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: **May 17, 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; Amanda Claycomb, data analyst, Melissa Stiles, administrative specialist; Jake Gill, counsel; Pramela Reddi, counsel

Subject	Presenter	Time Allotted
☐ Call to order, roll call, and approval of minutes	Chair Patterson	5 minutes
☐ Executive director's program update	Ralph Magrish	5 minutes
☐ Presentation by: America's Health Insurance Plans (AHIP) Questions from board members	Sean Dickson, senior vice president of pharmaceutical policy & strategy	25 minutes
☐ Board affordability review * Statement of Need and Fiscal Impact (SNFI) * Rule: discussion and approval	Cortnee Whitlock	55 minutes
☐ Board approval of final draft Generic drug report	Cortnee Whitlock	10 minutes
☐ Announcements	Ralph Magrish	5 minutes
☐ Public comment	Chair Patterson	10 minutes
☐ Adjournment	Chair Patterson	2 minutes

Next meeting

June 21, 2023, at 9:30 a.m.

Accessibility

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

How to submit public comment

Oral testimony

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

Written testimony

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

Open and closed sessions

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

Oregon Prescription Drug Affordability Board

Oregon Prescription Drug Affordability Board Meeting
Wednesday, April 19, 2023
Draft Minutes

Chair Akil Patterson called the meeting to order at 9:35 am and asked for the roll call.

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

Chair Akil Patterson asked if board members had any changes to the March 15, 2023, minutes on Pages 3-6 in the agenda packet: https://dfr.oregon.gov/pdab/Documents/20230419-PDAB-document-package.pdf and there were none. **Dr. Richard Bruno** moved to approve the minutes and **Robert Judge** provided a second.

MOTION by Richard Bruno to approve the March 15, 2023, minutes.
Board Vote:
Yea: Richard Bruno, Daniel Hartung, Robert Judge, Shelley Bailey, Akil Patterson
Nay: None.
Motion passed.

Program update: Executive Director Ralph Magrish welcomed Amanda Claycomb, research analyst, to the PDAB team. Staff held interviews for the data analyst position and anticipate introducing a new person next month. Staff has executed a contract with Jane Horvath of Horvath Health Care to provide policy and technical assistance. In May, the board will hear a presentation from AHIP, the trade association for insurance carriers. Ralph introduced Sarah Emond, executive vice president and chief operating officer of Institute for Clinical and Economic Review (ICER).

Sarah Emond, EVP and COO, Institute for Clinical and Economic Review (ICER), gave a presentation from Pages 7-19 in the agenda document about the nonprofit organization, independent of industry, doing health technology assessments. ICER does analyses of new drugs, looking at comparative clinical effectiveness, and whether price increases are supported by new evidence. She provided a list of ICER funding sources. She provided a link to a recent paper about using health technology assessments to advance health equity. ICER will evaluate clinical trial diversity and provide a rating for how well the clinical trial did in recruiting and studying the drug in a population that matches the prevalence for the disease. ICER will use a Health Improvement Distribution Index to estimate the impact a new treatment could have in addressing overall health disparities. In conjunction with the disability community, ICER has developed an alternative metric to quality-adjusted life years (QALY) to ensure ICER is valuing life extension the same for every patient, regardless of disability or status. The equal value of life years gained (evLYG) metric is available in every ICER report and can be used to help know what a fair price is for a new medicine. All of ICER reports are publicly available.
Shelley Bailey asked if the estimated discount on Slide 9 takes into consideration the 340B pricing, whether it was part of the net pricing, and whether more discounts were needed beyond 340B to achieve those goals?
Sarah Emond said it is difficult to know net prices of medicines because they are held as proprietary trade secrets between the plans and manufacturers. ICER uses a source called SSR Health, an independent consultant that estimates net based on volume and net revenue information reported by companies. It is all one big bucket and impossible to know whether it is 340B, rebates to PBMs, or patient assistance programs, she said. **Ralph Magrish** said in addition to having a license with ICER, staff has executed one with SSR Health.

Daniel Hartung asked how responsive manufacturers and industry are to some of the value metrics that ICER produces with different payers? From the payer perspective, how common is it for ICER reports to be used by payers to leverage discount price negotiation with manufacturers? **Sarah Emond** said industry is at the table, engaging, advocating for the value of their medicines. With only a few exceptions, manufacturers participate in the ICER review, providing data and comments on the economic model. Manufacturers do the same analyses that ICER does, including cost-effectiveness models and comparative clinical effectiveness. Manufacturers have cited ICER research in justification for their own price and private payers cite ICER work for coverage policy, price negotiations, or deliberations. About three-quarters of Medicaid departments rely on ICER's work. New York has leveraged ICER work to get about $500 million in supplemental rebates for their Medicaid program.

Richard Bruno asked for more detail on equal value of life years gained (evLYG) and how it compares to QALYs or other similar metrics and how that works with certain populations. **Sarah Emond** said the metric known as quality adjusted life year (QALY) was developed decades ago by American physicians and health economists to measure how much a drug improves quality of life and longevity. It has a limitation, which is, if there is a condition that extends life for a population with an underlying illness, comorbidity, or disability, an analysis could undervalue time and life extension. ICER uses the equal value of life years gain (evLYG) metric measures the time and life extension the same, no matter who a person is. ICER picks a point, a value, and everyone gets assigned that value. Decision makers can still highly value drugs that are delivering great improvements in quality of life and length of life and then protect against undervaluing drugs that extend the life of people with underlying disabilities.

Shelley Bailey asked if ICER gets the total cost of the disease data from payers or if there is another data source for total cost of the disease versus offset of the cost of the drug? **Sarah Emond** said ICER uses national averages for costs, including Medicare data, claims databases, and other sources. Patient advocacy organizations are excellent sources because they have done their own research on natural history and cost of care.

Daniel Hartung: What about weighing value metrics with budget impact of drugs that are a really good value but still budget busters? A lot of people need care – how does ICER grapple with those competing resource issues? **Sarah Emond**: In every analysis, ICER emphasizes the long-term value for money and benefit for patients over a lifetime. But for decision makers, affordability is an important component. ICER reports include a budget impact analysis, which sets the threshold for an increase in spending on a per-member-per-month basis, which is about twice the rate of medical inflation. If ICER predicts a potentially high-value, high-cost intervention would impact the ability of insurers and employers to offer affordable health insurance, ICER signals that alert so policymakers can talk about ways to manage that budget impact. Follow up options could include targeting the sickest patients, trying to get additional discounts for a particular drug, or using the ICER budget impact model tool to determine if the introduction of a particular drug would mean a budget impact for a state, she said.

Legislative Update: Jessie O'Brien, policy manager for the Division of Financial Regulation, gave a status of proposed bills being considering by the Oregon Legislature in the 2023 Session. See the summary on Pages 20-21 of the agenda packet, with links to the bills.

Rulemaking Advisory Committee: **Cortnee Whitlock** reviewed the notes and summary from the rulemaking advisory committee meeting held April 5. See the notes and summary on Pages 22-26 of the agenda packet. She said the public hearing will be held June 22 and public comment will be accepted through June 29.

Draft Affordability Review Rule: Cortnee Whitlock reviewed the draft affordability review on Pages 29-51 of the agenda packet, beginning with Section 3(a). The process begins by looking at the data provided by the Drug

Price Transparency (DPT) Program. Staff will take the top 25 drug lists from DPT and categorize them into high-level medications consistent on all reports. From there, the board will use the criteria in the rule to funnel down the data. She asked if board members had feedback. This table summarizes board member feedback:

Feedback	Rule Section	Board Member
* Expand insulin data to include current price increases since data is two years old.	(3)(a) C	Robert Judge
* Option 2 in F, CMS Medicare negotiation list. * Remove F or soften language (instead of "eliminate," use "not including"). * Hold off F until CMS negotiations go live.	(3)(a) F	Robert Judge, Daniel Hartung, Shelley Bailey
* Remove G, FDA shortage list. *Notes*: No need for drug shortage list criteria considering this board will not yet have upper payment limit authority. Often, when drugs come off the FDA approved shortage list, they have a considerable price increase.	(3)(a) G	Akil Patterson, Shelley Bailey, Robert Judge
*Option 2 in H, patent expiration dates, within 18 months instead of 3 years. *Notes*: Three years is a lifetime. Needs a narrower window. Board would miss potential opportunities for cost savings.	(3)(a) H	Akil Patterson, Shelley Bailey, Daniel Hartung, Robert Judge
*Add the word *net*: Changes in the prescription drug *net* wholesale acquisition cost over time."	(4)(b) C	Shelley Bailey
* Add information about the total cost of the disease and the drug price offset	(4)(b) G	Shelley Bailey
* Add language about rebates, discounts, and price concessions that 340B price concessions are part of. *Notes*: Patient assistance and coupon rebate paperwork is a very onerous process for patients.	(4)(b) K	Shelley Bailey, Richard Bruno
* Add definition of price to clarify the meaning.	(4)(b)	Robert Judge

Generic Drug Report: Cortnee Whitlock reviewed the draft report located on Pages 52-66 of the agenda packet. She asked if board members had any changes, and there were none. She asked Robert Judge if his earlier request to include a section on biologic and biosimilars was addressed in the draft report, and he said yes. The report will be in the May meeting packet for final approval by the board.

Public comment: The chair allocated three minutes for public comment. Dharia McGrew, regional vice president PhRMA, provided testimony to the board. PhRMA's written comments are posted online: https://dfr.oregon.gov/pdab/Documents/20230419-PDAB-public-comment.pdf.

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

2023 Drug Pricing Legislative Update – PDAB 5/17/23

DCBS-supported legislation

Bill #	Relating Clause	Bill Summary	Status
SB 192	Relating to prescription drugs; prescribing an effective date.	Requires pharmacy benefit managers to annually report to Department of Consumer and Business Services information about certain rebates, fees, price protection payments and other payments received from prescription drug manufacturers.	Alive, awaiting Senate floor vote. Passed Senate Health Care Committee 4/3. Passed Senate Rules Committee with additional amendments 4/27.
SB 404	Relating to prescription drugs; prescribing an effective date.	Requires pharmacy benefit managers and group purchasing organizations to annually report to Department of Consumer and Business Services information relating to prices, rebates, fees and similar information.	Alive, in Joint Ways and Means. Passed Senate Health Care Committee 3/22.

Active external legislation

Bill #	Relating Clause	Bill Summary	Status
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.	Alive, in House Revenue. No action to date.
HB 2725	Relating to pharmacy benefit managers; declaring an emergency.	Prohibits pharmacy benefit manager from imposing fees on rural pharmacies after point of sale.	Alive, referred to House Rules from House Behavioral Health & Health Care committee without recommendation.
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.	Alive, referred to House Rules from House Behavioral Health & Health Care committee without recommendation.
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.	Alive, referred to House Rules from House Behavioral Health & Health Care committee without recommendation.

SB 61	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.	Alive, in Senate Finance and Revenue. No action to date.
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.	Alive, passed Senate on 4/12. Work session in House Health scheduled for today. Amendment proposed to include provisions on copay accumulator programs from dead bill SB 565.

The Role of Health Insurance Providers in Keeping Prescription Drugs Affordable

Sean Dickson

Sr. Vice President, Pharmaceutical Policy & Strategy

May 17, 2023

About AHIP

AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone.

Visit www.ahip.org to learn how working together, we are Guiding Greater Health.

Where Does Your Health Care Dollar Go?

Your premium—how much you pay for your health insurance coverage each month—helps cover the costs of the medications and care you receive and improves health care affordability, access and quality for everyone. **Here is where your health care dollar really goes.**

This data represents how your commercial health plan premiums pay for medical care, as well as related services and essential operations. This data includes employer-provided coverage as well as coverage you purchase on your own in the individual market. Data reflects averages for the 2018-20 benefit years. Percentages do not add up to 100% due to rounding.

Sources: Where Does Your Health Care Dollar Go? AHIP, September 2022.

Rx Spending Growing at an Unsustainable Rate

U.S. spending on medicines reached $429 billion in 2022

Spending at list prices grew at 7.4% over the past 5 years, but payers' spending grew at 4.5% and patients' costs grew at 1.4%

In 2012, OOP was 18% of total drug costs, dropping to 13% in 2021

Sources: The Use of Medicines in the U.S., IQVIA institute, April 2023; National Health Expenditures, Centers for Medicare & Medicaid Services, April 2022.

Cost Saving Tools Under Attack

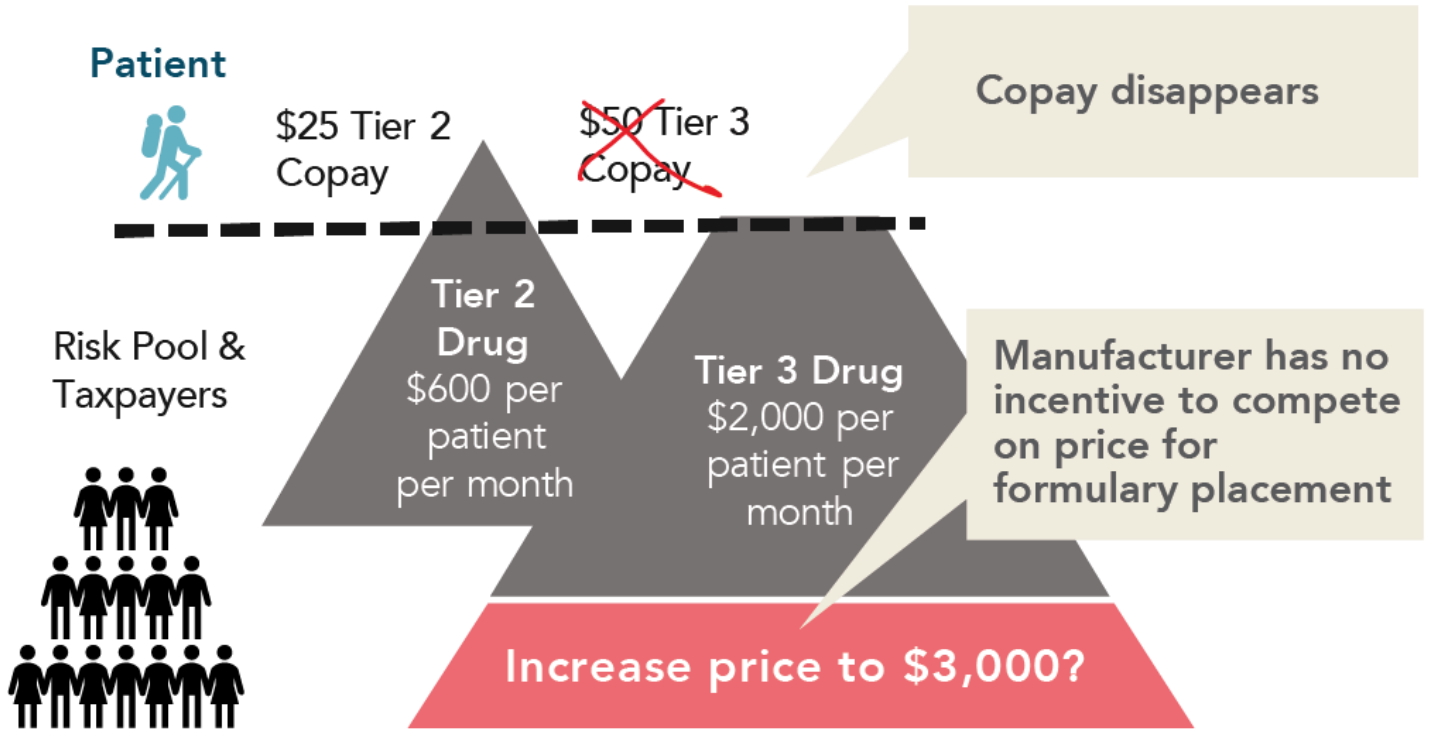
Copay Coupons Are A Kickback Keeping Drug Prices High

Coupons remove incentives for:

1. Patients to consider lower cost drugs and
2. Big Pharma to lower their prices

Coupons are **prohibited in Medicare and Medicaid.**

In these federal programs, **coupons are considered an illegal "kickback"** because they induce a patient to take a certain drug.



Sources: Special Advisory Bulletin Pharmaceutical Manufacturer Copayment Coupons, HHS OIG, September 2014.

How Copay Coupons Manipulate Drug Spending

Higher List Prices + Sales

- Drugs with coupons have a **higher annual price growth** (12-13%) than drugs without coupons (7-8%).
- Coupons **boosted retail sales of branded drugs by 60% or more** because of reduced sales of generics.

Increased Spending

- During the 5 years following generic entry, coupons **increase spending by an estimated $30 to $120 million per drug.**
- New Hampshire saw **$700 million more in drug spending annually** – $2.9 billion over 5 years – compared to neighboring Massachusetts, which had banned copay coupons.

Line Pharma's Pockets

- For one cancer drug, the manufacturer determined that enhancing the copay program 6 months before the loss of exclusivity would result in the greatest return on investment.
- This would keep more patients on the branded drug before a lower-cost generic entered the market.
- The manufacturer estimated **the rate of return for its copay assistance program was $8.90 for every dollar invested**.

Sources: When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization; US House Oversight Committee Drug Pricing Investigation; Novartis – Gleevec.

Rebates Hold Big Pharma Accountable

- Some claim that negotiating for lower drug costs makes drug prices go up. Common sense – and a growing body of research – says that's not true.
- Drug manufacturers only offer rebates to drugs that have competition – they do so to get better placement on formularies and be prescribed to more patients.
  - The most expensive drugs – those that have no competition – do not offer rebates.
- A recent analysis compared price increases for rebated and non-rebated drugs and found that price increases were roughly the same for both groups, so **rebates were not driving higher price increases**.
- The U.S. House Oversight Committee's multi-year Drug Pricing Investigation also concluded:
  - "This data, which has never before been shared with the public, **undermines industry claims that price increases are primarily due to increasing rebates and discounts paid to pharmacy benefit managers** (PBMs)."
  - "In addition, documents show that **PBMs secured contractual provisions that disincentivized drug companies from raising list prices. Without those provisions secured by PBMs, drug companies likely would have raised list prices more**."

Sources: Understanding Drug Rebates and Their Role in Promoting Competition; US House Oversight Committee Drug Pricing Investigation – Majority Staff Report.

Rebates Benefit All Consumers

- Health insurance providers are Americans' bargaining power, negotiating lower drug costs for everyone.
- While rebates only apply to a small percentage of prescription drugs, insurers pass on those negotiated savings to **all** consumers through lower out-of-pocket costs and/or premiums.
- Delivering rebates to a small number of patients at the point of sale means eliminating savings and increasing costs for all plan enrollees.

Focusing on how savings are distributed is a deliberate tactic to avoid the more serious issues surrounding the lack of competition, transparency, and accountability in drug pricing.

AHIP's Solutions for Affordability

- In 2021, AHIP undertook a year-long process with our members to develop solutions to improve affordability.
- The result is our **Healthier People Through Healthier Markets** Initiative.
- By improving competition in 10 key areas of our health care system, we can improve affordability and access for everyone.
- We are committed to working with federal and state officials and other stakeholders to take decisive action, and to advocate for the policy changes and necessary enforcement to make these solutions a reality.
- **Consumers deserve no less.**

State Solutions to Increase Prescription Drug Affordability

Accelerate the Availability of Biosimilars

- Ensure that state substitution laws do not create barriers to biosimilar access for patients.

Reform the System for Provider-Acquired Drugs

- Prevent harmful mark-ups and increased costs for patients by protecting the use of specialty pharmacies to access lower drug costs.

Address Drug Manufacturers' Abuse of Charitable Structures

- Put an end to drug manufacturer bait-and-switch tactics in the commercial market, such as coupons – which are already considered kickbacks by federal programs.
- Increase scrutiny of patient assistance charities.

Federal Solutions for Prescription Drug Affordability

Accelerate the Availability of Biosimilars

- Speed up the approval process for interchangeability of biosimilars.
- Shorten the exclusivity period for biologics.

Reform the System for Provider-Acquired Drugs

- Reform the system for reimbursing hospital-outpatient and physician-administered drugs.

Stop Drug Manufacturers from Engaging in Patent Games

- End pay-for-delay agreements which the FTC estimates cost Americans $3.5 billion in higher drug costs each year.
- Take actions to curb patent evergreening –making minor modifications to an old drug to obtain a new patent and extend a manufacturer's monopoly.
- Take steps to limit, and address the harm caused by, product hopping –moving patients from a product that is nearing the end of its patent exclusivity to a reformulation of the drug that has longer exclusivity.

Address Drug Manufacturers' Abuse of Charitable Structures

- Preserve the existing protections against abuse of charitable structures that exist with respect to federal programs.
- Put an end to drug manufacturer bait-and-switch tactics in the commercial market, such as coupons – which are already considered kickbacks by federal programs.
- Increase scrutiny of patient assistance charities

Thank You

Sean Dickson

Sr. Vice President, Pharmaceutical Policy & Strategy

sdickson@ahip.org

PDAB rulemaking timeline

Affordability review rule

- Board discussion: Feb. 15, March 15, and April 19
- Rulemaking advisory committee: April 5
- Board approval: May 17
- File with Secretary of State: May 25
- Public hearing: June 22
- Public comment deadline: June 29
- Board final approval: July 19
- File final with Secretary of State: July 25
- Effective date: Aug. 1, 2023

Dates may change

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NOTICE OF PROPOSED RULEMAKING
STATEMENT OF NEED AND FISCAL IMPACT

Filing caption: Model Rule for Prescription Drug Affordability Review
Public comment deadline: 6/29/2023
Effective Date: 8/1/2023

HEARING

Date: **6/22/2023**
Time: **11:00 to 11:45**
Officer: **Cortnee Whitlock**

Location: Labor & Industries Building
350 Winter St. NE
Basement, Conf Rm E
Salem, OR 97301

A hybrid meeting conducted in-person and virtually via Microsoft Teams.

NEED FOR RULE(S)

Provide background on why the rule is needed, including a short summary of the rulemaking authority and statutes implemented. Provide a summary of what the rule does. Describe the involvement of the RAC, including the types of stakeholders that were invited to and did participate. Specify if any of the stakeholders were small businesses.

The Prescription Drug Affordability Board (PDAB) was enacted as part of Senate Bill 844 (2021) within the Department of Consumer and Business Services with the purpose to protect consumers and other entities from the high cost of prescription drugs. The law provides authority for the PDAB to adopt rules necessary for the administration of the board (ORS 646A.693(18).

The prescription drug affordability review rule provides the framework and data points for the board to conduct the statutorily drug affordability reviews. The rule informs PDAB on the costs of prescription drugs by reviewing information from drug manufacturers, health insurance carriers, and pharmacy benefit managers. If a drug is deemed unaffordable, the board will provide recommendations on what changes are needed to make the drugs affordable. This rule is intended to increase access to affordable prescription drugs and reduce the financial burden on consumers.

A Rules Advisory Committee (RAC) met on April 5, 2023, and consisted of stakeholders from drug manufacturers, insurers, and pharmacy benefit managers (PBMs).

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Draft rules are available from Karen Winkel, Rules Coordinator, Division of Financial Regulation located at 350 Winter St. NE, Salem, OR 97301 and are available on the division's website: https://dfr.oregon.gov/laws-rules/Pages/proposed-rules.aspx

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT EQUITY IN THIS STATE:

(*Who is this going to impact and how might it impact one group of people differently than others?)*

The PDAB is tasked with evaluating the cost of prescription drugs, including ones that contribute to health inequities for communities of color.

Conducting an affordability review of prescription drugs can help ensure that individuals with lower incomes or limited access to healthcare are not disproportionately burdened by high drug costs. This can promote greater equity in terms of access to necessary medications. It is important for the PDAB to carefully consider the potential impacts of affordability reviews on equity and access to healthcare.

FISCAL AND ECONOMIC IMPACT:

Based on information available to DCBS, briefly discuss the cost of compliance for businesses, generally. State whether there are compliance costs for small businesses (independently owned and operated with fewer than 50 employees).

Cost of compliance for business under this rulemaking would be minimal as most of the business compliance standards are governed through the Drug Price Transparency Program. The Drug Price Transparency Program collects the data required under ORS 646A.689 (2) and (6), and ORS 743.025, and provides that data to the PDAB to identify the nine drugs and insulin product.

State licensed health insurance carriers will need to submit information to the PDAB consistent with requirements in statute that are referenced in this rule. Information collected through these data requests will inform the PDAB's decisions in conducting affordability reviews. Data requests will be made annually for drugs identified as candidates for affordability reviews as well as therapeutic alternatives. Drug manufacturers may submit information to the board on a voluntary basis once drugs are identified as candidates for affordability review selection. Compliance cost for small businesses are not anticipated as a result of this rule.

COST OF COMPLIANCE FOR SMALL BUSINESSES

(1) Identify any state agencies, units of local government, and members of the public (including specific interest groups) likely to be economically affected by the rulemaking.
Based on currently available information, the proposed rule would not have a fiscal or economic impact on state agencies, local government units, or the general public beyond the statutory requirements. The requirement to conduct affordability reviews has a fiscal impact on the Department of Consumer and Business Services due to the staffing and other resources required for this work. However, the rules solely provide detail and elaboration to this requirement and do not have a fiscal impact beyond the underlying statute.

(2)(a) Estimate the number and type of small businesses subject to the rule(s).
Pharmaceutical manufacturers are the primary business directly subject to the underlying statute. The board does not have data on the specific number of employees employed by pharmaceutical manufacturers. The rule should not have an impact on manufacturers beyond the underlying statutory requirements.

Based on the information available to the board, the proposed rule may have an impact on insurers beyond the underlying to statute. However, according to financial filings made to DFR, no insurers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated.

The RAC included representatives of prescription drug manufacturers, health insurers, pharmacy benefit managers, pharmacies, and consumer and patient advocates. Committee feedback suggested that it is unlikely that any of the manufacturers or other affected businesses are small businesses.

(2)(b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s).
Based on the available information, including feedback from the RAC, the proposed rules do not impose additional compliance costs beyond the underlying statutory requirements.

(2)(c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).
Based on current information, including feedback from the RAC, the proposed rules do not impose additional costs for professional services, equipment supplies, labor, and increased administration beyond the underlying statutory requirements.

How were small businesses involved in the development of the rule?
The rulemaking advisory committee was comprised of stakeholders within the pharmaceutical supply chain. This included representation of pharmacies and some pharmacies are small businesses.

Was an administrative rule advisory committee consulted?
Yes. DCBS and the PDAB convened a rulemaking advisory committee, which included representatives of prescription drug manufacturers, health insurers, pharmacy benefit managers, pharmacies, and consumer and patient advocates.

Did membership of the RAC represent the interests of persons and communities likely to be affected by the rule?
Yes. The RAC members included professionals from prescription drug manufacturers, health insurers, pharmacy benefit managers, pharmacies, and consumer groups. The rulemaking advisory committee met on April 5, 2023. Consumer groups represent the interests of Oregonians impacted by prescription drug costs.

RULE NUMBER AND SUMMARY

List each rule number and a short summary of what the rule does.

ADOPT: **OAR 925-200-0010: Selecting Prescription Drugs for Affordability Reviews**
RULE SUMMARY: The methodology for the Prescription Drug Affordability Board (PDAB) to select a subset of prescription drugs to prioritize for an affordability review.

ADOPT: **OAR 925-200-0020: Conducting an Affordability Review**
RULE SUMMARY: The process for the Prescription Drug Affordability Board (PDAB) to conduct an affordability review on a prioritized subset of prescription drugs.

STATUTORY REFERENCE

Statutory authority: ORS 646A.693 through 646A.697
Statutes implemented: ORS 183.325 through 183.410

Andrew R. Stolfi, Insurance Commissioner

Signature | Printed name | Date

LEGISLATOR NOTICE

If the rulemaking results from legislation passed within two years of this notice of proposed rulemaking, the agency must give notice to: 1) the legislator(s) who introduced the bill; and 2) the chair or co-chairs of all committees that reported the bill out. (Does not include referrals to other committees).

If the rule does not result from legislation within the last two years, notice shall be given to the chair or cochairs of any interim or session committee with authority over the subject matter of the rule. If notice cannot be given to these individuals, notice shall be given to the Speaker of the House and the President of the Senate.

Name	**Committee or Title**	**Email**
Senator Patterson	Chair Senate Health Care	Sen.DebPatterson@oregonlegislature.gov
Senator Manning Jr.	Senate Health Care	sen.jamesmanning@oregonlegislature.gov
Representative Campos	House Health Care	Rep.WlnsveyCampos@oregonlegislature.gov
Representative Schouten	House Health Care	Rep.SheriSchouten@oregonlegislature.gov

RULEMAKING ADVISORY COMMITTEE

Name	**Organization**	**Email**
Dharia McGrew	*PhRMA*	dmcgrew@phrma.org
Kevin Russell	*Oregon State Pharmacy Association*	kevinr@prescryptive.com
LuGina Mendez-Harper	*Prime Therapeutics*	lmendezharper@primetherapeutics.com
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Rick Blackwell	*PacificSource*	Richard.Blackwell@pacificsource.com
Christine Radkey	*Regence Blue Cross Blue Shield - Cambia Health Solutions*	Christine.Valerio@regence.com

DRAFT PRESCRIPTION DRUG AFFORDABILITY REVIEW

925-200-0010 Selecting Prescription Drugs for Affordability Reviews

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

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

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

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

(4) The date of U.S. Food and Drug Administration (FDA) approval of the prescription drug and whether the prescription drug was approved through an expedited pathway. Expedited approval includes fast track, priority review, accelerated approval, and breakthrough therapy designation. For brand-name drugs and biological products, whether there are any approved and marketed generic drugs or biosimilar drugs for the specific brand-name drug or biological product.

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

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

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

(a) Overall spend;

(b) Per-patient spend; and

(c) Patient out-of-pocket cost.

DRAFT PRESCRIPTION DRUG AFFORDABILITY REVIEW

925-200-0020 Conducting an Affordability Review

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

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

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

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

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

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

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

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

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

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

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

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

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

(l) Any information a manufacturer chooses to provide.

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

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

(A) Under resourced communities; or

(B) Regions with limited pharmacy access.

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

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

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

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

(f) Analysis to consider acquisition cost for pharmacies.

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

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

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

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

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

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

(A) Copayment and coinsurance impacts from:

(i) Patient assistance programs; and

(ii) Copay coupons;

(B) Deductible;

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

(D) Any other cost sharing data.

(k) Input from Specified Stakeholders:

(A) Patients and Caregivers

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

(I) The impact of the disease;

(II) Patient treatment preferences;

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

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

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

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

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

(i) The impact of the disease;

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

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

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

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

patients;

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

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

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

(D) Payers

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

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

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

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

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

(vi) Other costs to consider.

(l) Rebates, Discounts, and Price Concessions:

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

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

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

Oregon Prescription Drug
Affordability Board

Prescription Drug Affordability Board

Affordability review draft outline

Cortnee Whitlock
Board Policy Analyst

Selecting prescription drugs for affordability review

Prescription drugs selection:

1) Determine if any prescription medications are on each of the insurer reported top 25 lists.
2) Determine which drugs from the manufacturer reports need to be reviewed.
   a) Determine date of FDA approval and whether the drug was approved through an expedited pathway. Expedited approval includes ~~orphan~~, fast track, priority review, accelerated approval, breakthrough therapy designation.
   b) Determine if drugs are included in the manufacturer launch price or price increase reports for the same calendar year.
   c) Determine the date of FDA approval for orphan drug designation of a drug or biological product.
3) All insulin drugs marked in the U.S. and available in Oregon are subject to identification for an affordability review.
   a) Criteria for identification may include, but not limited to, those products with the highest carrier reported;
      A. Overall spend
      B. Per patient spend
      C. Patient out-of-pocket cost
   b) Pricing information relating to;
      A. Historical and current price increases shown as the increase of the WAC for the drug. Drug pricing reviewed for multiple NDCs for the same drug, a measure of central tendency will be used as a comparison ~~(percentage and gross)~~
      B. Manufacturer information submitted to the Drug Price Transparency program under ORS 646A.689

Black = draft rule presented to the board on 4/19; **Red** = updates

Selecting prescription drugs for affordability review (continued)

(3)(a)Prescription drugs selection:

4) For brand name drugs and biological products, determine whether there are any approved and marketed generic drugs or biosimilar drugs for the specific brand-name drug or biological product.

5) Where there are therapeutic alternatives, PDAB may consider the cost and availability of potential alternatives by evaluating utilization data and spending data.

6) Prescription drugs that have a patent expiration date or exclusivity expiration in the next eighteen months.

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Selecting prescription drugs for affordability review

925-200-0010 Prescription drugs selection:

1) Whether any prescription drugs are on each of the insurer reported top 25 lists under ORS 743.025.
2) Whether the prescription drug is included in the manufacturer new drug report or price increase report under ORS 646A.689 for the previous calendar year.
3) Historical and current manufacturer drug price increases, based on wholesale acquisition cost (WAC) information. For drugs with multiple nation drug codes (NDC), a measure of central tendency will be used for a price comparison.
4) The date of U.S. Food and Drug Administration (FDA) approval of the prescription drug and whether the prescription drug was approved through an expedited pathway. Expedited approval includes fast track, priority review, accelerated approval, and breakthrough therapy designation. For brand-name drugs and biological products, whether there are any approved and marketed generic drugs or biosimilar drugs for the specific brand-name drug or biological product.

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Selecting prescription drugs for affordability review

925-200-0010 Prescription drugs selection:

5) Where there are therapeutic alternatives, the cost and availability of potential alternatives.
6) Whether the prescription drugs have a patent expiration or data exclusivity expiration within 18 months.
7) For insulin drugs marketed in the U.S. and available in Oregon, criteria for selection may include, but not limited to, those products with the highest insurer reported:
   a) Overall spend;
   b) Per-patient spend; and
   c) Patient out-of-pocket cost.

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925-200-0020 Conducting an Affordability Review

2) PDAB conducts an affordability review by considering, to the extend practicable, the additional following factors:

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

~~A. Health inequities in~~ Under resourced communities; and

B. Regions with limited pharmacy access.

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

c) In addition to the criteria in subparagraph (1)(f): Consider the estimated net price. Cost and availability of therapeutic alternatives to the prescription drug in the state, including any relevant data regarding costs, expenditures, availability, and utilization related to the prescription drug and its therapeutic alternatives.

Therapeutic alternative is to mean "A drug product that contains a different chemical structure than the drug prescribed, but is in the same pharmacologic or therapeutic class and can be expected to have a similar therapeutic effect and adverse reaction profile when administered to patients in a therapeutically equivalent dosage."

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Conducting an Affordability Review (continued)

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

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

f) Analysis to consider acquisition cost for pharmacies

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

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

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Conducting an Affordability Review (continued)

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

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

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

~~*C. Identify if the sources it relies on use a quality-adjusted life-year analysis or a similar formula that takes 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. PDAB may not use quality-adjusted life year analysis or a similar formula to evaluate relative financial effects.*~~

j) In addition to the criteria in subparagraph (1)(k): Patient copayment or other cost sharing data, across different health benefit plan designs, ~~to the degree such information is publicly available and by contracted data sources,~~ including:

A. Copayment and coinsurance impacts from;

i. Patient assistance programs

ii. Copay coupons

~~B. Coinsurance;~~

B. Deductible;

C. Patient out-of-pocket costs; and

D. Any other copayment and cost sharing data.

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Conducting an Affordability Review (continued)

~~**(4)(b)I.** Impact on Safety Net Providers: When the prescription drug is available through section 340B of the federal Public Health Service Act~~

~~i. Information regarding safety net providers participating in the 340B, including information to assist with gathering input to assess the impact to safety net providers for a prescription drug under review that is available through Section 340B of the Federal Public Health Service Act, Pub. L. 78-410;~~

~~ii. The utilization of the prescription drug by the safety net provider's patients;~~

~~iii. Whether the safety net provider receives a 340B discount for the prescription drug;~~

~~iv. Where the safety net provider does not receive a discount, whether access to the prescription drug is impeded; and~~

~~v. Any other topics identified by safety net provider stakeholders for discussion.~~

Black = draft rule presented to the board on 4/19 **Red** = updates

Conducting an Affordability Review (continued)

k) Input from specified stakeholders

A. Patients and caregivers

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

I. Impact of the disease,

II. Patient treatment preferences,

III. Patient perspective on the benefits and disadvantages of using the drug,

IV. Caregiver perspective,

V. Available patient assistance in purchasing the drug.

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

Black = draft rule presented to the board on 4/19 **Red** = updates

Conducting an Affordability Review (continued)

B. Individuals with scientific or medical training: seek input from individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review by PDAB, including:

i. Impact of the disease,

ii. Perspectives on benefits and disadvantages of the prescription drug, including comparisons with therapeutic alternatives if any exist, and/or

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

Black = draft rule presented to the board on 4/19 **Red** = updates

Conducting an Affordability Review (continued)

C. Safety Net Providers: When the prescription drug is available through section 340B of the federal Public Health Service Act (42 U.S.C.256b):

~~i. Gather input to assess the impact to safety net providers for a prescription drug under review that is available through Section 340B of the Federal "Public Health Service Act", Pub.L. 78-410~~;

i. The utilization of the prescription drug by the safety net provider's patients;

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

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

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

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Conducting an Affordability Review (continued)

D. Payers

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

ii. Cost of the prescription drug to the payer;

iii. The availability of therapeutic alternatives on the formulary;

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

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

vi. Other costs to consider.

Black = draft rule presented to the board on 4/19 **Red** = updates

DRAFT

2023 Report for the Oregon Legislature

Generic Drug Report Pursuant to Senate Bill 844 (2021)

Oregon Prescription Drug
Affordability Board

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Executive summary

Background

The Oregon Legislature created the Prescription Drug Affordability Board in 2021 to find ways to make prescription drugs more affordable for Oregonians. Legislators were concerned about rising prescription drugs costs and their negative effect on patients and the health system in the state. The board met for the first time on June 23, 2022. Board members started immediately working on the road map provided in its founding legislation, Senate Bill 844 (2021). An early task was to study the generic drug market. The board presented its first report to the Legislature in December 2022, with recommendations that were later proposed as part of Senate Bill 404 in the 2023 legislative session. Now, in June 2023, the board is presenting to the Legislature an updated report that reviews generic spending, drug shortages, price fixing, pay for delay, spread pricing, market disrupters, and cost savings from biosimilars. This report is available on the PDAB website at https://dfr.oregon.gov/pdab/Pages/index.aspx.

What are generics?

Generics are small-molecule drugs synthesized through a chemical process and marketed once the patent has expired on the original, innovator branded product. The Food and Drug Administration (FDA) approved more than 900 generic products in 2022. Generics represent 91 percent of all prescriptions filled in the U.S., but only 18.2 percent of total drug spending. Generics and biosimilars saved the U.S. health care system $373 billion in 2021. Generics play a significant role in cost savings for Oregon Medicaid. There were 10,190 Medicaid prescriptions filled in 2021, 87 percent filled with generics. Total Medicare savings in Oregon due to generics and biosimilars was $951 million, saving the average Oregon Medicare enrollee $1,742 in 2021.

This report looks at:

- Drug shortages: Shortages typically occur with low-cost generics used by hospitals. In response, a consortium of hospital systems created an organization to secure, distribute, and eventually manufacture generic drugs. Using lower-cost generics helps the health system control costs.
- Price fixing: The U.S. Department of Justice has charged seven generic companies with collusion and price fixing. Each case involves a different

number of drugs, up to 1,200 generic products.

- Pay for delay: This occurs when generic manufacturers are offered a financial incentive not to enter a market.
- Spread pricing: Commonly used with generics, this practice occurs when the pharmacy benefit manager (PBM), which is a third-party administrator of prescription drug programs, reimburses a pharmacy the cost of the dispensed drug and then bills the health plan at a much higher price.
- Market disrupters: This can happen when nonprofits or state governments contract for the manufacturing of generic drugs and offer them at a low cost to patients. There is more opportunity for market disrupters to operate in the generic market because generic drugs are not patent protected and one manufacturer does not control the price or supply.
- Cost savings from biosimilars: A biosimilar is a biologic drug that is highly similar to, and has no clinically meaningful differences from, the FDA-approved reference biologic. They are taken the same way, have the same strength and dosage, and have the same potential side effects. Biologic products are more expensive to manufacture than biosimilars. Oregonians saved $3.6 billion on generics and biosimilars in 2021. Nationally, biosimilars saved $7 billion in 2021 and $13 billion since the first biosimilar was approved in 2015. One approach to improving biosimilar use is through reimbursement.

The federal Inflation Reduction Act of 2022 reinforces the importance of affordable, accessible health care, and promotes a more sustainable and effective system for the future. It also changes the way Medicare Part B will reimburse for biosimilars, which could increase biosimilar use and improve affordability for prescription drugs. This is significant because biosimilars are an important tool for promoting competition in the pharmaceutical industry. By reducing costs and making alternative treatments more accessible, they can help to broaden access to medicines for many patients. Additionally, these changes to Medicare Part B reimbursement create an incentive for health care providers to choose the most cost-effective treatment option for their patients, which can improve overall costs and make health care more affordable.

Conclusion

The study of generic drugs in the U.S. is important in today's health care landscape. By examining the safety and efficacy of generic drugs, we can ensure Oregon residents, state and local governments, commercial health plans, health care providers, licensed pharmacies and other stakeholders have access to affordable medications. Furthermore, understanding the regulatory processes surrounding generic drug approval can help streamline drug development and promote greater access to new and innovative therapies. Continued research and development of generic drugs are critical to improving health care outcomes and promote a more effective, efficient, and sustainable health care system for all.

Introduction

The Oregon Legislature created the Prescription Drug Affordability Board (PDAB) in 2021. One of the board's tasks is to conduct a study on the operation of the U.S. generic and biosimilar drug markets that includes drugs dispensed by pharmacists and drugs administered by physicians. The board presented its original report in December 2022. The 2022 report provided background on both generic and biosimilar products, markets, and licensing processes.[1] This 2023 report updates the initial work with more detail on generic and biosimilar market trends, and builds on the foundational information provided in 2022.

Generic drug products

Quick statistics

- Generics represent 91 percent of all prescriptions in the U.S., but just 18.2 percent of total drug spending.[2]
- Generics account for only 3 percent of total U.S. health care spending.[3]
- Generics and biosimilars saved the health care system $373 billion in 2021 in the U.S.[4]

Generics are small-molecule drugs synthesized through a chemical process and marketed once the patent has expired on the original, innovator branded product. These are tablets, capsules, oral liquids, and other self-administered formulations. As a group, they are referred to as multisource generics or multisource products if there is more than one manufacturer of the generic product. The Maryland PDAB published a report of the small-molecule generic market in June 2020.[5] Its key findings were:

- Generic drug prices are generally stable year to year despite large increases for certain products.
- Generic drug prices have a minimal effect on insurance premiums.
- Cost sharing for generic drugs is stable.
- Generic drug shortages of essential drugs present significant challenges for providers and patients.

The available data did not allow a determination of the effect of generics on Medicaid spending.

In general, the innovator product does not engage in price competition with multisource products. Innovator sales drop dramatically once the patent expires and generic equivalents enter the market.

2022 generic approvals

The Food and Drug Administration approved or tentatively approved more than 900 generic products in 2022. About 106 of these were first generics – the first generic on the market after the innovator patent expiration. First generics are allowed 180 days of exclusive market access.

[1] "2022 Report for the Oregon Legislature: Prescription Drug Distribution System and Generic Drug Reports Pursuant to Senate Bill 844 (2021)." Prescription Drug Affordability Board, Dec. 19, 2022. https://dfr.oregon.gov/pdab/Documents/reports/PDAB-Report-2022.pdf. Accessed April 10, 2023.

[2] "U.S. Generic and Biosimilar Medicines Savings Report: Generics and biosimilar medicines deliver more savings every year." Association for Accessible Medicines, September 2022. https://accessiblemeds.org/resources/blog/2022-savings-report. Accessed April 10, 2023.

[3] Ibid.

[4] Ibid.

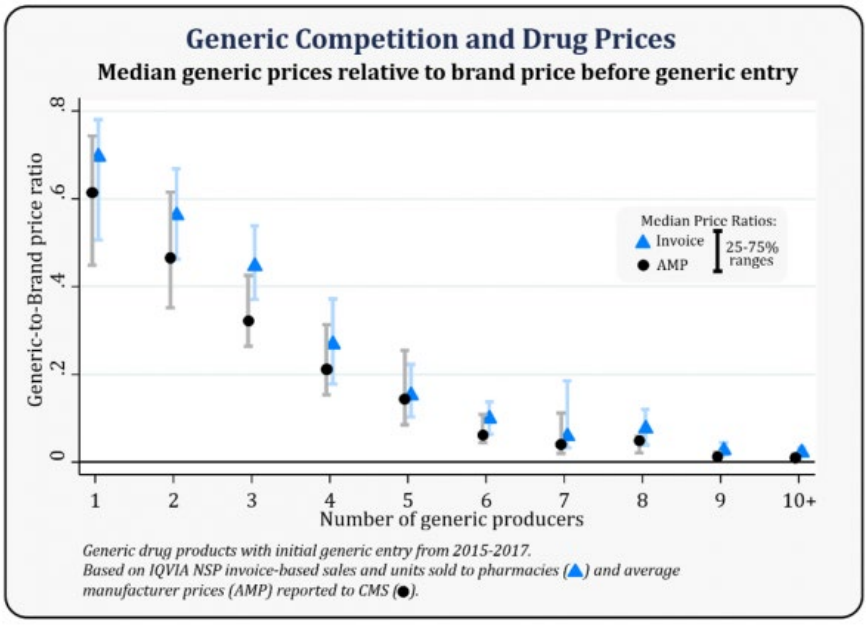
[5] "Study of the Operation of the Generics Drug Market." Maryland Prescription Drug Affordability Board, June 1, 2022. https://pdab.maryland.gov/documents/pdab_study_of_Operation_of_the_Generic_Drug_Market.pdf. Accessed April 11, 2023.

No other generic can enter the market during this market exclusivity period. The FDA initiative to encourage more generic products and market competition seems to be bearing fruit. The initiative encourages manufacturers to apply for licenses for products without generic competition. Along with streamlining initiatives, FDA also works more closely with applicants during the licensing process to minimize the extent to which applications have to be returned to the applicant for corrections.

Generic drug market trends and issues

The first generic generally does not provide much price relief because it can shadow the price of the innovator. Studies have shown that first generics might provide up to 30 percent price reduction relative to the brand – which is some price relief for consumers, but not the full potential. If there is a fifth manufacturer of the product, the savings can reach 85 percent of the innovator price.

Figure 1: How Generic Competition Helps Bring Down Drug Prices.[6]



Drug shortages

The products on the FDA national shortage list are typically low-cost generics used by hospitals. In response, a consortium of hospital systems created an organization to secure, distribute, and eventually manufacture generic drugs. Using lower-cost generics helps the health system control costs.

Even though the nation relies on generics for the majority of medication needs, it is not always a stable market for consumers or providers. The downside to multisource competition is that prices can go so low that some manufacturers may decide to exit the market for the product. At a minimum, this allows manufacturers who remain in the market to raise prices and stabilize the market. At worst, stiff price competition and manufacturer exits can lead to drug shortages because there is not enough remaining production capacity to meet demand, at least in the short term until remaining manufacturers can increase production. Drugs shortages have become such a significant issue that the FDA now tracks drug shortages and asks manufacturers for advance warning of material changes to their market participation that could produce a shortage.[7]

Other than a manufacturer exiting the product market, there are other circumstances that could produce a shortage. There could be a supply shortage if a factory goes offline to update manufacturing processes or resolve quality problems. Environmental disasters can force a manufacturing stoppage due to facility damage, loss of power, or lack of staffing. Environmental disasters could affect wholesaler storage facilities. Active pharmaceutical ingredients (API) shortages could occur for a number of different reasons that could affect all manufacturers of a product.

[6] "How Generic Competition Helps Bring Down Drug Prices." U.S. Food and Drug Administration, Sept. 12, 2022. https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices. Accessed April 10, 2023.

[7] "Drug Shortages." U.S. Food and Drug Administration, April 5, 2023. https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages. Accessed April 10, 2023.

Price fixing litigation

The opposite of stiff market price competition is price fixing. A lawsuit by the majority of states was filed in 2016.[8] Another lawsuit was filed in 2020 on behalf of 46 states and territories against 26 manufacturers.[9] States made the case that 1,200 drugs had increased in price an average of 450 percent in one year while some of the products increased up to 1,000 percent. The U.S. Department of Justice has charged seven generic companies with collusion and price fixing. Each case involves a different number of drugs, up to 1,200 generic products.[10] Some of the companies have also faced shareholder lawsuits based on the price fixing charges. A few of the companies have made financial settlements in one or more of the lawsuits.[11]

Pay for delay

Generic manufacturers sometimes have a financial incentive not to enter a market. Pay-for-delay agreements between generic and patent-holding pharmaceutical manufacturers prevent lower-priced generics from entering the market. These agreements tend to eliminate the 180-day period of exclusive market access for the first generic to market. According to the Federal Trade Commission (FTC), prescription drug pay-for-delay agreements cost consumers $3.5 billion every year.[12]

In 2013, the U.S. Supreme Court found these agreements to be legal within reason. The deals cannot be large and unjustified. The FTC monitors these agreements and has reported that the number of agreements has declined slightly since the Supreme Court decision.[13]

Only California has enacted a law penalizing prescription drug pay-for-delay agreements. An industry legal challenge succeeded in rolling back the scope and application of the state law, but state authority to pursue certain pay-for-delay deals was maintained.[14]

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[8] "Current Cases: Generic Drugs Price Fixing Litigation(filed 2016)." Washington State Office of the Attorney General. https://www.atg.wa.gov/antitrust-cases#generic%20drugs. Accessed April 12, 2023.

[9] Bartz, Diane and Stempel, Jonathan. "U.S. states accuse 26 drugmakers of generic drug price fixing in sweeping lawsuit." Reuters, June 10, 2020. https://www.reuters.com/article/us-usa-drugs-antitrust-lawsuit-idUSKBN23H2TR. Accessed April 12, 2023.

[10] "Generic Drugs Investigation Targets Anticompetitive Schemes. Division update Spring 2021." The United States Department of Justice, March 24, 2021. https://www.justice.gov/atr/division-operations/division-update-spring-2021/generic-drugs-investigation-targets-anticompetitive-schemes. Accessed April 12, 2023.

[11] "Pharmaceutical Companies Pay Over $400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs." The United States Department of Justice, Oct. 1, 2021. https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability. Accessed April 12, 2023.

[12] "Pay-for-Delay: When Drug Companies Agree Not to Compete. Federal Trade Commission." https://www.ftc.gov/news-events/topics/competition-enforcement/pay-delay. Accessed April 10, 2023.

[13] Paradise, Jordan. "The Status of California's Pay-for-Delay Legislation & Litigation." Food and Drug Law Institute. Fall 2022. https://www.fdli.org/2022/08/the-status-of-californias-pay-for-delay-legislation-litigation/. Accessed April 10, 2023.

[14] Ibid.

Pharmacy benefit managers generic spread pricing

The concerning practice of spread pricing by pharmacy benefit managers (PBM) typically involves generic drugs. The practice occurs when the PBM reimburses a pharmacy the cost of the dispensed drug, typically using a national average price to set the reimbursement. The PBM then bills the health plan for the drug at a much higher price, possibly even the brand product price. The Centene Corporation, the predominant PBM for Medicaid programs, has become known for its use of spread pricing in unwitting Medicaid programs.[15] It has been or is being investigated in 20 states and has already settled with 14, including Oregon in December 2022. As a general matter, the FTC decided in 2022 to study PBM business practices because of a concern for anti-competitive and other unfair trade practices.

Generic coverage and PBMs

Generic drug availability on health plan formularies can be impeded by brand drug patient assistance programs and rebates. Manufacturers of high-cost brand drugs may offer significant patient cost sharing assistance to greatly reduce the cost of otherwise costly patient coinsurance. Doctors may prescribe the high-cost patented product rather than an alternative generic treatment because the patient cost sharing is less. Similarly, branded manufacturers may offer substantial rebates that bring the PBM net cost of the brand to less than the cost of the generic , incentively the PBM to delay or block coverage of the generic. Consumers, however, pay cost sharing based on the market price of the drug, not the insurer/PBM net cost. This phenomenon can be taken to extremes, as in the 2022 CVS Caremark scheme.[16]

Generic market disrupters

Drug price increases have affected the generic market to extents similar to the patented market. But unlike the patent-protected brand market, there is more opportunity for market disrupters to operate in the generic market. This is because generic drugs are not patent protected; one manufacturer does not control the price or supply.

Civica and CivicaRx:

Civica began in 2018 as a consortium of hospital systems that provided capital for the manufacture of generics important to inpatient hospital care – drugs that are often in short supply and subject to price hikes. The organization has contracted for the manufacture of generic drugs but is now close to opening its own manufacturing plant in Virginia.

[15] "Centene Gives Big as It Courts Contracts and Settles Accusations of Overbilling." California Healthline, Dec. 15, 2022. https://californiahealthline.org/multimedia/centene-gives-big-as-it-courts-contracts-and-settles-accusations-of-overbilling/. Accessed April 12, 2023.

[16] Silverman, Ed. "A veritable playground: CVS whistleblower details how patients were charged higher drug prices." Stat, June 16, 2022. https://www.statnews.com/pharmalot/2022/06/16/cvs-whistleblower-silverscript-medicare-generics/. Accessed April 11, 2023.

Two years ago, Civica – through its operating unit CivicaRx – partnered with the Blue Cross Blue Shield Association and 18 of its health plans to supply generics at low cost to participating pharmacies and funding members.[17] Other health plans have subsequently joined. The first product of the initiative was a prostate cancer product. Civica recently announced it will begin manufacturing off-patent, long-acting insulins.[18] The products will be available to anyone. Civica will distribute the insulins through every distribution channel, but dispensing pharmacies must agree to limit charges to $30 per vial or $55 per pen. Health plans will direct their enrollees to participating pharmacies. Since Civica made this announcement, the three big brand insulin makers announced steep reductions in the price of their insulins.[19]

Cost Plus Drugs:

This company started in early 2022 as an online generic pharmacy with 350 generic drugs available. It began as a cash-only business that did not interact with health plans or PBMs. It charges product cost, delivery, and a 15 percent mark-up. It has moved quickly to expand its business model. In late 2022, Cost Plus announced it will work with a coalition of public and private employers who will connect their enrollees to Cost Plus generics.[20] To do this, the coalition created its own PBM based on a straight fee for a paid claim, which was $3 at the time of the announcement. This in itself is a market disruption. In March 2023, Cost Plus announced a contract with brand manufacturer Janssen to sell their patented anti-diabetic product Invokana for $294 per month, less than half the average retail price of $676 per month. The company now carries 1,100 drugs and will add a brand from IBSA Pharma.[21] Cost Plus is also working with independent and chain pharmacies across the country to expand access.

State drug manufacturing initiatives:

California and Washington have enacted laws that require the state to either manufacture or contract for distribution of affordable generic drugs. California recently signed a contract with Civica to manufacture insulins that will be available to cash-paying customers.[22] The manufacturing facility is expected to be located in California. Arizona, Illinois, Massachusetts, and New York all have proposed legislation that would follow the lead of California and Washington.

Generic multisource drugs and Medicaid

The Medicaid Drug Rebate Program (MDRP) began in 1990 and applies to branded drugs and generics. A generic manufacturer must provide to each state a 13 percent rebate for each of its products used in the state's Medicaid program, which is calculated for each calendar quarter. If the product price rose faster than the rate of

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[17] Silverman, Ed. "Civica Rx teams with Blue Cross Blue Shield to widen its alternative market for generics." Stat, Jan. 23, 2020. https://www.statnews.com/pharmalot/2020/01/23/civica-blue-cross-shield-generics-drug-prices/. Accessed April 11, 2023.

[18] Civica, 2023. https://civicarx.org/. Accessed April 12, 2023.

[19] Smith, Bram Sable and Young, Samantha. "Eli Lilly Slashed Insulin Prices. This Starts a Race to the Bottom." Kaiser Health News, March 2, 2023. https://kffhealthnews.org/news/article/eli-lilly-slashed-insulin-prices-this-starts-a-race-to-the-bottom/. Accessed April 12, 2023.

[20] Silverman, Ed. "True disruption: Mark Cuban's company will sell brand-name diabetes medicines from J&J." Stat, April 4, 2023. https://www.statnews.com/pharmalot/2023/04/04/janssen-diabetes-invokana-cuban-cost/. Accessed April 12, 2023.

[21] Emerson, Jakob and Twenter, Paige. "Leadership & Management: 10 exclusives Mark Cuban told Becker's in April." Becker's Hospital Review, April 11, 2023. https://www.beckershospitalreview.com/hospital-management-administration/10-exclusives-mark-cuban-told-beckers-in-april.html. Accessed April 12, 2023.

[22] "Governor Newsom announces $30 insulin through CalRX." Office of Governor Cavin Newsom, March 18, 2023. https://www.gov.ca.gov/2023/03/18/governor-newsom-announces-30-insulin-through-calrx/. Accessed April 12, 2023.

inflation, a manufacturer must pay an additional inflation penalty rebate for each unit of product dispensed in a state's Medicaid program. For years it has been suggested that Medicaid fee-for-service pharmacy benefit programs favored the use of more expensive innovator brands rather than the generic versions because of the larger rebates of the brand products. New York specifically requires coverage of the brand if the net is less costly than the generic.[23]

Oregon and generics

- Oregonians saved $3.6 billion in 2021 on generics and biosimilars according to the generic and biosimilar trade association, Association for Accessible Medicines (AAM).[24]
- The AAM also finds that the average Oregon Medicare enrollee saved $1,742 in 2021, and total Medicare savings in Oregon due to generics and biosimilars was $951 million in 2021. This is a savings for employer retiree health benefits programs, including state and local government retirees.[25]
- In 2021, Oregon Medicaid spent $778 million on prescription drugs, 81 percent was spent on brands, and 18.6 percent on generics, excluding biosimilars, which are technically patented brands. The fee-for-service program spent $135.5 million total and the Medicaid coordinated care organizations (CCO) spent $642.5 million.[26]
- There were 10,190 Medicaid prescriptions filled in 2021. Thirteen percent were filled with brands and 87 percent were filled with generics. Interestingly, 6 percent of prescriptions were for brands in fee-for-service programs, while 15 percent were for brands in the CCO programs. Without looking at the claims, it is impossible to tell what this means.[27]

[23] "NYRx, the Medicaid Pharmacy Program." Magellan Medicaid Administration. https://newyork.fhsc.com/providers/bltgp_about.asp. Accessed April 11, 2023.

[24] "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 11, 2023.

[25] "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 11, 2023.

[26] "MACStats: Medicaid and CHIP Data Book." The Medicaid and CHIP Payment and Access Commission (MACPAC), December 2022. https://www.macpac.gov/wp-content/uploads/2022/12/MACSTATS_Dec2022_WEB-508.pdf. Accessed April 25, 2023.

[27] Ibid.

Biologic and biosimilars

The original/first innovator biologic is called a reference product in the context of a discussion of biosimilars. Biosimilars are a category of biologics. Like all biologics, they can have patent-protected, branded products.

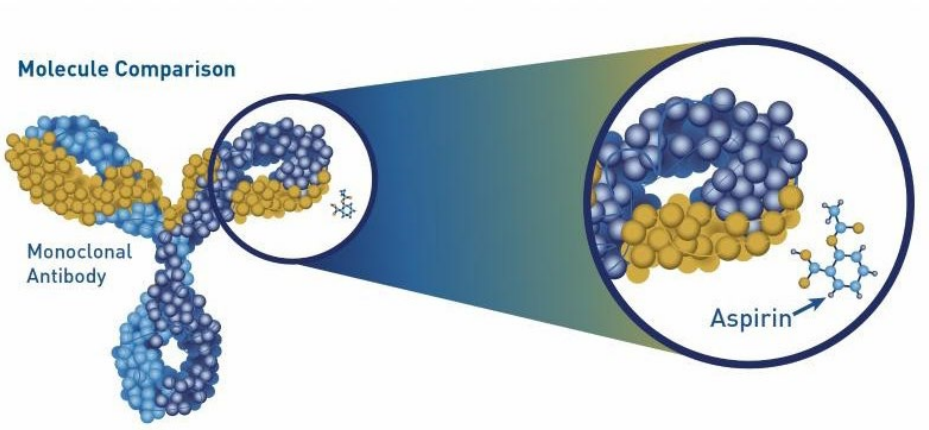
- FDA defines a biosimilar as a biologic that is highly similar to, and has no clinically meaningful differences from, the FDA approved reference biologic. This means biosimilars: [28]
  - Are given the same way (same route of administration).
  - Have the same strength and dosage form.
  - Have the same potential side effects.

Small molecule generics must be chemically identical within a tight range specified by the FDA. This tight standard is not possible with biologics because biologics are derived from living systems, such as bacteria, yeasts, and other cells. Living cells are not identical, unlike the chemical components of small molecule products. A biosimilar cannot be identical to the reference product, but is similar and can be expected to produce the same clinical results.

Biologics are made of large molecules, as opposed to small molecule drugs and their generics. The manufacturing process is complex. Some biologics such as insulin can be self-administered, but many biologic treatments are administered in outpatient clinic or inpatient settings. Congress created a new, separate approval pathway for biologic/biosimilars in the 2009 Biologics Price Competition and Innovation Act with processes for the first biologic and for biosimilar approval. Prior to a dedicated approval pathway, biologics such as insulins, were approved through the existing pathway that is now only for small molecule drugs.[29]

There were 40 biosimilar products on the U.S. market as of December 2022.[30] The first U.S. biosimilar was approved in 2015. The first biosimilar in the EU was approved in 2006. There are 69 on the market in Europe.[31]

Figure 2: A molecule comparison of monoclonal antibody and aspirin shows the difference in large and small molecule drugs.[32]



[28] "Biosimilar and Interchangeable Biologics: More Treatment Choices." U.S. Food & Drug Administration, Oct. 12, 2021. https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices. Accessed April 11, 2023.
[29] "Review and Approval." U.S. Food & Drug Administration, Dec. 13, 2022. https://www.fda.gov/drugs/biosimilars/review-and-approval. Accessed April 11, 2023.
[30] "Biosimilar Product Information." U.S. Food & Drug Administration. Dec. 19, 2022. https://www.fda.gov/drugs/biosimilars/biosimilar-product-information. Accessed April 11, 2023.
[31] Figg, Anthony E., et al. "How the U.S. Compares to Europe on Biosimilar Approvals and Products In the Pipeline." Biosimilars Law Bulletin, March 14, 2022. https://www.biosimilarsip.com/2022/03/14/how-the-u-s-compares-to-europe-on-biosimilar-approvals-and-products-in-the-pipeline-updated-march-14-2022/. Accessed April 11, 2023.
[32] "Overview for Health Care Professionals." U.S. Food & Drug Administration, Dec. 13, 2022. https://www.fda.gov/drugs/biosimilars/overview-health-care-professionals. Accessed April 11, 2023.

Interchangeable biosimilars

FDA defines an interchangeable biosimilar product as a biosimilar that meets additional requirements to demonstrate that there is no additional risk when substituted for the reference product at the pharmacy.[33] It is not an indication of superior quality relative to a biosimilar without the designation.

An interchangeable biosimilar product may be substituted at the pharmacy counter without the intervention of the health care professional who prescribed the reference product, much like how generic drugs are routinely substituted for brand name drugs at the pharmacy. This is commonly called pharmacy-level substitution and is subject to state pharmacy laws.

New proposed state laws would limit plan ability to cover biosimilars, when launched, by requiring step therapy (use reference product first) or requiring delayed biosimilar coverage until the new calendar year. This is very different than laws to facilitate biosimilar substitution at the pharmacy counter, which has been the trend of the last few years.[34]

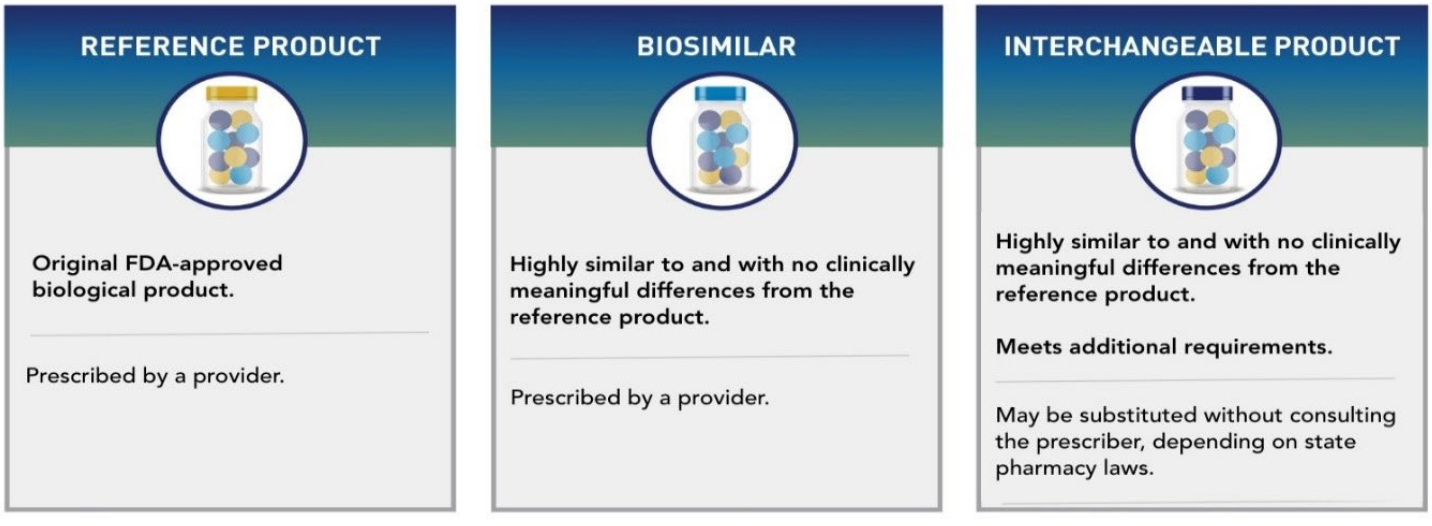
Cell and gene therapy biologics

The FDA defines cell and gene therapies as therapy that modifies or manipulates the expression of a gene or to alter the biological properties of living cells for therapeutic use.[35] The FDA has approved both cellular and gene therapy products that are regulated by the FDA Center for Biologics. Gene and cell therapies can use a patient's own cells that are modified and returned to the patient. Treatments can mitigate or cure a person's inherited disease. There are 27 approved cell and gene therapies. These one-time therapies can and do cost millions of dollars for a one-time treatment.[36]

Biosimilar costs and savings

Biologic products are much more costly to manufacture than small molecule chemical products. Biologics do not achieve the same manufacturing efficiencies as small molecules because the process is complex and remains complex for each batch of product. Biosimilars saved $7 billion nationally in 2021 and $13 billion

Figure 3: A comparison of reference products, biosimilars, and interchangeable products.[37]



[33] "Biosimilar and Interchangeable Biologics: More Treatment Choices." Consumer Updates, U.S. Food & Drug Administration, Oct. 12, 2021. https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices. Accessed April 12, 2023.

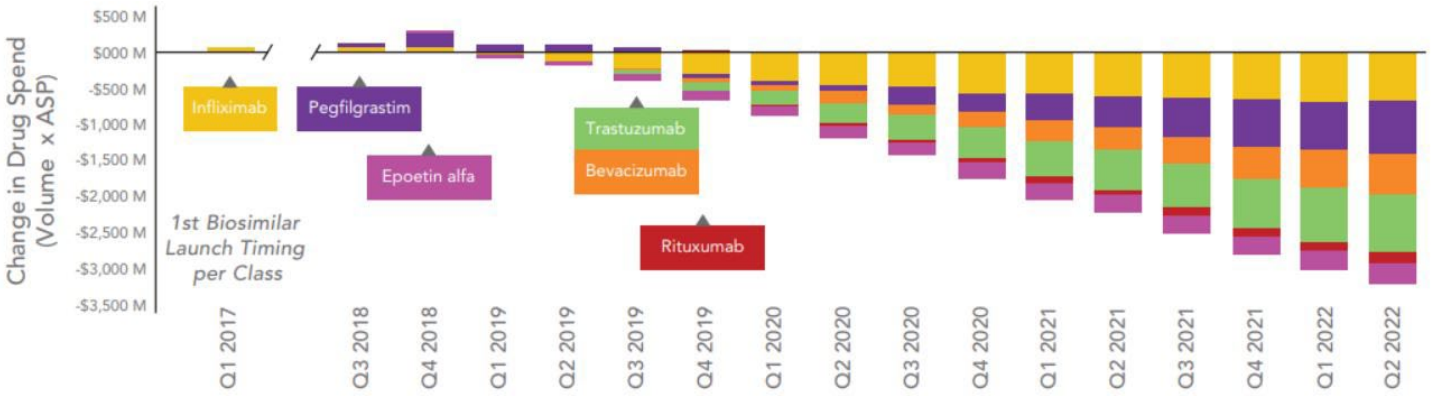
[34] "Eliminate Threats to Coverage of Lower-Cost Biosimilar Medicines." Association for Accessible Medicines, January 2023. https://accessiblemeds.org/sites/default/files/2023-01/AAM-BC-Eliminate-Threats-Coverage-Lower-Cost-Biosimilar-Medicines-2023.pdf. Accessed May 2, 2023.

[35] "Approved Cellular and Gene Therapy Products." U.S. Food & Drug Administration. Dec. 16, 2022. https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products. Accessed April 11, 2023.

[36] Ibid.

[37] "Overview for Health Care Professionals." U.S. Food & Drug Administration, Dec. 13, 2022. https://www.fda.gov/drugs/biosimilars/overview-health-care-professionals. Accessed April 11, 2023.

Figure 4: Estimated Change in Total Drug Spend for Amgen Biologics After Biosimilar Competition.[38]



since the first biosimilar was approved in 2015.[39] This graphic shows the impact of biosimilar competition on reference biologics using Amgen reference products.

Biosimilar market uptake

The adoption of biosimilar has been slower than hoped. There are several reasons for this. One is clinician reticence to use a biosimilar without full knowledge or trust that the treatment will have the same clinical outcome as the reference product. This is where the designation as interchangeable is important to improve uptake of biosimilars.

In addition to prescriber reticence, reference product makers encourage use of reference products over biosimilar competitors, similar to branded efforts to thwart generic uptake. Reference product sponsors provide tens of thousands of dollars to individual patients to buy down the patient's out-of-pocket costs for the reference product. Biosimilars often do not have the financial ability to compete on patient assistance without raising their market price. In the face of biosimilar competition, reference product sponsors will also offer very high rebates as incentive for the PBM to keep the biosimilar off the formulary in favor of the reference product. In this instance, the PBM and insurer reduce the net cost of the reference product below the cost of the biosimilar. Here again, the biosimilar company may not have the ability to compete on rebates without raising their list prices.

In addition to FDA efforts to designate interchangeable products, states have been creating laws for biosimilars substitution patterned after mandatory/voluntary generic substitution at the pharmacy. Oregon has had a biosimilar substitution law since 2016. It was updated in 2019. Most states have generic substitution laws and have for years. As of June 2019, the majority of states have enacted laws concerning the substitution of a lower cost, interchangeable, biosimilar product for the reference biologic. About 35 states have enacted biosimilar substitution laws as of 2019.

Most of the state's biosimilar substitution bills and laws are permissive. The pharmacist may offer to substitute a biosimilar if "dispense as written" is not on the prescription. There may be other requirements that precede the substitution. There may be requirements that apply after the substitution has been made, such as notifying the prescriber within a set period of days about the substitution. A few states require the specific affirmation from a prescriber that substitution is permitted before substitution can occur. Some of the laws require prescription pads to have a checkbox for "dispense as written" and a checkbox for "substitution allowed." In some states that require a substitute biosimilar, pharmacists can only do so if the

[38] "2022 Biosimilar Trends Report." Amgen Biosimilars, 2022. https://www.amgenbiosimilars.com/commitment/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-81397-2022-Amgen-Biosimilars-Trend-Report-Oct-2022.pdf. Accessed April 11, 2023.
[39] "U.S. Generic and Biosimilar Medicines Savings Report: Generics and biosimilar medicines deliver more savings every year." Association for Accessible Medicines, September 2022. https://accessiblemeds.org/resources/blog/2022-savings-report. Accessed April 10, 2023. [39] Horvath, Jane. Horvath Health Policy, April 2023.

"substitution allowed" box is checked. In other words, lack of a "dispense as written" indication is not sufficient for biosimilar substitution in some states.[40]

Some states require the pharmacist to proactively offer information about lower cost biosimilars without requiring a substitution. Mandatory substitution of a biosimilar for the reference product seems to be almost always subject to the permission of the patient in addition to any other requirements that limit dispensing.

Another approach to improving biosimilar uptake is reimbursement. Included in the federal Inflation Reduction Act of 2022 was a change in how Medicare Part B will reimburse for biosimilars.[41] Before the Inflation Reduction Act change, providers were reimbursed for the administered biosimilar at the average sales price (ASP) of the reference product plus 6 percent. Per the new law, providers will be reimbursed the ASP plus 8 percent for the biosimilar, if the biosimilar manufacturer's ASP is less than the ASP of the reference product. This incentivizes the provider to use the biosimilar and requires the manufacturer to keep the biosimilar price below the original reference product. This counters the possibility that biosimilars come to market priced close to the reference product in order to offer rebates, for instance. The Medicare change to plus 8 percent means the Medicare patient will pay a bit more out of pocket for the biosimilar relative to ASP plus 6 percent.[42]

As more biosimilars come to market, the threats to reference products market dominance become more acute, which is why all these reference product market strategies have been developed. Biosimilar companies are responding by bringing their biosimilar to market at two different list prices, a high price with rebates to PBMs and health plans, and a lower price for health plans and PBMs willing to pay less to reimburse providers and forego rebates.

This phenomenon affects drugs other than biosimilars. Amgen started this two-price market strategy when it launched its very expensive biologic treatment for familial hyperlipidemia, Repthatha. Amgen has reprised the strategy for its biosimilar, Amjevita, which will compete with Humira and other Humira biosimilars.

The effects of generics and biosimilars on health care spending and insurance premiums

The Association for Accessible Medicines found that Oregon, in total, saved $3.6 billion in drug costs due to generics and biosimilars in 2021.[43] Nationally, generics saved the U.S. health system $366 billion and biosimilars saved $7 billion in 2021.[44]

Data is not currently available for determining the effects of generics and biosimilars on Oregon insurance premiums. There is little national data available about generic and biosimilar effects on insurance premiums specifically. The impact on premiums of small molecule generics in any one year would depend on the number of brands losing expiration, the amount that a plan spent on the brand(s) in the prior years before expiration, the percentage of plan spending dedicated to the patented products before expiration, and the speed with which multiple generics enter the market.

Determining the effect of biosimilars on Oregon health insurance premiums will require similar information to what is required to understand their effect on national insurance premiums. Because biologics are so expensive, the effect of biosimilars may be more readily apparent than the impact of generics.

[40] Horvath, Jane. Horvath Health Policy, April 2023.

[41] Cohen, Joshua. "Inflation Reduction Act Provision Aims To Further Spur Biosimilar Uptake With Temporary Add-On Payment In Medicare Part B." Forbes, Oct. 5, 2023. https://www.forbes.com/sites/joshuacohen/2022/10/05/inflation-reduction-act-provision-aims-to-further-spur-biosimilar-uptake-with-temporary-add-on-payment-in-medicare-part-b/?sh=42c2a0c77bcd. Accessed April 12, 2023.

[42] Horvath, Jane. Horvath Health Policy, April 2023.

[43] "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 11, 2023.

[44] Ibid.