 2022 was used.

[10] Inflation rates obtained from the US Bureau of Labor Statistics website. Accessed from page https://www.bls.gov/cpi/tables/supplemental-files/ on 1/11/24.

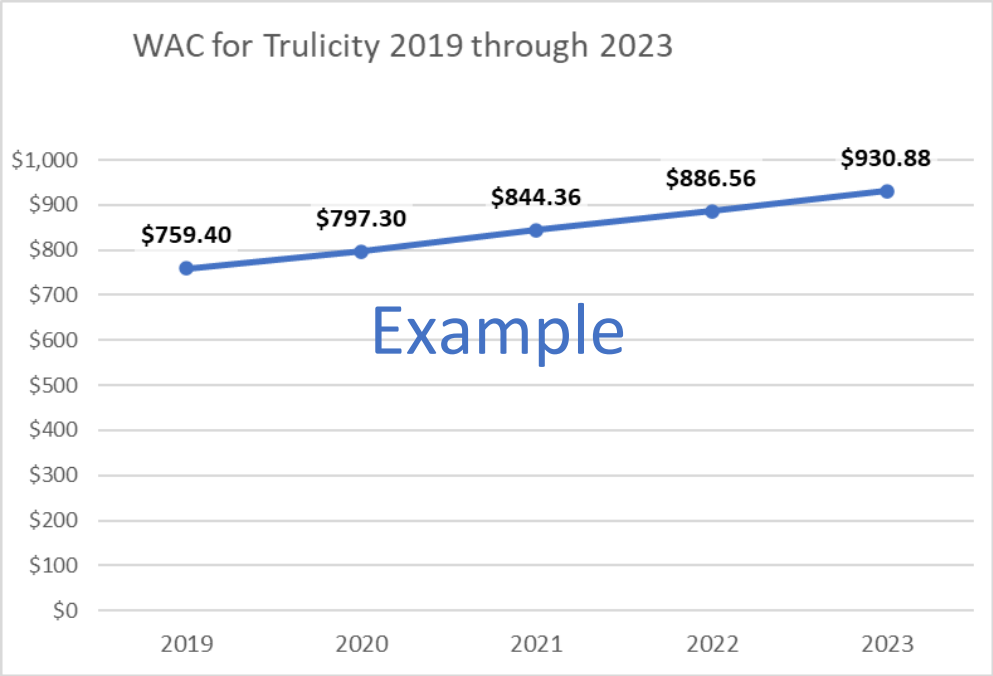


Figure 1 «M_01_Drug_Name» WAC from 2019-2023

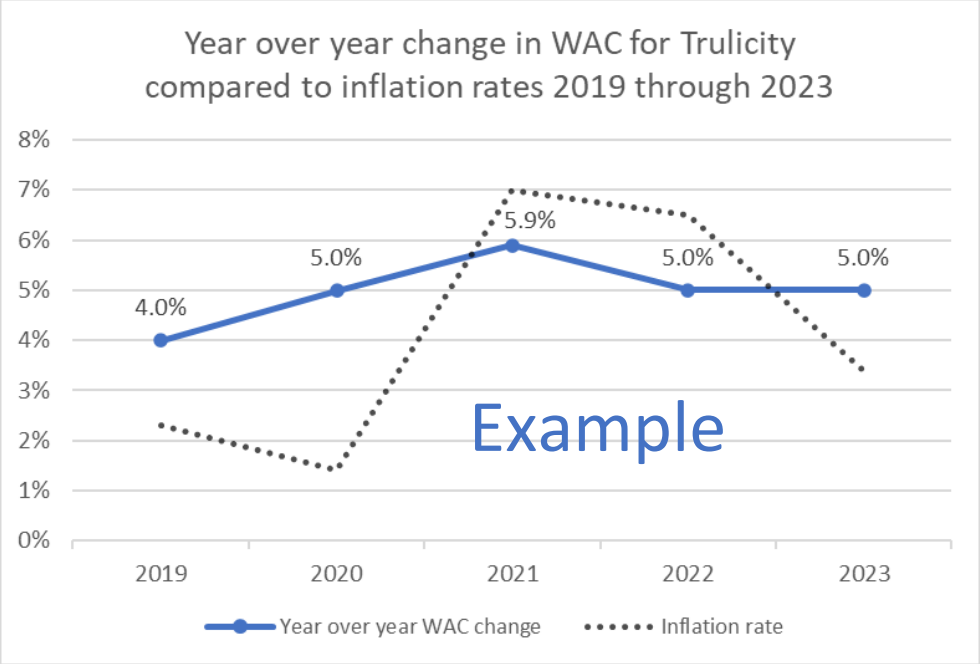


Figure 2 Year over year change in WAC compared to inflation rates[11]

[11] Inflation rates obtained from the US Bureau of Labor Statistics website. Accessed from page https://www.bls.gov/cpi/tables/supplemental-files/ on 1/11/24.

Package WAC was reviewed as an indication of historic price trends for the drug. However, WAC does not account for discounts, rebates, or other changes to the drug's cost throughout the supply chain. This increase outpaced inflation in **[insert appropriate years]**.[12]

Pharmacy acquisition costs

Effect of price on consumers' access to the drug

Estimated average monetary price concession

ORS 646A.694(1)(d) and OAR 925-200-0020(1)(d) & (2)(d) & (2)(L)(A-B). Data source information provided from data call.

[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.]

Based on the information received from the carrier data call, the average gross cost of the drug per enrollee for commercial carriers was **[table3Col3]** before any discounts, rebates, or other price concessions. The average net cost per enrollee discounts, rebates, and other price concessions was **[table3Col4]**, meaning that insurers reported an average of **[100% - figure2blue box total]** discount on the initial drug cost.

Table 1 Net cost estimate based on carrier submitted 2022 data

Payer line of business	Total enrollees	Average spend per enrollee pre-discount	Percent spend per enrollee pre-discount	Average spend per enrollee post discount	Percent spend per enrollee post discount
Commercial					

[12] Inflation rates obtained from the US Bureau of Labor Statistics website. Accessed from page https://www.bls.gov/cpi/tables/supplemental-files/ on 1/11/24.

The total gross drug cost reported from the carrier data call prior to price concessions for «M_01_Drug_Name» in 2022 was **[100% - figure2blue box total]**. The percentage breakdown of gross to net costs of the price concessions is represented in Figure 4.

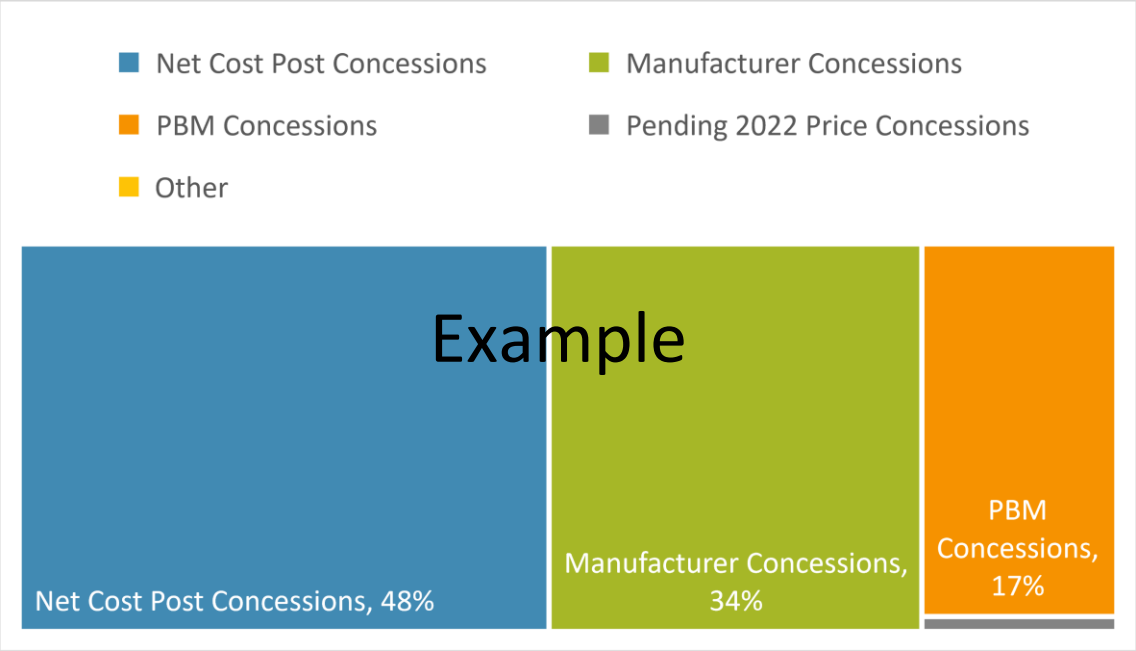


Figure 3 Breakdown of 2022 gross to net costs

Estimated total amount of the price concession

ORS 646A.694(1)(e) and OAR 925-200-0020(1)(e) & (2)(d) & (2)(L)(A-B). Limitations in scope and resources available for this statute requirement. Possible data source carrier data call.

[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.]

Estimated price for therapeutic alternatives[13]

ORS 646A.694(1)(f) and OAR 925-200-0020(1)(f), (2)(c) & (2)(m). Data source information provided from APAC.

- [Estimated net price
- Cost and availability

[13] Therapeutic alternative to mean a drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved, compendia-recognized as off-label use for the same indication, or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose. ORS 925-200-0020(2)(c) PDAB 1-2023: Prescription Drug Affordability Review (oregon.gov). Accessed 01/09/2024.

- Data regarding costs, expenditures, availability, and utilization]

Comparative effectiveness to therapeutic alternatives:

-

Table 2 Average healthcare and average patient OoP costs for «M_01_Drug_Name» vs therapeutic alternatives

Drug	Average gross healthcare spend per enrollee per year[14]	Average patient out-of-pocket cost per year[15]
Subject drug		
Average		

Average gross spend per enrollee per year was **[table8GrossSpendForDrug]** vs. an average of **[table8col2Total]** across this drug and all identified therapeutic alternatives. Average out of pocket costs for patients was **[table8averageOopForDrug]** per patient per year, vs. an average of **[table8Col2Total]** across this drug and all identified therapeutic alternatives.

Estimated average price concession for therapeutic alternatives

ORS 646A.694(1)(g) and OAR 925-200-0020(1)(g) & (2)(d) & (2)(L)(A-B). Limitations in scope and resources available for this statute requirement.

[Expected price concession, discounts or rebates manufacturers provide to health insurance plans and pharmacy benefit managers in this state for therapeutic alternatives.]

Estimated costs to health insurance plans

ORS 646A.694(1)(h) and OAR 925-200-0020(1)(h) & (2)(h) & (m). Data source information provided from APAC and data call.

[14] APAC total gross spend for drug and total unique enrollees for drug.
[15] APAC total copay, deductible, and coinsurance spend for drug and total unique enrollees for drug. Averages across commercial, Medicaid, and Medicare plans

In 2022, **[drugName]** had **[table1Col3Total]** claims across **[table1Col2Total]** enrollees. Total gross cost of the drug was **[table1Col4Total]** or **[table1Col5Total]** per enrollee per year, and **[table1Col6Total]** per claim per year.

Table 3 2022 Gross cost estimates based on APAC data[16]

Payer line of business	Total enrollees	Total claims	Total spend amount	Average spend amount per enrollee	Average spend amount per claim
Commercial					
Medicaid					
Medicare					
Total					

The carrier data call[17] submissions were analyzed to determine the total gross annual spend, total number of claims and enrollees, the average amount paid for claim and per enrollee, and out-of-pocket (OoP) costs for enrollees. Additional OoP information can be found in Table 3 below.

Table 4 2022 data call reported costs to Oregon payers and enrollees

Market	Data call total annual spend (payer paid)	Total unique claims	Total of paid claims	Total unique enrollees	Average paid claim	Average paid per enrollee	Total annual out-of-pocket cost for enrollees	Out-of-pocket cost per enrollee
Individual								
Small Group								
Large Group								
OEBB								
PEBB								
TOTAL								

Figure 3 represents the percentage of annual spend by market type reported in the carrier data call by commercial carriers. <Identify highest market group> represent the largest annual spend of <indicate percentage of highest market> of the Oregon market.

[16] Based on 2022 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information is prior to any price concessions such as discounts or coupons.
[17] Cost information from the data call is the cost of the drug after price concessions.

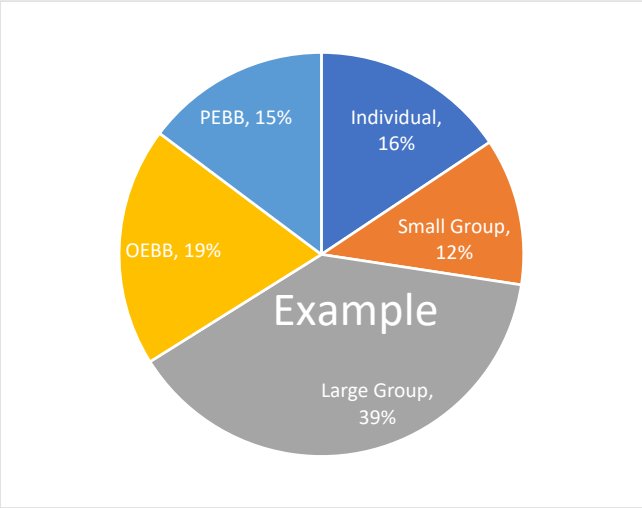


Figure 4 Data call total annual spend (payer paid)

Cost to the state medical assistance showed that the fee-for-service program had a gross annual average of **[table4Col3Total]** for approximately **[table4Col5Total]** «M_01_Drug_Name» claims. The drug was listed as a preferred drug and required prior authorization**.** Oregon's coordinated care organizations (CCOs) paid **[table5Col2]** for **[table5Col3]** claims averaging a **[table5Col4]** per paid claim.

Table 5 2022 Gross amount paid for Medicaid/Oregon Health Plan fee for service

Fee for Service[18]							
2022 Quarter	**Drug name on report**	**Amount paid**	**% Total fee for service costs**	**Claim count**	**Average paid per claim**	**Preferred drug list (PDL)**	**Prior auth**
Q1							
Q2							
Q3							
Q4							
Annual Average:							

[*If drugs are not indicated in every quarter provide statement: Drug not indicated in <Q1-Q$> of top 40 quarterly reports of the pharmacy utilization summary report provided by Oregon State University drug use research and management program.]

[18] Source: Oregon State University Drug Use and Research Management DUR utilization reports 2022. DUR Reports | College of Pharmacy | Oregon State University

Table 6 2022 Gross amount paid for Medicaid CCOs

Medicaid CCOs			
Drug	**Amount paid**	**Claim count**	**Average paid per claim**

Label and off-label indications

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

Impact on patient access to the drug

ORS 646A.694(1)(i) and OAR 925-200-0020(1)(i). Data source information provided from carrier data call.

Review of rejected claims and drug benefit designs

Carriers reported **«M_11_Data_call_total_number_of_claims»** claims for «M_01_Drug_Name» in 2022. Of those claims **«Paid_Claims»** were paid and **«Rejected_Claims»** were rejected.[19] Based on this information, on average, **«M__rejected»%** of «M_01_Drug_Name» claims were rejected in 2022.

Pharmaceutical claims may be rejected for a variety of reasons including patients trying to fill the prescription too soon or errors in the submitted claim. Pharmacists may also submit multiple claims for the same prescription should the initial claim be rejected. Therefore, claims information should only be used as a general baseline.

As part of the carrier data call, information was collected regarding prior authorizations and approval for the drug. Insurers reported a wide variety of plan designs for «M_01_Drug_Name». Unfortunately, the data call did not include the number of Oregonians under each plan listed, so DCBS was unable to determine the volume of Oregonians under plans that required prior authorization. Carriers reported a variety of plans, some with a more restrictive plan design and other plans with a more accessible plan design for the drug.

Information on how many carrier and market combinations were evaluated that had at least one plan that represented the following for «M_01_Drug_Name»:

[19] For the purpose of this review the terms "denied" and "rejected" for claims are used interchangeable.

Table 7 Plan design analysis

Percent of carrier/market combinations that had one or more plans that:[20]	
Required prior authorization	
Did not require prior authorizations	
Drug was excluded on the plan formulary	
Drug was non-preferred on the plan formulary	
Drug was preferred on the plan formulary	
Required step therapy	
Did not require step therapy	

Note: percentages can equal over 100% as some carrier and market combos may have multiple plans that fall under different designs. For example: Carrier A may have three plans in the small group market that require prior authorization but two other plans in the small group market that do not require prior authorization.

Relative financial impacts to health, medical or social services costs

ORS 646A.694(1)(j) and OAR 925-200-0020(1)(j) & (2)(i)(A-B). Limitations in scope and resources available for this statute requirement.

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

- 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.
- To the extent information can be quantified, the total cost of the disease and the drug price offset.]

Estimated average patient copayment or other cost-sharing

ORS 646A.694(1)(k) and OAR 925-200-0020(1)(k) & (2)(j)(A-D). Data source information provided from APAC and carrier data call. Data limitations with patient assistance programs

The APAC database[21] and the carrier data call were analyzed to determine the average patient copayment for commercially insured enrollees or other cost-sharing for the prescription drug.

[20] Less than 5% of all total Rx claims was omitted from carrier entries that were considered unusable.

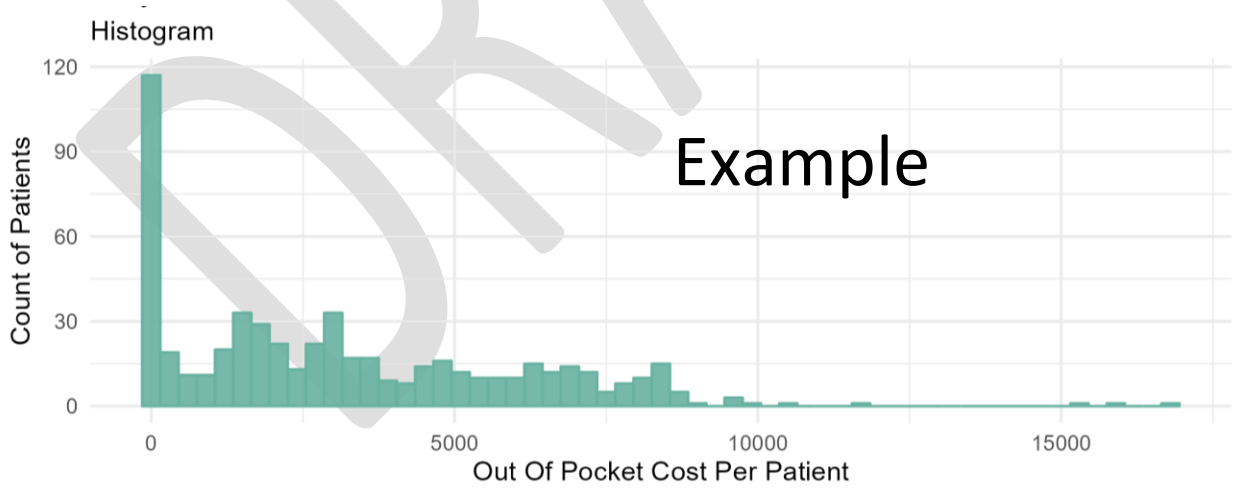
[21] Costs from the APAC database are prior to any price concessions such as discounts or coupons. Cost information from the data call is the cost of the drug after price concessions.

Table 8 Out of pocket costs

2022 Average annual patient out of pocket costs		
Value	**APAC (commercial plans only)[22]**	**Data Call[23]**
Average Co-Pay		
Average Coinsurance		
Average Deductible		
Average Total Out-of-Pocket Costs for Patients[24]		

Table 8 indicates plan designs reported in the carrier data call, when a co-pay applied for Ozempic, the co-pay ranged from **$5.00** up **$250.00**. If the coinsurance was greater than 0%, the coinsurance ranged from 10% up to 100%.

The average patient out-of-pocket costs for the APAC data may be impacted by mandatory state reporting requirements, the exclusion of data from health plans with fewer than 5,000 covered lives and is prior to price concessions. The carrier data call out-of-pocket costs are from reports collected by DCBS from commercial carriers and may be affected by price concessions.



[new histogram chart goes here]

Figure 5 Patient count to OoP cost per patient

[22] Medicaid and Medicare were excluded from cost information.
[23] Data call refers to cost information collected from the health insurance plans by DCBS on prescription drugs under both pharmacy and medical benefits after price concessions.
[24] For patients who used the drug at least once in the 2022 calendar year.

Table 9 OoP costs central tendency of <drug name> costs in 2022

Out of Pocket costs per patient per year[25]		
Min	*The lowest amount any one patient paid*	
Average	*Patients pay this much on average*	
Median	*Half of patients pay more than this amount and half pay less*	
Mode	*The largest number of patients pay this amount*	
Max	*The highest amount any one patient paid*	

Figure 5 shows the breakdown of out-of-pocket costs based on APAC data for <Drug name>. A majority of patients taking <Drug name> have **<amount>** out-of-pocket costs. Table 9 represents the central tendency of <Drug name> with patients spending an average of **<low range>** with the highest spend at **<high range>**.

[description of PPPY]

[REPLACE WITH APPROPRIATE TEXT: For plan designs reported in the carrier data call, when a co-pay was greater than $0, the co-pay ranged from $5.00 up to $250.00. If the coinsurance was greater than 0%, the coinsurance ranged from 10% up to 50%.]

The average patient out-of-pocket costs for the APAC data may be impacted by mandatory state reporting requirements, the exclusion of data from health plans with fewer than 5,000 covered lives and is prior to price concessions. The carrier data call out-of-pocket costs are from reports collected by DCBS from commercial carriers and may be affected by price concessions.

Information from manufacturers

ORS 646A.694(1)(L) and OAR 925-200-0020(1)(L). Information provided from manufacturers and information with sources from contractor(s).

Drug indications

- FDA Approved:
- Off Label Uses:

Clinical efficacy

Clinical safety

[25] For patients who used the drug at least once in the 2022 calendar year.

- FDA safety warnings and precautions:
  -
- Contraindications:
  -
- Common side effects:
  -
- Safety advantages or disadvantages:

Input from Specified Stakeholders

ORS 646A.694(3) and OAR 925-200-0020(2)(k)(A-D)

Patients and Caregivers:

[Seek input from patients and caregivers affected by a condition or disease

- Condition or disease that is treated by the prescription drug under review by gathering information related to:
  - The impact of the disease;
  - Patient treatment preferences;
  - Patient perspective on the benefits and disadvantages of using the prescription drug;
  - Caregiver perspective on the benefits and disadvantages of using the prescription drug; and
  - Available patient assistance in purchasing the prescription drug.

- Attempt to gather a diversity of experience among patients from different socioeconomic backgrounds.]

Individuals with Scientific or Medical Training

[Individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review, including:

- The impact of the disease;
- Perspectives on benefits and disadvantages of the prescription drug,
- including comparisons with therapeutic alternatives if any exist; and
- Input regarding the prescription drug utilization in standard medical
- practice, as well as input regarding off label usage]

Safety Net Providers

[Providers that care for uninsured patients and patients with low income and receive discounted prices on prescription drugs through section 340B:

- The utilization of the prescription drug by the safety net provider patients;

- Whether safety net providers receive a 340B discount for the prescription drug;
- Where safety net providers do not receive a discount, whether access to the prescription drug is impeded; and
- Any other topics identified by safety net provider stakeholders.]

Payers

- [Total cost of care for disease(s);
- Cost of the prescription drug to the payer;
- The availability of therapeutic alternatives on the formulary;
- Coverage mandates and impacts to per member per month or premiums;
- Affordability concerns of the prescription drug, from employer groups and other plan sponsors; and
- Other costs to consider.]

Appendix

Appendix A:

Oregon Prescription Drug
Affordability Board

Prescription Drug Affordability Board

Generic drug report draft outline

Cortnee Whitlock
Board Policy Analyst
April 17, 2024

2024 timeline: PDAB generic drug report

- Staff posts draft report to the website – ***April 10***
- Board reviews draft report – ***April 17***
- Board sends report feedback by – ***April 24***
- Initial internal design review – ***April 29***
- Generic drug report posted online – ***May 8***
- Board approves final report – ***May 15***
- Final internal design review – ***May 20***
- Final report posted to the website – ***May 27***
- Generic drug report sent to the Oregon Legislature – ***May 30***

2023 Report for the Oregon Legislature
Generic Drug Report Pursuant to Senate Bill 844 (2021)

Contents

Background

What are prescription drugs and what role do generics play? Prescription drugs are intended for the diagnosis, cure, mitigation, treatment, or prevention of disease.[1] Generics are created to be the same as already-marketed, brand-name prescription drugs in dosage, safety, strength, performance and use, working the same way and providing the same clinical benefit.[2] However, generic drugs usually cost less for patients and the Oregon health care system. In 2021, the use of generics and biosimilars in the Oregon Medicare system brought about a savings of $951 million.[3]

The work of the Prescription Drug Affordability Board (PDAB) is to consider prescription drugs that may create affordability challenges for Oregonians and the state's health care system. If medications are not affordable, Oregonians may be unable to take them as prescribed, resulting in poor health outcomes. When the Legislature created PDAB in 2021 through Senate Bill 844, it asked the board to study generic drugs and their affordability for patients. The board has prepared two generic drug reports for the Legislature so far. In 2022, the board's report focused on the supply chain, drug shortages, and the need to reform patent laws to encourage the use of generics. The 2023 report looked at the cost savings from biosimilars, which work the same as biologic drugs, but are less expensive to manufacture.

Authorized Generics

Authorized generics refer to drugs sold by brand-name drug manufacturers or their licensees under generic labels. Although authorized generics constitute a small portion of filled prescriptions, brand manufacturers often use authorized generics to maintain high drug prices and undermine generic competition.[4] There are three primary reasons why brand manufacturers use authorized generics:

1. To maintain market share after generic drugs have entered the market.
2. As a bargaining chip in pay-for-delay settlement deals with generic manufacturers before the entry of independent generic drugs, thereby delaying generic competition.

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[1] "Prescription Drugs and Over-the-Counter (ORC) Drugs: Questions and Answers." U.S. Food & Drug Administration, November 13, 2017. https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/prescription-drugs-and-over-counter-otc-drugs-questions-and-answers. Accessed April 5, 2024.

[2] Generic Drugs: Questions & Answers." U.S. Food & Drug Administration. March 16, 2021. https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers#q1. Accessed April 5, 2024.

[3] "Generic and Biosimilar Medicines Save Oregon Patients Billions." Biosimilars Council, a division of Association for Accessible Medicines. https://accessiblemeds.org/sites/default/files/2023-01/AAM-2022-generic-biosimilar-savings-Oregon.pdf. Accessed April 5, 2024.

[4] Rome BN, Gunter SJ, Kesselheim AS. Market dynamics of authorized generics in Medicaid from 2014 to 2020. *Health Services Research*. 2023;58(4):953-959. doi:10/gs3g4m

3. To allay public concern and criticisms concerning the high prices of brand-name drugs.[5]

A recent study of entacapone (Comtan), a medication used for Parkinson's disease, showed that the presence of multiple authorized generics can lead to increased spending when there is limited independent generic competition. The manufacturer of brand-name entacapone successfully delayed effective competition by signing settlement agreements with several generic manufacturers. These generic manufacturers produced and sold authorized generics instead of independent generics, which undermined the ability of generic competition to lower the drug's price.[6]

Manufacturer Strategies to Prevent/Delay Generic or Biosimilar Competition

Manufacturers use various tactics to prevent generics from entering the market and delay competition. These tactics include "pay-for-delay" settlements, misuse of citizen petitions, product hopping, secondary patenting, limited supply agreements, and patenting FDA-mandated risk evaluation and mitigation strategies (REMS).[7]

Pay-for-delay

Delaying the introduction of new generics to the market can significantly impact healthcare costs, particularly for Medicaid programs. According to a study published in *Health Affairs*, the cost of delays in generic drug entry, primarily due to patent litigation, resulted in around $761 million in excess spending by state programs. From 2010 to 2016, 69 brand-name drugs were expected to lose market exclusivity. Of these, 45% either did not face competition from generics by the end of the study period or had the introduction of generics delayed by over a quarter.[8]

Citizen petition

A 2020 study revealed that misuse of the FDA's citizen petition process by brand name manufacturers resulted in a financial burden of $1.9 billion on the government and American

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[5] Dusetzina SB, Keating NL, Huskamp HA. Authorized Generics and Their Evolving Role in Prescription Drug Pricing and Access. *JAMA Internal Medicine*. 2021;181(4):423-424. doi:10.1001/jamainternmed.2020.8450

[6] Rome BN, Egilman AC, Patel NG, Kesselheim AS. Using Multiple Authorized Generics to Maintain High Prices: The Example of Entacapone. *Value Health*. 2023;26(3):370-377. doi:10.1016/j.jval.2022.08.013

[7] Vokinger KN, Kesselheim AS, Avorn J, Sarpatwari A. Strategies That Delay Market Entry of Generic Drugs. *JAMA Intern Med*. 2017;177(11):1665-1669. doi:10.1001/jamainternmed.2017.4650

[8] Dave CV, Sinha MS, Beall RF, Kesselheim AS. Estimating the Cost of Delayed Generic Drug Entry To Medicaid. *Health Aff (Millwood)*. 2020;39(6):1011-1017. doi:10.1377/hlthaff.2019.00673

taxpayers.[9] This process is intended to provide individuals and advocates an avenue to shape FDA decision-making. Yet, it has been observed that pharmaceutical companies sometimes misuse citizen petitions to delay the entry of generic drugs into the market. Even a delay of ninety days can generate hundreds of millions of dollars in revenue for brand-name drug companies, making the filing of these petitions worthwhile despite their spurious nature.[10]

Product hopping

Manufacturers have also been known to engage in "product hopping," a tactic in which a newer, ostensibly improved version of a drug is released as the original product nears generic competition. Patients are then encouraged to switch to this newer version, often generating increased profits for brand-name drugs. For instance, several product hops occurred when the FDA phased out off-patent chlorofluorocarbon (CFC) albuterol inhalers in 2009 in favor of eco-friendlier hydrofluoroalkane (HFA) versions for which generics were not yet available. This type of product hop is believed to have led to billions of dollars in additional health care spending in the U.S. Regulatory reforms, and policies should be implemented so manufacturers are prevented from product hopping and generics enter markets in a timely manner.[11]

Limited supply agreement

Like generic drugs, biosimilars face challenges upon entering the market, including various delay tactics from manufacturers. From 2016 to 2019, the FDA approved five biosimilars for the popular drug adalimumab (Humira). However, patent litigation delayed the market entry of these biosimilars until 2023. It is estimated that if adalimumab biosimilars had been launched upon approval, biosimilar competition would have saved Medicare $2.19 billion between 2016 and 2019, highlighting the importance of timely biosimilar entry.[12]

Despite biosimilars entering the market in 2023, Humira, manufactured by AbbVie, continues to dominate the market due to the release of an updated version in 2018. This has complicated biosimilar competition because biosimilar versions of adalimumab need to mimic changes made by the brand-name manufacturer in order to be considered interchangeable with Humira.

Drug tier placement

[9] Feldman R. The Burden on Society from Eleventh-Hour "Citizen Petitions" Filed to Slow Generic Drugs. *Maryland Law Review Online*. 2020;79:1.
[10] Ibid.
[11] Wouters OJ, Feldman WB, Tu SS. Product Hopping in the Drug Industry - Lessons from Albuterol. *N Engl J Med*. 2022;387(13):1153-1156. doi:10.1056/NEJMp2208613
[12] Lee CC, Najafzadeh M, Kesselheim AS, Sarpatwari A. Cost to Medicare of Delayed Adalimumab Biosimilar Availability. *Clin Pharmacol Ther*. 2021;110(4):1050-1056. doi:10.1002/cpt.2322

When prescription drug formularies place brand and biosimilar drugs on the same tier, it can create market issues. In a recent example, one biosimilar manufacturer attempted a two-price strategy to improve formulary coverage. This led to pharmacy benefit managers (PBM) preferring the higher priced biosimilar for payer coverage formularies, potentially negative effects the ability of Humira biosimilars to generate savings through competition.[13] Indeed, recent analyses suggest that biosimilar competition has yet to translate into lower out-of-pocket costs for patients using biologics.[14]

One obstacle to timely biosimilar competition is the impact of litigation. The Biologics Price Competition and Innovation Act (BPCIA), established in 2010 as part of the Affordable Care Act, aimed to create an abbreviated approval pathway for biosimilars. However, according to an article published in *Health Affairs*, the BPCIA has faced two main challenges that limit biosimilar competition: (1) noncompliance from biosimilar manufacturers with the litigation process outlined in the BPCIA biosimilar approval pathway; and, (2) the enforcement of a large number of patents by biologic manufacturers.[15] As a result, patent infringement litigation often delays biosimilar entry for years after biosimilars receive FDA approval.

Generic- & Biosimilar-Related Litigation and Legislation

The Hatch-Waxman Act of 1984 is the primary federal law in the U.S. that governs how generic drugs are brought to the market. It provides some significant provisions, such as enticing generics to challenge a brand-name drug patent with a lucrative 180-day exclusivity for being the first to come to market. Additionally, it allows generics to show bioequivalence to a reference brand drug without undergoing expensive and duplicative clinical trials. It also enables patent infringement litigation as soon as generics file for approval from the FDA. This helps determine whether the brand manufacturer's patents prevent generic entry and whether the generic does not have to enter "at risk."[16] Despite federal laws supporting prompt generic market entry, litigation concerning trade agreements and limiting “skinny labeling,” in which generic manufacturers can enter the market only for drug indications that no longer have market exclusivity, have further delayed generic entry and produced excess costs in the U.S.

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[13] Rome BN, Kesselheim AS. Biosimilar Competition for Humira Is Here: Signs of Hope Despite Early Hiccups. *Arthritis Rheumatol*. 2023;75(8):1325-1327. doi:10/gs3g33

[14] Feng K, Russo M, Maini L, Kesselheim AS, Rome BN. Patient Out-of-Pocket Costs for Biologic Drugs After Biosimilar Competition. *JAMA Health Forum.* 2024;5(3):e235429. doi:10.1001/jamahealthforum.2023.5429

[15] Van de Wiele VL, Kesselheim AS, Sarpatwari A. Barriers to US Biosimilar Market Growth: Lessons From Biosimilar Patent Litigation. *Health Aff (Millwood)*. 2021;40(8):1198-1205. doi:10.1377/hlthaff.2020.02484

[16] Kesselheim AS, Darrow JJ. Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era? *Yale J Health Policy Law Ethics*. 2015;15(2):293-347. doi:10.1001/jamainternmed.2022.5419

healthcare system.[17] An assessment was performed on the frequency of biosimilars marketed with skinny labels from 2015 to 2021, finding that use of skinny labels led to a median of 2.5 years of earlier biosimilar competition through 2021. The investigators estimate this saved Medicare $1.5 billion through 2020, emphasizing the importance of skinny labels to ensure timely biosimilar competition for high-cost biologics.[18]

Recently, a U.S. Judge of the Eastern District of Pennsylvania approved a settlement in an antitrust class action brought by direct pharmaceutical purchasers. The plaintiffs alleged that Sun Pharmaceutical Industries Ltd., Taro Pharmaceutical Industries Ltd., and others participated in a scheme to fix generic drug prices. The approved settlement amounts to $85 million.[19] However, it is important to note that on another front, a federal district court judge in Pennsylvania ruled that states were not entitled to a share of the profits that generic manufacturers allegedly made from their price-fixing scheme.[20] The case encompasses potential class action lawsuits related to price fixing of generic drugs in violation of the Sherman Act and state antitrust laws. Currently, there are claims concerning 18 drugs against several pharmaceutical manufacturers, and the scope has been expanded to include claims brought by 40 States through their Attorneys General.[21]

Generic & Biosimilar Drug Pricing

The high prices of some off-patent drugs are influenced by various market dynamics and manufacturer behaviors, including market consolidation, drug shortages, and anticompetitive practices among generic drug manufacturers. Articles reviewed highlight recent trends in the regulatory approval, manufacturing, and pricing of generic drugs in the U.S. This includes the impact of competition on generic drug prices, strategies that manufacturers use to delay generic entry, such as "pay-for-delay" or "reverse-payment" settlements, and the role of the FDA in prioritizing review of generic drug applications for markets with few manufacturers.[22] Suggested potential policy solutions to address these issues include greater antitrust enforcement, reducing barriers to generic drug entry, and

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[17] Walsh BS, Bloomfield D, Kesselheim AS. A Court Decision on "Skinny Labeling": Another Challenge for Less Expensive Drugs. *JAMA*. 2021;326(14):1371-1372. doi:10.1001/jama.2021.0006

[18] Egilman AC, Van de Wiele VL, Rome BN, et al. Frequency of Approval and Marketing of Biosimilars with a Skinny Label and Associated Medicare Savings. *JAMA Intern Med*. 2023;183(1):82-84. doi:10.1001/jamainternmed.2022.5419

[19] Generic pharmaceutical drugs direct purchasers $85M class action settlement - Top Class Actions

[20] https://www.fiercepharma.com/pharma/generic-drugmakers-win-one-lose-one-price-fixing-sweeping-case-involving-49-states-20

[21] https://www.paed.uscourts.gov/mdl/mdl-2724-re-generic-pharmaceuticals-pricing-antitrust-litigation

[22] Gupta R, Shah ND, Ross JS. Generic Drugs in the United States: Policies to Address Pricing and Competition. *Clinical Pharmacology & Therapeutics*. 2018;105(2):329-337. doi:10.1002/cpt.1314

novel solutions to minimize drug shortages, such as drug importation and non-profit drug manufacturing. [23]

Although generic drug prices are meant to offset the high initial prices of brand-name drugs, rising prices of generic products are a cause for concern. A study using Medicaid State Drug Utilization Data (2012-2018) found that price spikes for generic drugs are associated with injectable products, fewer manufacturers, and shortages.[24] While fewer price spikes seem to be occurring over time, the costs can still be substantial.

A study assessed whether generic competition will be an effective mechanism for high-priced specialty drugs, using commercial claims data to investigate treatments for chronic myeloid leukemia. The analysis found that, between 2001 and 2016, the list price of imatinib, more than doubled. Generic imatinib was highly anticipated to provide more cost savings compared to the high price of the brand. Imatinib was first approved in 2003 and is an effective cancer drug but had low patient adherence due to its costs. The first generic imatinib entered the market in 2016, but the launch price was only 8% lower than that of the brand name drug.[25] Using data from Medicare Part D, a study was done to estimate spending on imatinib, to see if this changed upon generic entry. While the acquisition cost for imatinib fell ($59), the markup cost increased substantially, and Medicare beneficiaries faced out of pocket costs of $80 to $400 per fill.[26] This indicates that barriers to entry may be significant, and few firms entered the generic market to sell the drug, leading to minimal price reduction.

Another article highlights several reasons why the decline in acquisition cost for generic imatinib was not passed on to Medicare patients, including rebates provided by drug manufacturers to incentivize higher priced drugs and spread pricing used by pharmacy benefit managers to create profits and benefit from higher drug prices.[27]

Lastly, a study examining the association between generic drug prices and market competition showed nearly half of the 1,120 generic drugs examined exist in a baseline duopoly-like state. Generic drugs with low competition were associated with greater price

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[23] Tessema FA, Kesselheim AS, Sinha MS. Generic but Expensive: Why Prices Can Remain High for Off-Patent Drugs. *Hastings Law Journal*. 2020;71:1019

[24] Patel AN, Kesselheim AS, Rome BN. Frequency of Generic Drug Price Spikes and Impact on Medicaid Spending. *Health Aff (Millwood)*. 2021;40(5):779-785. doi:10.1377/hlthaff.2020.02020

[25] Cole AL, Dusetzina SB. Generic Price Competition for Specialty Drugs: Too Little, Too Late? *Health Affairs*. 2018;37(5):738-742. doi:10.1377/hlthaff.2017.1684

[26] Dusetzina SB. Medicare Part D Payments for Generic Imatinib From 2017 to 2023. *JAMA Internal Medicine*. 2024;184(1):104-105. doi:10.1001/jamainternmed.2023.3932

[27] Crosson FJ, Kesselheim AS. Why Some Patients Overpay for Specialty Generic Drugs. *JAMA Internal Medicine*. Published online November 20, 2023. doi:10.1001/jamainternmed.2023.6071

increases (63.8%) than drugs with high competition (9.7%).[28] Reviews showed several potential reasons for this trend, including the lack of financial incentive in smaller markets, delays in generic regulatory, and consolidation among generic drug manufacturers. Those with low competition were associated with greater price increases than those with high competition.

Overall, studies are showing the complexities of the U.S. drug market, highlighting the need for greater competition and policy solutions to ensure affordable access to necessary medications.

Generics in Other Countries

It is widely known that Americans pay more for prescription drugs than people in other developed countries. A 2017 study compared the prices of generic drugs in the United States with thirteen European countries. The study found that generic drug prices varied significantly among European countries and were generally higher than in the U.S. However, the U.S. has recently seen sharp price increases for some generic products. The study also noted that uptake of generic prescriptions is slower in Europe than in the U.S. The report highlights differences between US regulatory and pricing strategies and those used in Europe, where internal reference pricing and tendering for generic drugs are more common.[29]

Another report compared U.S. drug prices to those of 32 comparable Organization of Economic Co-operation and Development (OECD) countries. The report found that while U.S. prices for brand name drugs were more than four times higher than in other countries, average prices for unbranded generics were 33% lower in the U.S. than in peer countries.[30] This finding emphasizes the effect of robust competition on price.

Generic Formulary Placement

Formulary decisions for generic drugs can vary across health plans and PBMs, particularly between commercial and government plans (e.g., Medicare and Medicaid). A formulary outlines which drugs are covered and any describes restrictions such as prior authorization

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[28] Dave CV, Kesselheim AS, Fox ER, Qiu P, Hartzema A. High Generic Drug Prices and Market Competition: A Retrospective Cohort Study. *Ann Intern Med*. 2017;167(3):145-151. doi:10.7326/M16-1432

[29] Wouters OJ, Kanavos PG, McKee M. Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending. *The Milbank Quarterly*. 2017;95(3):554-601. doi:10.1111/1468-0009.12279

[30] Mulcahy AW, Schwam D, Lovejoy SL. International Prescription Drug Price Comparisons: Estimates Using 2022 Data. RAND Corporation; 2024. https://www.rand.org/pubs/research_reports/RRA788-3.html

requirements, quantity limits, or step therapy prerequisites. Typically, health plans only pay for drugs listed on their formulary, and most plans require copays. Most drug formularies are organized into tiers, with Tier 1 usually covering generics and having the lowest copay cost. The higher the tier number, the higher the out-of-pocket costs for patients. Concerns have been raised that some generic drugs may be provided less favorable formulary placement over their branded counterparts, as brand name manufacturers offer more substantial rebates or discounts on their products to payors.

A study conducted in 2021 analyzed the plan coverage of brand-name drugs and their associated generics across Medicare Part D plans (2013-2019). The results indicated that shifting from a lower to a high cost-sharing tier could increase out-of-pocket patient costs.[31] Even if generic drugs have favorable formulary placement, branded drugs may be placed on a better coverage tier due to rebates or other price concessions manufacturers offer. Findings from a study done on Medicare Part D found that 72% of Part D formularies placed at least one branded drug on a lower cost-sharing tier than its generic.[32] In comparison, 30% of formularies had at least one branded drug with fewer utilization management controls than its associated generic.[33] The study's author highlighted rebates' role in this brand-over-generic placement and how such practices can increase patient out-of-pocket costs and overall healthcare spending.

Generic Drug Shortages

Drug shortages are a widespread problem that affects certain medications more frequently than others. Multiple causes of these shortages exist, with significant economic and clinical implications. An article addressing the causes and impact of drug shortages proposes several strategies countries can implement to manage present and prevent future shortages. These strategies include addressing the current shortage, making operational improvements to identify possible shortages in advance, making policy changes, and enhancing education and training for healthcare professionals on managing these shortages.[34]

A literature review of over 400 papers conducted between 2001 and 2019 studied drug shortages. Most of the documents described the shortages and their negative impacts, while fewer papers discussed strategies to prevent or respond to the shortages. The review

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[31] Dusetzina S, Juliette Cubanski P, Andrew W. Roberts P, et al. Trends in Medicare Part D Coverage of Generics with Equivalent Brand-Name Drugs. 2021;27. doi:10.37765/ajmc.2021.88701

[32] Socal MP, Bai G, Anderson GF. Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics Are Available. *JAMA Internal Medicine*. 2019;179(6):832-833. doi:10.1001/jamainternmed.2018.7824

[33] Ibid.

[34] Shukar S, Zahoor F, Hayat K, et al. Drug Shortage: Causes, Impact, and Mitigation Strategies. *Frontiers in Pharmacology*. 2021;12. doi:10.3389/fphar.2021.693426

recommends that more attention be given to working toward long-term policy solutions to address this issue.[35]

Policy solutions aimed at addressing drug shortages must target the root cause of the shortage. Policymakers have three levers at their disposal to tackle the issue:

- Reducing the likelihood of a shortage
- Minimizing the size or scope of a shortage
- Mitigating the impact of a shortage[36]

An effective policy solution should incorporate all three levers and create a framework for existing legislative proposals on drug shortages. This framework should assess the strengths and weaknesses of each proposal, such as hospital billing changes, transparency, and domestic manufacturing.

Several factors have been shown to increase the risk of generic drug shortages. A study assessed the association between generic shortages, price, market competition, and market size, finding that only the price was associated with a risk of shortage.[37] Low-priced generic drugs were found to be more likely to experience shortages, while shortages were associated with a modest increase in drug prices.

Another research letter examined the impact of shortages on generic drug prices, finding that prices for generic drugs in shortage between 2015 and 2016 increased more than twice as quickly (7.3% before the shortage, 16.0% after the shortage) in the absence of a shortage.[38] This phenomenon was more pronounced among drugs with three or fewer manufacturers.

Drug shortages particularly impact generic drugs. A study published in *Value in Health* in 2018 found that generic low-priced medicines were more likely to experience shortages, while shortages were associated with a modest increase in drug prices. Another analysis of a cohort of 77 drugs losing market exclusivity between 2010 and 2013 found that oral small-molecule drugs and drugs with large markets tended to have more stable prices and competition.[39] On the

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[35] Tucker EL, Cao Y, Fox ER, Sweet BV. The Drug Shortage Era: A Scoping Review of the Literature 2001–2019. *Clinical Pharmacology & Therapeutics*. 2020;108(6):1150-1155. doi:10.1002/cpt.1934

[36] Wosińska ME. Drug Shortages: A Guide to Policy Solutions. Brookings Institution. Published March 14, 2024. https://www.brookings.edu/articles/drug-shortages-a-guide-to-policy-solutions/

[37] Dave CV, Pawar A, Fox ER, Brill G, Kesselheim AS. Predictors of Drug Shortages and Association with Generic Drug Prices: A Retrospective Cohort Study. *Value Health*. 2018;21(11):1286-1290. doi:10.1016/j.jval.2018.04.1826

[38] Hernandez I, Sampathkumar S, Good CB, Kesselheim AS, Shrank WH. Changes in Drug Pricing After Drug Shortages in the United States. *Ann Intern Med*. 2019;170(1):74-76. doi:10.7326/M18-1137

[39] Frank RG, Mcguire TG, Nason I. The Evolution of Supply and Demand in Markets for Generic Drugs. *The Milbank Quarterly*. 2021;99(3):828-852. doi:10.1111/1468-0009.12517

other hand, smaller markets and injectable drugs had fewer market entrants, higher exit rates, greater price instability, and an increased risk of shortages.[40]

Potential drivers of generic drug shortages include weak market incentives, supply chain complexities, and inadequate incentives for high-quality manufacturing practices, which are considered primary issues that lead to shortages.[41] Increased consolidation among group purchasing organizations and offshoring of supply chain entities can create further market imbalances. Researchers propose involving the FDA and payers in strategies to incentivize high-quality generic drug production to remedy these dynamics.[42]

Generic & Biosimilar Substitution

State laws surrounding generic substitution can significantly impact the adoption and use of generic drugs. According to a 2022 Value in Health report, patients in states that require consent or pharmacist notification to substitute with generics tend to use generics less, while mandating versus permitting generic substitution and protecting pharmacists from liability had no significant effects.[43]

In Oregon, pharmacists may substitute a drug product with a generic that is the same in strength, quantity, dose, dosage form, and therapeutic equivalency. State law requires pharmacists to post a sign at the counter that reads, "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." Doctors may also specify that no substitutions be allowed.[44]

Another study surveyed state-level generic drug substitution regulations, which dictate how pharmacists can substitute prescriptions for brand-name drugs with lower-cost generics or biosimilars. The survey found that there is significant variation in these laws across states, with only one-third of states requiring that pharmacists automatically substitute branded prescriptions with an FDA-approved generic. Additionally, 15% of states require patient

[40] Ibid.
[41] Hernandez I, Hershey TB, Donohue JM. Drug Shortages in the United States: Are Some Prices Too Low? *JAMA*. 2020;323(9):819-820. doi:10.1001/jama.2019.20504
[42] Hernandez I, Hershey TB, Donohue JM. Drug Shortages in the United States: Are Some Prices Too Low? *JAMA*. 2020;323(9):819-820. doi:10.1001/jama.2019.20504
[43] Rome BN, Sarpatwari A, Kesselheim AS. State Laws and Generic Substitution in the Year After New Generic Competition. *Value Health*. 2022;25(10):1736-1742. doi:10.1016/j.jval.2022.03.012
[44] Oregon Revised Statutes 689.515. https://www.oregonlegislature.gov/bills_laws/ors/ors689.html

consent for substitution.[45] When examining substitution of biologics with an interchangeable biosimilar, 45 states had more stringent requirements, such as mandatory physician notification. This highlights the potential barriers to biosimilar uptake in the U.S.

Conclusion

Over the past three years, the Prescription Drug Affordability Board has been studying the generic drug market and has produced reports for the Oregon Legislature. This 2024 report identifies both challenges and solutions to relying on generic drugs as a cost-effective solution in Oregon. The report highlights changes at the federal level, such as patent reform and eliminating citizen petition system abuse, could be helpful. It also suggests that changing the formularies used by health plans and PBMs could encourage the use of generics and biosimilars for cost savings. The report also provided ideas for overcoming generic drug supply chain shortages. The Prescription Drug Affordability Board believes that expanding the use of generic drugs and biosimilars may be one of the ways to make prescription drugs more affordable for Oregonians and the state's healthcare system.

[45] Sacks CA, Van De Wiele VL, Fulchino LA, Patel L, Kesselheim AS, Sarpatwari A. Assessment of Variation in State Regulation of Generic Drug and Interchangeable Biologic Substitutions. *JAMA Intern Med*. 2021;181(1):16. doi:10/gjjdfn

Oregon Prescription Drug
Affordability Board

Senate Bill 192
UPL Constituent Group Engagement Plan Status Update

Ralph Magrish
Executive Director
April 17, 2024

Senate Bill 192, Section 3

"(1) The [PDAB] shall develop a plan for establishing upper payment limits [(UPLs)] on drugs sold in this state that are subject to affordability reviews. The plan shall include:

(a) A methodology for establishing UPLs;

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

(c) An analysis of how UPLs would be enforced; and

(d) An analysis of how UPLs 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…; and

(E) Other forms of insurance that provide pharmaceutical benefits…."

Senate Bill 192, Section 3

"(2) No later than September 15, 2024, the [PDAB] shall report to the interim committees of the Legislative Assembly related to health…, the following information:

(a) A detailed explanation of the plan developed under subsection (1) of this section.

(b) An analysis of potential savings from or costs of implementing the plan with respect to:

(A) The state;

(B) Insurers;

(C) Hospitals;

(D) Pharmacies; and

(E) Consumers."

Recommend UPL Approaches

- In January 2023, DCBS contracted with Myers and Stauffer LC, a national Certified Public Accounting (CPA) firm with pharmacy pricing and consulting expertise
- Through this engagement, Myers and Stauffer is soliciting constituent feedback to support the development and recommendation of UPL approaches
- Constituent group goals:
  - Understand concerns, questions, support, or opposition to UPLs
  - Gather feedback about the process and utilization of setting UPLs and methods to implementation
  - Solicit input for additional data considerations or alternative approaches for the UPL model

Constituent Feedback

- Identifying constituents for focus group sessions (i.e., carriers, hospitals/health systems, 340B covered entities, and pharmacies)
- Disseminating constituent survey (April 2024)
  - Intended to set a baseline for understanding the UPL concept
  - Solicits initial responses that can be further explored during focus group sessions
- Hosting virtual constituent focus group meetings (May 2024)

Constituent Feedback

- Pre-meeting constituent survey approach:
  - Questions broadly applicable to constituent groups
  - Targeted questions specific to individual constituent groups
  - “SWOT” format (strengths, weaknesses, opportunities, threats)
- Example survey questions:
  - How do you anticipate that an upper payment limit would impact your organization's drug spending and budgetary considerations?
  - What kind of impact do you think an upper payment limit would have on a patient’s ability to afford their medications?
  - What recommendations, if any, do you have regarding the potential administrative burdens or operational challenges associated with implementing an upper payment limit?

Constituent Feedback

- Constituent focus group approach:
  - Anticipate 1-2 sessions per focus group
  - Designed to facilitate dialogue and solicit clarification or information post-survey
- Example focus group questions:
  - What would an ideal drug affordability or upper payment limit program look like within Oregon?
  - What barriers or challenges do you see to implementing UPLs?
  - What concerns do you have about the state implementing a UPL?

PDAB forums across Oregon in April, May

- The Prescription Drug Affordability Board is hosting in-person and online community forums across Oregon. The board invites people to learn why drug costs are so high and share stories about medication cost and impact. Find times, locations: dfr.oregon.gov/pdab/

In person:
Portland: April 2
Lincoln City: April 9
Woodburn: April 15 - *Foro en Español*
Medford: April 25 - *ASL interpretation*
Bend: April 30

Online:
May 8 – *Spanish & ASL interpretation*
May 14 – *Spanish & ASL interpretation*

Take the community forum survey:

https://dfr.oregon.gov/pdab/

Contact us

pdab@dcbs.oregon.gov

971-374-3724

Oregon Prescription Drug
Affordability Board

DO YOU THINK YOUR PRESCRIPTION DRUGS COST TOO MUCH?

Learn why drug costs are so high

The Prescription Drug Affordability Board was created to find ways to make prescription drugs more affordable for Oregonians by making recommendations to the Oregon Legislature.

Help us identify solutions to high drug costs

Please come share your story at a community forum with board staff about how prescription drug prices and medication costs have affected you.

In-person forums

Portland – Tuesday, April 2, 6-8 p.m.
Portland State Office Building
800 NE Oregon St.

Lincoln City – Tuesday, April 9, 6-8 p.m.
Cultural Center
540 NE Highway 101

Woodburn – Monday, April 15, 5-7 p.m.
Woodburn Public Library
Multipurpose Room
280 Garfield St.
FORO EN ESPAÑOL

Medford – Thursday, April 25, 6-8 p.m.
Rogue Community College HEC
Presentation hall, 101 S Bartlett St.
ASL provided

Bend – Tuesday, April 30, 6-8 p.m.
East Bend Library
62080 Dean Swift Road

Online forums

Wednesday, May 8, noon to 2 p.m.
Join ZoomGov Meeting
https://www.zoomgov.com/j/1609683098?pwd=ZFVvNHdGV1dMYm5GWWQ1ZWlkcEl4UT09

Meeting ID: 160 968 3098

Passcode: OregonPDAB

Dial by your location: 669 254 5252
FORO EN ESPAÑOL
American Sign Language provided

Tuesday, May 14, 6-8 p.m.
Join ZoomGov Meeting
https://www.zoomgov.com/j/1617060370?pwd=YlhObURQRTcyTTJrSkx2ZjB0S3RUUT09

Meeting ID: 161 706 0370 Passcode:
OregonPDAB

Dial by your location: 669 254 5252
FORO EN ESPAÑOL
American Sign Language provided

Oregon Prescription Drug
Affordability Board

¿USTED CREE QUE EL COSTO DE LOS MEDICAMENTOS RECETADOS ES MUY ALTO?

Conozca por qué los costos de los medicamentos son tan altos
La Junta de Asequibilidad de Medicamentos Recetados se formó para encontrar maneras de hacer que los medicamentos recetados sean más económicos para los habitantes de Oregon a través de recomendaciones a la Legislatura de Oregon.

Ayúdenos a identificar soluciones a el costo alto de los medicamentos
Venga a compartir su historia en el foro comunitario con el personal de la junta sobre cómo le han afectado los precios y los costos de los medicamentos recetados.

Foro en Español

Woodburn April 15, 5-7 p.m.
Woodburn Public Library
Multipurpose Room
280 Garfield St, Woodburn, OR 97071

Oregon Prescription Drug
Affordability Board