

Oregon Prescription Drug Affordability Board

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

Agenda

This is a regular meeting. *Date*: Jan. 15, 2025 | *Time*: 9 a.m. This agenda is subject to change.

	Meeting name Meeting location Zoom link	Prescription Drug Affordability Board Virtual Register for meeting	Chain Judg Kenr Staff Corth Step Doyl analy	nd Members: Chair Shelle r Amy Burns; Daniel Hartu e; Christopher Laman; Jol nedy; Lauri Hoagland. T Ralph Magrish, executiv nee Whitlock, senior polic hen Kooyman, project ma e, data analyst; Pei-Chen yst; Melissa Stiles, admini ialist; Jake Gill, counsel; P usel	ung; Robert hn Murray; Dan ve director; cy analyst; anager, Heather Choo, research istrative
Purpose		Subject		Presenter	Estimated Time Allotted
Informational and vote	Call to order and	roll call		Chair Shelley Bailey	2 minutes
Informational	Board declaratio	n of conflict of interest		Chair Shelley Bailey	2 minutes
Discussion and vote	Board approval	of 12/18/2024 minutes		Chair Shelley Bailey	2 minutes
Informational	Executive directo	or's program update		Ralph Magrish	5 minutes
Informational	General public co	omment: <i>limited to 3 minu</i>	ites.	Chair Shelley Bailey	10 minutes
Discussion and vote	Board annual po	licies review and vote		Cortnee Whitlock	30 minutes
Discussion	Board review of	carrier data call template	•	Staff	30 minutes
Break	The board will ta	ke a break		Chair Shelley Bailey	5 minutes
Discussion		data sets and OAR 925-20 upcoming affordability	00-	Staff	90 minutes
Informational	Announcements			Chair Shelley Bailey	2 minutes
Vote	Adjournment			Chair Shelley Bailey	2 minutes

Next meeting

Feb. 19, 2025, at 9 a.m. New start time for board meetings in 2025.

Accessibility

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

How to provide testimony to the board

The Prescription Drug Affordability Board invites people to provide testimony. **Oral:** To speak to the board during the public comment portion of the agenda, please submit the <u>PDAB public comment form</u> no later than 24 hours before the PDAB meeting. Each speaker has three minutes for oral testimony. **Written:** to provide written comments to the board, please submit the <u>PDAB public comment form</u> with attachments no later than 72 hours before the PDAB meeting. The board reviews all written comments. All written comments are posted on the 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 to everyone but news media and staff. No action will be taken in the executive session.



Oregon Prescription Drug Affordability Board (PDAB) Regular Meeting Wednesday, December 18, 2024 Draft Minutes

Web link to the meeting video: <u>https://www.youtube.com/watch?v=clL-J-IPQD4</u> Web link to the meeting materials: <u>https://dfr.oregon.gov/pdab/Documents/20241218-PDAB-document-package.pdf</u>

Call to order and roll call: Chair Shelley Bailey called the meeting to order at 9:31 am and roll was called.

Board members present: Chair Shelley Bailey, Vice Chair Amy Burns, Dan Hartung, Lauri Hoagland, Robert Judge, Dan Kennedy, Chris Laman, John Murray **Absent:** None

Robert Judge said he would be leaving the meeting around 11:30 a.m. due to a scheduling conflict.

Declaration of conflict of interest: Robert Judge and John Murray disclosed potential conflicts of interest. View at video minute <u>00:00:40</u>.

Approval of board minutes: Chair Bailey asked for a motion and second to approve the board minutes as shown on <u>Pages 3-4</u> of the agenda materials, with any amendments. Dan Kennedy made a motion to approve the minutes and John Murray provided a second. View at video minute <u>00:02:05</u>.

MOTION to approve the November 20, 2024, minutes

Board Vote:

Yes: Dan Hartung, Lauri Hoagland, Robert Judge, Dan Kennedy, Chris Laman, John Murray, Vice Chair Amy Burns, Chair Shelley Bailey No: None

Motion passed 8-0

Executive director's program update: Ralph Magrish provided a program update. View the video at minute <u>00:03:50</u>.

Public comment: Chair Bailey called on the people who signed up in advance to speak to the board: Eric Lohnes, PhRMA, Lorren Sandt, Caring Ambassadors Program, Terrell Sweat, Johnson and Johnson, Ranier Simons, Community Access National Network, Jen Laws, Community Access National Network, Brian Warren, Biotechnology Innovation Organization. The board received 10 written comments, which are posted on the <u>PDAB website</u>. View the speakers at video minute <u>00:05:13</u> and minute <u>00:28:15</u>.



Board discussion and vote on policy recommendations for the Oregon Legislature: Cortnee Whitlock, board policy analyst, and Chair Shelley Bailey led board members in a discussion for ten policy recommendations. Recommendation 9 was added with edited language from recommendation 8, resulting in 11 policies being voted on. Board members voted to approve policy recommendations 1-5, 7, and 9-11 for including in the annual report. View the draft updated policy recommendations on Pages 6-9 of the agenda materials. View the updated recommendations with board changes on Pages 10-14. View the discussion and votes at video minute <u>00:21:38</u>.

MOTION to approve policy recommendations 1-3 to include in the annual report.

Motion made by Dan Hartung with a second by Amy Burns.

Board vote:

Yes: Dan Hartung, Lauri Hoagland, Robert Judge, Dan Kennedy, Chris Laman, John Murray, Vice Chair Amy Burns, Chair Shelley Bailey No: None **Motion passed 8-0**

MOTION to approve policy recommendation 4 to include in the annual report.

Motion made by Robert Judge with a second by Amy Burns.

Board vote:

Yes: Dan Hartung, Lauri Hoagland, Robert Judge, Dan Kennedy, Chris Laman, John Murray, Vice Chair Amy Burns, Chair Shelley Bailey No: None Motion passed 8.0

Motion passed 8-0

MOTION to approve policy recommendation 5 as amended by the board today to include in the annual report.

Motion made by Dan Hartung with a second by John Murray.

Board vote:

Yes: Dan Hartung, Lauri Hoagland, Dan Kennedy, Chris Laman, John Murray, Vice Chair Amy Burns, Chair Shelley Bailey No: None Abstain: Robert Judge **Motion passed 7-0**

MOTION to approve policy recommendation 6 as amended by the board today to include in the annual report.

Motion made by Dan Kennedy with a second by John Murray.

Board vote:



Yes: Lauri Hoagland, Dan Kennedy, John Murray, Chair Shelley Bailey No: Dan Hartung, Robert Judge, Chris Laman, Vice Chair Amy Burns **Motion failed 4-4**

MOTION to approve policy recommendations 7 to include in the annual report. Motion made by Chris Laman with a second by Dan Kennedy.

Board vote:

Yes: Lauri Hoagland, Robert Judge, Dan Kennedy, Chris Laman, John Murray, Vice Chair Amy Burns, Chair Shelley Bailey No: Dan Hartung **Motion passed 7-1**

MOTION to approve policy recommendation 8 to include in the annual report. Motion made by John Murray with a second by Dan Kennedy.

Board vote:

Yes: Lauri Hoagland, Dan Kennedy, John Murray, Chair Shelley Bailey No: Dan Hartung, Robert Judge, Chris Laman, Vice Chair Amy Burns **Motion failed 4-4**

MOTION to approve policy recommendations 9 as amended by the board today to include in the annual report.

Motion made by John Murray with a second by Amy Burns.

Board vote:

Yes: Dan Hartung, Lauri Hoagland, Dan Kennedy, Chris Laman, John Murray, Vice Chair Amy Burns, Chair Shelley Bailey No: Robert Judge **Motion passed 7-1**

MOTION to approve policy recommendation 10 as amended by the board today to include in the annual report.

Motion made by Dan Kennedy with a second by John Murray.

Board vote:

Yes: Dan Hartung, Lauri Hoagland, Dan Kennedy, John Murray, Chair Shelley Bailey No: Chris Laman, Vice Chair Amy Burns Absent for the vote: Robert Judge **Motion passed 5-2**

MOTION to approve policy recommendation 11 as amended by the board today to include in the annual report.



Motion made by Dan Hartung with a second by Dan Kennedy.

Board vote:

Yes: Dan Hartung, Lauri Hoagland, Dan Kennedy, John Murray, Chair Shelley Bailey No: Chris Laman, Vice Chair Amy Burns Absent for the vote: Robert Judge **Motion passed 5-2**

Board discussion and vote on annual report to the Oregon Legislature: Cortnee Whitlock led the board in a discussion of the annual report. The board voted to approve the annual report and send to the Oregon Legislature and Health Care Cost Growth Target program in December. View the annual report on Pages 15-31 of the agenda materials. View the discussion and votes at video minute <u>02:40:33</u>.

MOTION to approve the annual report as amended by the board today with the policy recommendations voted on by the board today, and deliver to the Oregon Legislature and Health Care Cost Growth Target program by Dec. 31, 2024, as required in ORS 646A.696. Motion made by Dan Kennedy with a second by Lauri Hoagland.

Board vote:

Yes: Dan Hartung, Lauri Hoagland, Dan Kennedy, Chris Laman, John Murray, Vice Chair Amy Burns, Chair Shelley Bailey No: None Absent for vote: Robert Judge **Motion passed 7-0**

The agenda item about the board receiving the initial, preliminary list of prescription drugs and insulin for affordability review was postponed due to lack of time.

Announcements: Chair Bailey announced the next meeting will be Jan. 15, 2025. Meetings will begin at 9:00 a.m. in 2025. View at video minute <u>02:44:40</u>.

Adjournment: Chair Bailey adjourned the meeting at 12:30 pm with all board members in agreement. View at minute <u>02:45:10</u>.



Title: Policies and Procedures

Policy Number: 01

Annual Approval Date: July 20, 2022; Aug. 23, 2023; add date

Date Issued: June 23, 2022 Dates Reviewed: June 23, 2022; Aug. 23, 2023; <u>add date</u> Amendment Date Approved: July 20, 2022; Aug. 23, 2023; <u>add date</u>

1. Statutory authority.

The Prescription Drug Affordability Board is convened under <u>ORS 646A.693 through ORS</u> <u>646A.697</u>. Nothing in this document is intended to be contrary to these, or any, rules, statutes, constitutional provisions, or relevant judicial decisions. To the extent there is any inconsistency, the rules, statutes, Constitution, and judicial decisions govern.

2. Purpose.

The Prescription Drug Affordability Board (PDAB) is established by statute to protect residents of Oregon, state and local governments, commercial health plans, health care providers, pharmacies licensed in this state, and other stakeholders within the health care system in this state from the high costs of prescription drugs.

The board is directed to collect and evaluate information concerning the cost of prescription drugs in Oregon; perform affordability reviews of those prescription drugs; study the entire prescription drug distribution and payment system in this state and polices adopted by other states and countries that are designed to lower the list price of prescription drugs; and make recommendations to the legislative assembly to make prescription drugs more affordable in the state.

The board is required to provide reports to the Legislative Assembly on the following schedules:

No later than June 1 of each calendar year, the board shall submit a report to the legislative assembly on the generic drug marketplace.

No later than December 31 of each calendar year, the board shall submit a report to both the Legislative Assembly and the Health Care Cost Growth Target program at the Oregon Health Authority that includes:

- (1) Price trends for the list of drugs provided by Department of Consumer and Business Services (DCBS) to the board;
- (2) The prescription drugs reviewed for affordability reviews; and

(3) Any recommendations for legislative changes necessary to make prescription drugs more affordable in Oregon.

The board has rulemaking authority to adopt criteria for drug affordability reviews and to provide consultation to DCBS in the adoption of annual fees to be paid by manufacturers to meet the cost of program and board administration costs.

3. Board member selection process

Individuals interested in serving on the board may apply through the Oregon Boards and Commissions website.¹ Applicants must be residents of Oregon with expertise in health care economics and clinical medicine. Openings will be communicated to the public through a notice or other consumer alert. The board application process is open to the public at all times.

4. Term length and vacancies

The board consists of eight members appointed by the Governor under <u>ORS 646A.693 to</u> <u>646A.697 Senate Bill 192 (2023)</u>, and who are subject to Senate confirmation. The term duration for each member of the board is four years after the first appointed terms. Terms for the first appointed board are as follows:

- (1) Two board members shall serve for a term ending December 31, 2024.
- (2) Three board members shall serve for a term ending December 31, 2025.
- (3) Three board members, including the chairperson shall serve for a term ending December 31, 2026.

5. Conflict of interest

The board's conflict of interest policy is set forth in the Prescription Drug Affordability Board Policy No. 03.

6. Responsibilities of the chair and vice chair

The members of the board will elect one member to serve as chair and one member to serve as vice chair for the duration of their appointment to the inaugural board. The chair provides leadership for the board, presides over all board meetings, and provides strategic planning to help the board comply with its statutory duties and responsibilities. The vice chair presides over a board meeting in their absence. The chair works with board staff to develop board meeting agendas as set forth in Section 8. The chair also ensures member compliance with the Conflict of Interest Policy No. 03.

7. Open records and meetings

¹ Boards & Commissions, Office of Oregon Governor Tina Kotek. <u>https://www.oregon.gov/gov/Pages/board-list.aspx</u>

The board activities are subject to the Oregon Public Meetings Law, <u>ORS Chapter 192</u>. Consistent with those laws, board activities generally will be conducted in public pursuant to public notice requirements, unless public meetings laws permit particular matters to be discussed in executive session to receive legal advice from the Oregon Department of Justice, to consider trade secret, confidential, or proprietary data that is not otherwise available to the public or other grounds found in <u>ORS 192.660</u>.

The board records are generally subject to the Oregon's Public Records Laws, subject to any exclusions from disclosure contained in <u>ORS 192.340 through ORS 192.390</u>.

8. Meetings

The board will hold meetings at least every six weeks. The chair of the board may decide to cancel or postpone a meeting when there are no prescription drugs to review whether as a result of incomplete data or the need for further analysis and no other board business to conduct. The meetings may be referred to as meetings or hearings depending on what types of business the board plans to conduct. The board has discretion to set the time for its meetings. The board may decide to adjourn a meeting or hearing to the next available day because a meeting or hearing is running long or for any other reason. A member can participate in person, by phone, or virtually. Board meetings are broadcast live over the internet, other than executive sessions.

The board will provide the opportunity for public comment at each meeting. Public comment can be submitted in writing or alternatively, given orally during the designated time. Persons giving oral comments should introduce themselves with their name and affiliation, if any. The board is not obligated to respond to comments. The amount of time allocated for public comment will be determined by the <u>board</u> chair of the board in consultation with board staff.

Unless otherwise invited to speak or present by the board, persons or organizations wanting to offer public oral comment shall identify themselves no later than 24 hours before the PDAB meeting through a sign-up process administered by board staff. The board's public comment policy is set forth in the Prescription Drug Affordability Board Policy No. 04.

9. Meeting agendas, materials, and recordings

Board staff will post notices of upcoming meetings, meeting agendas, packets, minutes, and recordings on the Prescription Drug Affordability Board website. The meeting agenda will be designed to ensure the board meets its statutory obligations. The board chair in collaboration with the staff will prepare a draft agenda and provide it to the members prior to the board meeting or hearing.

10. Quorum, decisions, and voting

A majority of the eight (8) person board constitutes a quorum. Five members must be present to have a quorum. Voting will be conducted by a member roll call. Motions to conduct board business should flexibly follow the processes set forth in Robert's Rules of

Order (e.g. motion, second, discussion, vote). <u>ORS 174.130</u> requires a majority of board members to concur for the motion to pass. If a vote ends in a tie, the motion fails.²

11. Executive session

The board may, at any time, retire into executive session to consult with the assigned assistant attorney(s) general at the Oregon Department of Justice or as permitted by <u>ORS</u> <u>192.660</u>. The board will meet in executive session to discuss trade secret information. The board will not deliberate concerning whether to subject a prescription drug to an affordability review, or otherwise make any <u>final</u> decision of the board in executive session.

Upon reconvening the open meeting at the conclusion of the executive session, all members will maintain the confidentiality of the information discussed and/or legal advice provided in executive session.³ The board will ensure that electronic recordings of executive sessions are securely stored and will only be disclosed if required under the Oregon Public Records Law, ORS Chapter 192.

12. Meeting attendance, absences, and participation

Board members are expected to make every effort to attend <u>all</u> board meetings. Members may participate in a meeting in person, by telephone, <u>computer</u>, or any other means of electronic communication by which all persons participating in the meeting can hear each other at the same time. If a member is unable to attend a meeting, the member must notify the chair and executive director prior to the meeting. Under <u>ORS 182.010</u> through <u>ORS 182.020</u>, any member of a state board or commission appointed by the governor who fails to attend two consecutive meetings of the board or commission, whether regular, adjourned or special, shall forfeit office unless the member is prevented from attending by the serious illness of a member or the family of the member or for any other cause that in the judgment of the governor constitutes a valid reason for failing to attend. The governor shall immediately appoint a successor.

Members on average are expected to have approximately 10-15 hours of work participation per month including board meetings, meetings with board staff, and review of board materials.⁴

13. Board members are public representatives

³ Attorney General's Public Records and Meetings Manual 2019, II. Public Meetings, E. Executive (Closed Sessions). Oregon Department of Justice. https://www.doj.state.or.us/oregon-department-of-justice/publicrecords/attorney-generals-public-records-and-meetings-manual/ii-public-meetings/#_Toc11743475 <u>4 Boards & Commissions, Office of Oregon Governor Tina Kotek. https://www.oregon.gov/gov/Pages/board-</u>

² Attorney General's Public Records and Meetings Manual 2019, Appendix K – Parliamentary Procedure, Quorums and Voting. Oregon Department of Justice. https://www.doj.state.or.us/oregon-department-of-justice/public-records/public-records-and-meetings-law/

<u>list.aspx</u>

Members of the board are public representatives, appointed by the governor to protect residents of this state, state and local governments, commercial health plans, health care providers, pharmacies licensed in this state and other stakeholders within the health care system in this state from the high costs of prescription drugs. Members accept appointment to the board with the understanding that they will represent the public interest in their actions and decisions on the board.

14. Use of state email accounts

State email accounts should be used only to send or receive information to or from the board staff. When sending or replying to board staff, members should not reply all so as to avoid a situation of appearance of board business being discussed in a setting that should otherwise be public. If board members receive communications from the public about board business, board member should forward those communications to the PDAB Executive Director Ralph Magrish at <u>Ralph.M.Magrish@dcbs.oregon.gov</u>.

15. Board Issued iPads

Board members are provided <u>state-issued</u> iPads <u>and-that</u> should be used only to conduct board business. Board members are <u>required</u> to log into their iPads <u>at least every 45 days</u>, <u>change passwords every 90 days regularly</u> and comply with security procedures and instructions to update systems when notified through email <u>or text messages</u>. If a member has <u>an any</u>-login issues, <u>or if</u> the iPad is damaged or stolen, they are to contact DFR techs or PDAB staff as soon as possible.

Members are to return their iPads to DFR techs or PDAB staff once their service term ends.

16. Coordinating with other entities

The board may, from time to time, coordinate with other boards, commissions, industry, educational institutions, and state agencies where the responsibilities and interests overlap in creating transparency for the cost of prescription drugs and determining the affordability of prescription drugs for Oregon consumers.

Board members are not obliged to speak about board business outside of board meetings and may delegate the request to staff.

Board members are to disclose at the beginning of each board meet any meetings or work conducted with entities or individuals related to board activities since the last board meeting. This includes serving on other boards, committees, or engaging in business matters related to the pharmacy supply chain.

17. Interaction with the media and lobbyists

Unless otherwise delegated to them by <u>the board chair and the executive director</u> a majority vote of the board, individual board members do not have the authority to speak on behalf of the board. The board operates as a single entity when communicating with

external parties. If board members receive media<u>or lobbyist</u> requests related to their board work and participation, they should notify the PDAB Executive Director Ralph Magrish at <u>Ralph.M.Magrish@dcbs.oregon.gov</u>.

18. Department of Consumer and Business Services staff

Board staff shall provide support to the board including serving as the recording secretary for the board; coordinating board meeting times, location (virtual or otherwise), materials, and other logistics; compiling information necessary for the board to conduct affordability reviews, administrative rule development, drafting and filing, policy issue brief development, data analysis, and additional tasks as delegated by the board.

The staff may also provide support to the board in preparing policy recommendations to the Legislative Assembly and preparation of annual reports to the Legislative Assembly (pursuant to ORS 646A.695 and ORS 646A.693 through ORS 646A.697).

The DCBS Oon behalf of the board, DCBS may enter into contracts with qualified, independent third parties for services necessary to carry out the powers and duties of the board. All contractors are required to enter into a nondisclosure agreement to protect trade secret, confidential, or proprietary information.

The board may also delegate particular tasks to DCBS on a case-by-case basis to perform its duties.

19. Annual review

The board will review this policy and the conflict of interest policy at least annually.



Title: Board Delegation Policy

Policy Number: 02

Annual Approval Date: July 20, 2022; Aug. 23, 2023; add date

Date Issued: June 23, 2022 Dates Reviewed: June 23, 2022; July 20, 2022; Aug. 23, 2023; add date

1. Statutory authority

The Prescription Drug Affordability Board is convened under <u>ORS 646A.693 through 646A.697</u>. Nothing in this document is intended to be contrary to these, or any, statutes, constitutional provisions, or relevant judicial decisions. To the extent there is any inconsistency, the statutes, constitution, and judicial decisions govern.

2. Purpose

- a. To clarify when staff within the Department of Consumer and Business Services (DCBS) may perform work on behalf of the Prescription Drug Affordability Board.
- b. To provide guidance to the board regarding their duties and responsibilities with respect to staff.

3. Board support

Staff from the Department of Consumer and Business Services shall provide support to the board including serving as the recording secretary for the board; coordinating board meeting times, location (virtual or otherwise), materials, and other logistics; compiling information necessary for the board to conduct affordability reviews, administrative rule development and drafting, policy issue brief development, data analysis, and additional tasks as delegated by the board.

Staff may also provide support to the board in preparing policy recommendations to the Legislative Assembly and preparation of annual-reports to the Legislative Assembly pursuant to <u>ORS 646A.969.693 – through 646A.697</u>.

DCBS, Wwith the approval from the board, DCBS may enter into contracts with qualified, independent third parties for services necessary to carry out the powers and duties of the board. All third-party contractors are required to agree to contractual provisions that address confidentiality and non-disclosure to protect trade-secret, confidential, or proprietary information. Third party contractors are to disclose any conflict of interests prior to entering into contract agreement and if any conflicts occur under the time of the contract.

The board may also delegate particular tasks to DCBS on a case-by-case basis to perform its duties.

4. Policy statement

The board delegates its authority to sstaff to perform the following functions on the bsoard's behalf. The board may also delegate its authority to staff in other specific policies and procedures, or during meetings through oral direction or by written resolution. The board may elect to perform any of these duties at its discretion, including delegation of any of these duties to an individual board member.

Board meetings pursuant to Oregon Public Meetings Law, ORS Chapter 192

- a. Facilitate public meetings and board executive sessions, including scheduling meetings, arranging meeting platforms and/or locations, and sending calendar invitations and board-related notices.
- b. Provide public notice of board meetings and agenda items on the board website and Oregon Transparency website.
- c. Develop agendas for board meetings in coordination with the board chair.
- d. Serve as the recording secretary for the board and prepare meeting minutes for consideration by the board.
- e. Prepare board materials.
- f. Distribute agenda and materials in support of the board agenda to each board member.
- g. Review meeting materials and agenda items with legal counsel prior to the board meeting.
- h. Record all meetings.
- i. Provide minutes and recordings of board meetings on the board website.
- j. Record and securely store recordings of all executive sessions entered into by the board at board meetings.

Contracts

- a. Pursuant to and in compliance with state law and procurement policies, facilitate contracts for work deemed necessary by the board to carry out its powers and duties and ensure contract deliverables requested by the board, if any, are prepared and presented to the board.
- b. The board determines that to necessarily carry out its powers and duties, DCBS is authorized to contract on its behalf for work related to the following:
 - i. Data identification, collection, and analysis related to pharmaceutical markets and supply chains, prescription drug pricing, and other state and federal programs related to prescription drug pricing;
 - ii. Data, research, analysis, and supporting materials to inform the process for and

conducting of affordability reviews;

- iii. Equity and cultural responsiveness related to the **b**Board's activities; and
- iv. Data, research, analysis, and supporting materials for board consideration in identifying potential policy recommendations to the Legislative Assembly and compiling board recommendations.

Administration

- a. Serve as the custodian of record for the board in accordance with Oregon Public Records law (<u>ORS Chapter 192</u>).
- b. Maintain records for the board in accordance with board retention policies and all applicable laws and regulations, including but not limited to securely storing information, documents, and records received by the board and executing the board's destruction policy.
- c. Establish and maintain an electronic mail account for the board for submission of public comment, public inquiries, or submissions of information for board consideration.
- d. Receive and respond to requests related to the board in accordance with any applicable board policies and all applicable laws and regulations and seek assistance of legal counsel in connection with any such request, if necessary.
- e. The executive director or any other staff for the board may accept service on behalf of the board.
- f. Draft and issue correspondence on behalf of the board, including with stakeholders, to communicate board positions and determinations, provide notice of board activities, respond to administrative or ministerial requests made to the board, and/or seek additional information on behalf of the board.
- g. Receive and maintain documents and correspondence addressed or submitted to the board and ensure the board's review of such materials, if necessary.
- h. Draft reports and memoranda pertaining to work completed by or on behalf of the board.
- i. Maintain the board's public webpage and ensure the webpage contains the following:
 - i. Conflicts of interest disclosed to the board pursuant to <u>ORS 646A.693</u>.
 - ii. Reports prepared for the Health Care Cost Growth Target program pursuant to <u>ORS</u> <u>646A.696</u>.
 - iii. Reports prepared for the Legislative Assembly pursuant to <u>ORS 646A.963 through</u> <u>646A.697</u>.
 - iv. Notice of board meetings and hearings.
 - v. All agendas, non-confidential and non-privileged meeting materials, and boardapproved meeting minutes.

- vi. List of board members.
- vii. Instructions for submitting materials for the board's consideration.
- viii. Contact information for submitting requests pursuant to Oregon Public Meetings Law, <u>ORS Chapter 192.</u>
- ix. Policies and procedures adopted by the board.
- x. Resolutions, orders, and any other memorialized decisions by the board.
- xi. Findings, reports, and studies conducted by the board, redacted for confidential information as necessary.
- xii. Notices of proposed rulemaking and rulemaking hearing information.
- xiii. Regulations and guidance adopted by the board.
- xiv. List of all prescription drugs the board determines to be unaffordable.
- xv. Any material specifically requested by the board.

Support for performance of board duties

- a. Facilitate rulemaking conducted by the board, including but not limited to:
 - i. Draft rules for consideration by the board.
 - ii. Effectuate publication and/or filing of notices of draft proposed regulations approved by the board, and adopted rules in the Oregon Bulletin, on the Oregon Secretary of State's website.
 - iii. Submit requests for advice from Oregon Department of Justice.
 - iv. Compile the official rulemaking record for all rulemaking conducted by the board, including receipt and inclusion of any public comments.
- b. Collect and provide conflicts of interest to the board by distribute conflict of interest forms and coordinate completion of disclosures when required by law.
- c. Draft reports required by <u>ORS 646A.6963 and through ORS 646A.697</u>, and present drafts to the board for review, amendment, and approval.
- d. Coordinate with legislative staff regarding any legislative hearings or presentations.
- e. Coordinate the secure collection of and access to data and information on behalf of the board pursuant <u>ORS 646A.6943, ORS 646A.696, andthrough ORS 646A.697</u>, including by working with other state agencies, stakeholders, and presenting material received to the board, and entering into memoranda of understanding or data use agreements as needed and approved by the board.
- f. Request notification and copies of any notices of membership withdrawal received by the board pursuant to <u>ORS 646A.693</u>.
- g. Assist in the collection and presentation of data, information, or analysis necessary for the board to perform its duties related to affordability reviews and as may be further specifically addressed in other board policies.



Title: Conflict of Interest

Policy Number: 03

Annual Approval Date: Aug. 3, 2022; Aug. 23, 2023; add date

Date Issued: Aug. 3, 2022 Dates Reviewed: Aug. 3, 2022; Aug. 23, 2023<u>; add date</u> Amendment Date Approved: Aug. 3, 2022; Aug. 23, 2023; <u>add date</u>

1. Purpose

To ensure that the Oregon Prescription Drug Affordability Board conducts business for the benefit of the public and in the absence of personal, financial, or otherwise improper interests. The purpose of this policy is to describe the statutory requirements regarding conflicts of interest.

2. ORS Chapter 244

Board members will adhere to the requirements of <u>ORS Chapter 244</u>, the Government Ethics Act, and the Oregon Administrative Rules, Chapter 199, of the Oregon Government Ethics Commission (OGEC), which can be found here: <u>https://secure.sos.state.or.us/oard/displayChapterRules.action?selectedChapter=143</u>

Guidance regarding these laws can be found on the OGEC website: <u>https://www.oregon.gov/ogec/Pages/default.aspx</u>

Board members will disclose, in accordance with subsection 4 of this policy, any potential or actual conflicts of interest as defined in <u>ORS 244.020(1) and (13)</u>:

- (1) "Actual conflict of interest" means any action or any decision or recommendation by a person acting in a capacity as a public official, the effect of which would be to the private pecuniary benefit or detriment of the person or the person's relative or any business with which the person or a relative of the person is associated unless the pecuniary benefit or detriment arises out of circumstances described in subsection (13) of this section."
- (13) "Potential conflict of interest" means any action or any decision or recommendation by a person acting in a capacity as a public official, the effect of which could be to the private pecuniary benefit or detriment of the person or the person's relative, or a business with which the person or the person's relative is associated, unless the pecuniary benefit or detriment arises out of the following:

(a) An interest or membership in a particular business, industry, occupation or

other class required by law as a prerequisite to the holding by the person of the office or position.

- (b) Any action in the person's official capacity which would affect to the same degree a class consisting of all inhabitants of the state, or a smaller class consisting of an industry, occupation or other group including one of which or in which the person, or the person's relative or business with which the person or the person's relative is associated, is a member or is engaged.
- (c) Membership in or membership on the board of directors of a nonprofit corporation that is tax-exempt under section 501(c) of the Internal Revenue Code."

Board members, under ORS 244.120 (2), will also:

- (a) When met with a potential conflict of interest, announce publicly the nature of the potential conflict prior to taking any action as a board member; or
- (b) When met with an actual conflict of interest, announce publicly the nature of the actual conflict and:
 - (A) Except as provided in subparagraph (B) of this paragraph, refrain from participating as a board member in any discussion or debate on the issue out of which the actual conflict arises or from voting on the issue.
 - (B) If the board member's vote is necessary to meet a requirement of a minimum number of votes to take official action, be eligible to vote, but not to participate as a public official in any discussion or debate on the issue out of which the actual conflict arises.

Please note that if the requirements of recusal under <u>ORS 646A.693</u> apply, the board member must recuse themselves from the decision, even if the board member would otherwise be allowed to vote under <u>ORS 244.120(2)(b)(B)</u>.

3. ORS 646A.693

Board members will adhere to the requirements of <u>ORS 646A.693</u> as follows:

Recusal

- (a) A member of the board shall recuse themselves from decisions related to a prescription drug if the member, or an immediate family member of the member, has received or could receive any of the following:
 - (A) A direct financial benefit of any amount deriving from the result or finding of a study, review or determination by or for the board; or
 - (B) A financial benefit from any person that owns, manufactures, or provides prescription drugs, services or items to be reviewed by the board that in the aggregate exceeds \$5,000 per year.

(b) For the purposes of paragraph (a) of this subsection, a financial benefit includes honoraria, fees, stock, the value of the member's or immediate family member's stock holdings and any direct financial benefit deriving from the result or finding of a study, review or determination by or for the Board.

Disclosure of conflicts of interest

- (a) A conflict of interest shall be disclosed:
 - (A) By the board when hiring board staff;
 - (B) By the governor when appointing members to the board; and
 - (C) By the board, when a member of the board is recused in any final decision resulting from a review of a prescription drug.
- (b) A conflict of interest shall be disclosed at the earlier of:
 - (A) Prior to the first board meeting after the conflict is identified; or
 - (B) Within five days after the conflict is identified.
- (c) A conflict of interest disclosed under this section shall be posted on the <u>board</u> website <u>in</u> <u>the board minutes</u>. <u>of the board unless t</u> he <u>board</u> chair <u>of the board may</u> recuses the member from any final decision resulting from a review of a prescription drug.
- (d) A posting <u>in the minutes</u> under paragraph (e) of this subsection shall include the type, nature and magnitude of the conflict of interest of the member involved.

<u>Gifts</u>

Members of the board, staff, and third parties that contract with the board may not accept any gift or donation of services or property that creates a potential conflict of interest or has the appearance of biasing the work of the board.

4. Procedures for identifying and managing conflicts of interest

Prior to each board meeting, board members will review the draft agenda and identify any potential or actual conflicts of interest under <u>ORS 244.120</u> or <u>ORS 646A.693</u>-(conflict of interest).

When a board member determines they have a conflict of interest, the board member must inform the board chair and vice-chair, recuse themselves and fill out and submit the conflict of interest form to pdab@dcbs.oregon.gov.

The board member will also notify the board staff to help ensure that the member does not have access to information on matters for which the member must recuse themselves and to ensure the conflict of interest is appropriately posted.

Potential contractors will disclose any prior or current work in the pharmaceutical business sector that could give rise to a potential or actual conflict of interest as defined in <u>ORS 244.020</u>.

Contractors will ensure that qualified personnel selected to perform work for the board have no professional, familial or financial conflict of interest relating to the pharmaceutical business sector. In connection with any particular project or work to be performed, the board reserves the right to reject any proposed personnel. In the event the board rejects the proposed personnel, the contractor will be required to provide other personnel who are acceptable to the board.

5. Annual review

The board will review this policy at least annually.



Title: Conflict of Interest Form

Policy Number: 03

Annual Approval Date: Aug. 3, 2022; Aug. 23, 2023; add date

Date Issued: Aug. 3, 2022 Dates Reviewed: Aug. 3, 2022; Aug. 23, 2023<u>; add date</u>

CONFLICT OF INTEREST FORM

The Prescription Drug Affordability Board (PDAB) asks that <u>you board members</u> complete this conflict of interest disclosure required by <u>ORS Chapter 244</u>.

This form is due annually or when a conflict is disclosed by a board member under <u>ORS</u> <u>646A.693</u> or when a conflict is disclosed by a contractor under <u>ORS 244.020</u>. You may wish to retain a copy of this form.

Instructions: Please fill in the appropriate box. If a conflict of interest is indicated, fill out questions 1 and 2 and include activities occurring currently or during the past year. Return by email to: pdab@dcbs.oregon.gov

Declaration (check one):

- I confirm that neither I nor any immediate family member nor any business with which I am associated have any personal or business interest in or potential for personal gain from any of the organizations or projects linked to PDAB. I also confirm that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me. I undertake to inform the board chair of any conflict or potential conflict of which I become aware immediately following any announcement by the board or the PDAB staff which may concern me. I also undertake to inform the board chair of any change in these circumstances, including – if an issue arises – during the course of my association with PDAB as a board member, board staff, contractors, and assigned assistant attorneys general.
- I confirm that I or my immediate family member have a financial or other interest in the subject/matter of the work in which I will be involved, which may be considered as constituting a real, potential or apparent conflict of interest.
 If this section is checked please answer the following questions.

1. Financial benefit

If you or an immediate family member (see definition below) have a direct or indirect ownership or investment, or can benefit from any person that owns, manufactures, or provides prescription drugs, please note the name of the source, ownership percentage and any income generated from the ownership or investment interest. Financial benefit includes honoraria, fees, stock, the value of the member's or immediate family member's stock holdings and any direct financial benefit deriving from the result or finding of a study, review or determination by or for the board.

Name & address of source	Financial benefit	Received by	

Immediate family member - Means any person living in the same household as a board member, a staff member, and/or a contractor working on behalf of the board.

Does an income source listed above do business, or could it reasonably be expected to do business, with the public body you wish to serve or over which you may have authority? **Yes** \Box **No** \Box

Does an income source listed above have a legislative or administrative interest in the public body you wish to serve or over which you may have authority? Yes Vo No

2. Shared business with lobbyist

If you or a member of your household shared a partnership, joint venture, or similar substantial economic relationship with a paid lobbyist during the immediately preceding calendar year, or were employed by or employed a paid lobbyist during that time, please list the following: Note: owning stock in a publicly-traded company in which the lobbyist also owns stock is not a relationship which requires disclosure.

Name of Lobbyist	Business Name	Business Type

Name	Date
Signature	
Please retu	<pre>urn by email to: pdab@dcbs.oregon.gov</pre>

From the Oregon Government Ethics Commission, A Guide for Public Officials can be reviewed at: <u>https://www.oregon.gov/ogec/Documents/2021%20PO%20Guide%20Final%20Adopted.pdf.</u>



Title: Public Comment

Policy Number: 04

Annual Approval Date: Jan. 18, 2023; Aug. 23, 2023; add date

Date Issued: Aug. 3, 2022

Dates Reviewed: Aug. 3, 2022; Aug. 17, 2022; Jan. 18, 2023; Aug. 23, 2023<u>; add date</u> Amendment Date Approved: Jan. 18, 2023; Aug. 23, 2023; <u>add date</u>

1. Purpose

The opportunity for public comment will be provided at each Prescription Drug Affordability Board (PDAB) meeting according to <u>ORS 646A.693(13)</u>.

2. Policy Statement

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

The PDAB public comment form's purpose is to:

1) Sign up to provide comments, written or oral;

2) Assist board staff with time allotments for meeting agenda items; and

3) Disclose interest or affiliation.

Having an interest or affiliation does not prevent written or oral comments from being provided, but is included on the form for transparency purposes. Prior to the public comment, the board chair will <u>ask speakers to give their name and affiliation before they</u> <u>begin speaking.</u> <u>state whether the form has been completed and any interest or affiliation of the speaker.</u>

Written comments

For written comments, the PDAB public comment form is to be submitted no later than 72 hours before the PDAB meeting. The form is located on the Oregon Prescription Drug Affordability Board website. Written comments will be posted to the PDAB website.

Oral comments

For oral comments, the PDAB public comment form is to be submitted no later than 24 hours before the PDAB meeting. The form is located on the Oregon Prescription Drug

Affordability Board website. Individuals who did not sign up before the deadline will have the opportunity to speak at the next meeting. Speakers will be called to speak in the order in which they sign up. The board chair will ask the speakers to introduce themselves with their name and affiliation, if any.

The amount of time allocated for oral public comment will be determined by the board chair in consultation with board staff. When there are multiple requests to comment on a particular topic, the board chair may limit or expand the total time for comment or reduce the time allotted for each speaker. Any changes will be announced at the beginning of the public comment agenda item. Due to board meeting time constraints, only one person per organization will be added to the list of public comment speakers for each board meeting.



Title: Public Comment Form

Policy Number: 04

Annual Approval Date: July 20, 2022; Aug. 23, 2023

Date Issued: June 23, 2022 Dates Reviewed: June 23, 2022; July 19, 2022; Aug. 23, 2023; add date Amendment Date Approved: July 20, 2022; Aug. 23, 2023; add date

Public Comment Form

Use this form to provide public comment <u>orally or in writing</u> and to disclose an interest or affiliation. Failure to complete this form does not disqualify a speaker from commenting. However, <u>persons who opt not to complete the</u> form should be advised it will be publicly stated prior to their oral testimonyadministrative staff will request the form be completed to assist with organization of public comment. Due to board meeting time constraints, only one person per organization will be added to the list of public comment speakers for each board meeting. Public comment will be posted to the PDAB website <u>on the board calendar and materials page</u>.

Instructions: Please read all information and fill in areas with an asterisk (*). <u>Please-S</u>-submit the form no later than 24 hours before the PDAB meeting for oral comments and no later than 72 hours before the PDAB meeting for written comments. If you need assistance, <u>please-</u>call the PDAB office at 971-374-3724 or send an email to <u>pdab@dcbs.oregon.gov</u>.

COMMENTER INFORMATION		
*Name:	*Date:	
*Organization, if applicable:	*Topic/Drug:	
Email Address:	Phone Number:	
Are written comments submitted with this form?	Yes 🗆 No 🗆	
Do you plan to offer oral comment in addition to the written submission?	Yes 🗆 No 🗆	
*Are you an employee, or volunteer of, or a lobbyist for, a pharmaceutical maindustry, prescription drug supply chain, advocacy group, or other? *If yes , please identify the entity / organization:	anufacturer, trade association, the health care Yes	
*Do you or your organization receive funding from a pharmaceutical manufa industry, prescription drug supply chain, advocacy group, or other? *Have you been asked to provide comments? *If yes , please identify the entity / organization:	acturer, trade association, the health care Yes I No I Yes No I	
*If you are a researcher or clinician, do you currently receive grants or other advocacy group, or other? *If yes , please identify the entity:	funding from any pharmaceutical entity, Yes D No D	
*Are you involved in or have you been involved in any research funded directly or indirectly from any pharmaceutica entity, advocacy group, or other? Yes No I *If yes, please describe the type of compensation:		
Is there any other information about yourself that the board should know?		



Department of Consumer and Business Services Division of Financial Regulation Data Call for Health Insurance Companies in Oregon

Instructions for completing this report. Due Date: TBD

This information is being collected by DCBS under the authorities granted in ORS 731.296 and ORS 646A.693 through ORS 646A.693.697 in support of the Oregon Prescription Drug Affordability Board.

The purpose of this Excel workbook is for health insurers to report required data for prescription drugs under both pharmacy and medical benefits for policies or certificates issued in Oregon during 2023. All information submitted for this purpose will be confidential and will not be disclosed except as provided in ORS 705.137.

Health insurers should fill out the information on each of the worksheets listed below (Company Information, Data Limitations and Notes, Claims and Cost, Plan Design, and Price Concessions). Upon completion, please return the file using the following naming convention "[Company Name] 2023 Data Call - [Market Type].xlsx". (Example: "ABC Company 2023 Data Call - Large Group.xlsx" This file was completed by ABC Company on for their 2023 data for their Large Group market type.) The file name indicates year that the carrier collected the information (2023) and is not reflective of the year of collection by the Prescription Drug Affordability Board (2024/2025).

Fields highlighted in yellow are required

Click the links just below to go to a specific section of the instructions or

information

Company Information Data Limitations and Notes

Claims and Cost

Plan Design

Price

Concessions

FAQ

Definitions

Plan Types Reference

Company Information

<u>Click here to go to the "Company Information" worksheet.</u> Click here to return to the beginning of the instructions.

Company Name and NAIC Code:

Enter your company's name. Format: alpha-numeric

Enter your company's NAIC code. Format: numeric value

Primary Contact: Enter the name, phone number, and email address of your company's primary contact for this data request.

Format: alpha-numeric

Note: Ensure the primary contact is an individual. Please do not list a shared email box in place of a real person.

Secondary Contact: If there is an additional contact or shared email/phone number you would like to include, list that information under in the secondary contact fields. *Format: alpha-numeric*

Authorizing Authority: Enter the name, phone number, and email address of the supervisor or manager responsible for approving the data provided in this workbook. *Format: alpha-numeric*

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

Market Type: Select the market from the drop-down box in cell B12. Format: alpha-numeric

Note: If the market type of "other" is selected, a new required field will appear in cell B13 ("**Market Type Notes**"). Please enter a description of the market type in this cell (B13). *Format: alpha-numeric*

Note: If your company serves more than one market type, please fill out a separate version of this workbook for each market your company serves. Example: A company that has both small and large group markets will send two files, one for each market type. File 1 - "Company Name 2023 Data Call - Small Group" and File 2 - "Company Name 2023 Data Call - Large Group"

Data Limitations and Notes (Optional) Click here to go to the "Data Limitations and Notes" worksheet. Click here to return to the beginning of the instructions.

Use this tab to list any limitations or quality concerns regarding the data you are supplying or the methodology used to obtain the information provided. This tab can be skipped if there are no data limitations or quality concerns.

Section: To list any data concerns, select the section name from the drop-down list in column A. Select "All" when noting data limitations and quality concerns that impact all worksheets or data. *Format: alpha-numeric*

Data Point: If the data limitation and concerns apply to a specific data point (example: number of prescriptions), select the impacted data point from the drop-down list in column B. Select "all" from this drop-down field for notes about the data or methodology that are not limited to a single data point. *Format: alpha-numeric*

Data Quality of Limitation Notes: Enter your selected note here. Format: alpha-numeric

List any additional data limitations, concerns, or notes in new rows as needed.

Use this worksheet to list the claim and cost information for each of the listed prescriptions drugs and NDCs. **Note**: This worksheet contains intentionally hidden fields (Columns A-E) designed for Prescription Drug Affordability Board administrative use only. No data entry is required for these hidden columns.

Note: If there were no claims for a listed NDC but the drug is covered on your formulary (not excluded), please enter 0 for all required fields on that NDC row.

Prescription Drug Name and Therapy Class: No action is needed unless you are entering an additional NDC as instructed below (see National Drug Code(s) instructions). These fields are otherwise pre-populated with the drug information based on the drugs identified by the Prescription Drug Affordability Board for review. Format: alpha-numeric

National Drug Code(s): For your convenience, any 11-digit NDCs associated with the drugs found in our records have been listed. If your company records show additional NDCs for any given drug that are not pre-populated in the table, please add the additional NDCs and associated information below the last NDC in the worksheet. You may add as many as necessary. Format:11-digit numeric value, no dashes.

Coverage: Select from the drop-down box whether the prescription drug was prescribed under the pharmacy benefit, medical benefit, both (medical and pharmacy benefit), or excluded from your coverage. If "excluded" is selected (indicating that the drug/NDC is excluded from your formulary) and no claim and cost information exists for the drug/NDC, please leave the remaining required fields blank for that row. The remaining yellow highlighted fields for that row will be removed as they are not required for excluded drugs. Format: alpha-numeric characters

Number of Enrollees: The number of enrollees who filed claims for the prescription drug in the reporting year. Format: numeric Number of Prescriptions: The number of prescription claims received for the prescription drug in the reporting year. Use claim data based on the date of service. Format: numeric

Note: for 30-day versus 90-day supplies, count 30-day supplies as one and 90-day supplies as three. If 30-day or 90-day supplies are not applicable to the drug, such as drugs with a course of treatment less than one month, use the "Data Limitations and Notes" tab to note the impacted drug and the unit of measurement used for the associated claims.

Total Number of Claims: Enter the total number of claims for the listed drug in the reporting year. Format: numeric

Total Annual Plan Spending (Allowed Dollar Amount): The total payments made under the policy to health care providers on behalf of covered members, including payments made by issuers and member cost sharing. *Format: currency* **Note**: The total annual plan spending should reflect the total after all rebates and price concessions have been applied.

Total Annual Deductible Costs for Enrollees: The total deductible costs for enrollees for the listed drug in the reporting year. *Format:* currency

Total Annual Copay Costs for Enrollees: The total copay costs charged to enrollees for the listed drug in the reporting year. Format: currency

Total Annual Coinsurance Cost for Enrollees: The total coinsurance cost charged to enrollees for the listed drug in the reporting year. Format: currency

Total Other Enrollee Costs: Use this field to enter the total dollar amount of any additional costs or fees charged to enrollees in the reporting year that were associated with the listed drug that do not fall under deductibles, co-pay, or coinsurance. If a value is added to this field, please add an explanation for these added costs to the "Notes" field. The "Notes" field will highlight yellow in this case until completed. If no additional fees applied, enter "0". *Format: currency*

Total Annual Out of Pocket Costs for Enrollees: This field is automated and no action required. This field represents the sum of the Total Annual Deductible Costs for Enrollees, Total Annual Copay Costs for Enrollees, Total Annual Coinsurance Costs for Enrollees, and Total Other Enrollee Costs . *Format: currency*

Notes: If "Total Other Enrollee Costs" were listed, please enter a brief description or explanation regarding the nature and type of the additional fees. The "Notes" field will highlight yellow in this case until completed. *Format: alpha-numeric*

Plan Design

Click here to go to the "Plan Design" worksheet.

Click here to return to the beginning of the instructions.

Click here to go to "Plan Types Information".

Note: This worksheet contains intentionally hidden fields (Columns A-E) designed for Prescription Drug Affordability Board administrative use only. No data entry is required for these hidden columns.

Use this worksheet to provide formulary information for the selected market for each listed drug. Each drug of interest is listed once; however, additional rows should be added below the last row of data in the table to accommodate all formulary and plan types for each drug.

Examples:

1. A drug is represented across several plan types (e.g. C-HMO, C-PPO, C-POS)

2. Under plan A for a drug, the formulary status is preferred, but under Plan B it in non-preferred.

3. Under Plan A for a drug, the copay formulary status is a fixed fee but under Plan B it is a percentage of the cost Each variation should be listed as an individual row of data to capture all relevant forms of coverage for the drug.

Prescription Drug Name and Therapy Class: No action is needed unless you are entering an additional rows to accommodate additional plan types for a given drug. The table is pre-populated with one row for each drug representing the drugs of interest for the Prescription Drug Affordability Board review. To add a new row, navigate to the row directly below the last row of data in the table and select the Prescription Drug Name and Therapy Class from each drop-down list respectively. Next, enter data in the fields for each new row. *Format: alpha-numeric*

Plan Type: Select the plan type from the drop-down list provided. For more information about plan types go to the "Plan Types Information" worksheet. Only one plan type can be selected from the drop-down list for each row (e.g. C-HMO to indicate a commercial HMO). Additional types should be added after the last row of data in the table. If the plan type is not listed choose "Other" and provide information in the notes regarding the plan type. The "Notes" field will highlight yellow in this case until completed. *Format: alpha-numeric*

Formulary Status: Indicate whether the drug is preferred, non-preferred, or excluded on the formulary drug list. If "Excluded" is selected, the yellow highlighting on the remaining required fields will be removed and no further entry is needed for that row. *Format: alpha-numeric*

Copay Formulary Status: Indicate whether the drug has a co-payment formulary status that is fixed fee or percentage of cost. It should be one or the other and not both for each row. If the drug is excluded from the formulary, leave blank. *Format: alphanumeric*

Note: When the Copay formulary status is selected, either the "Fixed Fee Copay" or "Percentage of Coinsurance" field will highlight yellow indicating that it is a required field based on the selection. Only the highlighted field should be completed as required. **Fixed Fee Copay:** This field is required and will be highlighted yellow if the selected copay formulary status is "Fixed Fee". Indicate the fixed fee amount of the drug. If the copay formulary status is not "Fixed Fee", this field should be left blank. If the drug is excluded from the formulary, leave blank. *Format: currency*

Percentage of Coinsurance: This field is required and will be highlighted yellow if the selected co-pay formulary status is "Percentage of Cost", specify the percentage of coinsurance for the prescription drug. If the copay formulary status is not "Percentage of Cost", this field should be left blank. If the drug is excluded from the formulary, leave blank. *Format: percentage*

Step Therapy Required: Indicate whether the drug requires step therapy in the prior authorization process by choosing "Yes" or "No" from the drop-down selection box. If the drug is excluded from the formulary, leave blank. *Format: alpha-numeric*

Prior Authorization Required: Select "Yes" if prior authorization is required for the drug, or "No" if prior authorization is not required for the drug. If the drug is excluded from the formulary, leave blank. *Format: alpha-numeric*

Number of Approved Prior Authorizations: Enter the number of approved claims subject to prior authorization. Format: numeric

Number of Denied Prior Authorizations: Enter the number of denied claims subject to prior authorization. Format: numeric

Provider Administered: Indicate if this drug is provider administered by selecting "Yes" or "No". If the drug is excluded from the formulary, leave blank. *Format: alpha-numeric*

Third party payment allowed for the drug: If third-party payments are allowed, select "Yes". If third-party payments are not allowed, select "No." If the drug is excluded from the formulary, leave blank. *Format: alpha-numeric*

Third party payment for the drug is applied to member out-of-pocket: If third party payments are allowed and can be applied toward patient out-of-pocket costs (such as deductibles), select "Yes". If third party payments are allowed but cannot be applied toward patient out-of-pocket cost, select "No". If third party payments are not allowed, select "Not Applicable". If the drug is excluded from the formulary, leave blank. *Format: alpha-numeric*

Notes: Use this field to list any needed explanations based on field selections or any notes your company wishes to share regarding the plan design for the listed drug. *Format: alpha-numeric*

Price Concessions

Click here to go to the Price Concessions tab

Click here to return to the beginning of the instructions.

Note: This worksheet contains intentionally hidden fields (Columns A-E) designed for Prescription Drug Affordability Board administrative use only. No data entry is required for these hidden columns.

Use this worksheet to enter the aggregate price concession data for each listed drug. See the definitions tab for a definition of price concessions.

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

Prescription Drug Name and Therapy Class: These fields are pre-populated with the drugs identified for Prescription Drug Affordability Board review. No action required for these fields. *Format: alpha-numeric*

Coverage: Select from the drop-down box whether the prescription drug was prescribed under the pharmacy benefit, medical benefit, both (medical and pharmacy benefit), or excluded from your coverage. *Format: alphabetic characters*

Total Number of Claims: No action is required for this field. This is an automated field that sums all of the claims based on a prescription drug name in the "Claims and Cost" worksheet. For example - For Drug 1, you reported 100, 20, 50, and 30 total claims for four different NDCs in the "Claims and Cost" worksheet. The sum of these values (200) is fed into the price concession sheet for that drug. *Format: numeric value*

Number of Claims with Price Concessions Applied: Enter the number of claims for the prescription drug in which a price concession was applied in the reporting year. *Format: numeric*

Total Cost of the Drug Before Price Concessions: Enter the total dollars paid for prescription drug claims in the pharmacy and medical benefits before price concessions were applied. *Format: currency*

Total Price Concessions from Manufacturer: Enter the total dollar amount of all price concessions received from the manufacturer for the prescription drug in the reporting year. *Format: currency*

Note: If there is a lag in the rebate and price concession data your company receives, enter the actual numbers that are available at the time of this data call for the reporting year. There will be a separate field for any anticipated price concessions that have not yet been received for the reporting year.

Total Price Concessions from PBM: Enter the total dollar amount of all price concessions received from the pharmacy benefit manager (PBM) for the prescription drug in the reporting year. *Format: currency*

Note: If there is a lag in the data your company receives, enter the actual numbers that are available at the time of this data call for the reporting year. There will be a separate field for any anticipated price concessions that have not yet been received for the reporting year.

Total Estimated Price Concessions Not Yet Received: Use this field to report any price concessions for the reporting year that have not yet been received as of this data call but are anticipated (example: pending rebates not yet received). *Format: currency*

Total Other Rebates and Price Concessions (including PAPs): List the total dollar amount of any other price concessions for the prescription drug in the reporting year. If there were no other rebates or price concessions, enter 0. If there were other rebates and price concessions, please add a note to the Notes field explaining the nature and details of these amounts. *Format: currency* **Total Price Concessions:** No action required for this field. This field will automatically calculate the sum of the price concession fields. *Format: currency*

Price Concessions Percentage: No action required for this field. This field will automatically calculate the total sum of rebates and discounts divided by the total cost before rebates and discounts. *Format: percentage*

Notes: If a dollar amount was listed for "Total Other Rebates and Price Concessions (including PAPs)", enter a brief description or explanation regarding the nature of these rebates or price concessions in this field. *Format: alpha-numeric*

Definitions

Term	Definition
Total Annual Plan Spending	The total payments made under the policy to health care providers on behalf of covered members, including payments made by issuers and member cost sharing. The total annual plan spending should reflect the total after all rebates and price concessions have been applied.
Preferred (formulary status)	There is an agreement with the pharmacy benefit manager (PBM) where the drug will be placed on the formulary.
Non-Preferred (formulary status)	Drugs that have a higher tier level and/or copay amount; often require prior authorization.
Excluded (formulary status)	Drugs that are not covered under the drug formulary.
Rebate	A type of price concession that occurs after a product or service is paid, typically by the entity receiving the rebate, such as a rebate from the manufacturer to the insurer/PBM after a pharmacy claim has been paid. The amount reported by the insurer is the amount passed directly to the insurer from the PBM or the manufacturer and does not include rebates retained by the PBM in lieu of fees.
Patient Assistance Program (PAP)	A type of price concession paid by (or on behalf of) the manufacturer for some portion of the patient point of service cost sharing as required by the health plan, including the deductible. Plans that allow these payments are to report this amount whether the health plan uses the accumulator or maximizer model to track the amount of the assistance.
Price Concession	Any negotiated or required reduction in the cost of drug to the insurer, including, but not limited to, discounts and rebates

FAQ

Question: There is a lag in when our company receives data regarding rebates. Should we report estimates?

Answer: For any months you have data available, include the actual price concession amounts. For any remaining months the actual price concession data is not yet available, such as any lag in rebates, report the estimated amount of pending rebates and price concessions in the "Estimated price concessions not yet received" column.

Company Information - Provide the following information (required fields will highlight yellow until the requested data is entered). **Note**: If "Other" is chosen for **Market Type**, a new field (**Market Type Notes**) will appear below Market Type. Please fill in the note field to describe the "Other" market.

	Company										
Company											
Name											
NAIC Code											
	Contact Information										
Contact			Phone								
Туре:	Name	Job Title	Number	Email	Notes						
Primary Contact (required)											
Secondary Contact (optional)											
Authorizing Authority (required)											
Technical Contact (required)											
	Market Type Information										
Market Type											

Data Limitations and Notes

Section	Data Point 🗸	Data Quality or Limitation Notes
	Y	

Claims and Cost

Prescription Drug Name	Therapy Class	Drug Type	National Drug Code	Coverage	Number of Enrollees	Number of Prescriptions	Total Number of Claims	Total Annual Plan Spending (Allowed Dollar Amount) 🔽	Total Annual Deductible Costs for Enrollees	Total Annual Copay Costs for Enrollees	Total Annual Coinsurance Cost for Enrollees 🥃	Total Other Enrollee Costs	Total Annual Out of Pocket Cost for Enrollees	Notes 💌
Drug 1	Class 1	Brand	58672499698		T									
Drug 1	Class 1	Brand	38326049329											
Drug 2	Class 2	Generic	00245415713											
Drug 2	Class 2	Generic	37560897130											
Drug 2	Class 2	Generic	78544977210											
Drug 3	Class 3	Brand	55992297376											
Drug 4	Class 4	Brand	23358743582											
Drug 5	Class 5	Brand	40995233886											
Drug 5	Class 5	Brand	81236447665											
Drug 6	Class 1	Brand	20560178402											
Drug 6	Class 1	Brand	58953133764											
Drug 6	Class 1	Brand	61755911130											
Drug 7	Class 2	Brand	71464256041											
Drug 7	Class 2	Brand	39481004439											
Drug 8	Class 2	Brand	19456769125											

Plan Design

Prescription Drug Name	Therapy Class	Drug Type 🗸	Plan Type 🗸	Formulary Status	Copay Formulary Status	Fixed Fee Copay	Percentage of Coinsurance	Step Therapy Required	Prior Authorization Required	Number of Approved Prior Authorizations	Number of Denied Prior Authorizations		applied to member	Notes
Drug 1	Class 1	Brand		- -										
Drug 2	Class 2	Generic												
Drug 4	Class 4	Brand												
Drug 5	Class 5	Brand												
Drug 6	Class 1	Brand												
Drug 7	Class 2	Brand												
Drug 8	Class 2	Brand												

Price Concessions

Prescription Drug Name	Therapy Class	Drug Type	Coverage	Total Number of Claims	Concessions	Total Cost of the Drug Before Price Concessions	Total Price Concessions from Manufacturer	Total Price Concessions from PBM	Estimated Total Price Concessions Not Yet Received	Total Other Rebates and Price Concessions (including PAPs) 🗸	Total Price Concessions	Price Concessions Percentage	Notes
Drug 1	Class 1	Brand		v -							\$-		
Drug 2	Class 2	Generic									\$-		
Drug 4	Class 4	Brand									\$-		
Drug 5	Class 5	Brand		-							\$-		
Drug 6	Class 1	Brand		-							\$-		
Drug 7	Class 2	Brand		-							\$-		
Drug 8	Class 2	Brand		-							\$-		
				-							\$-		
				-							\$-		
				-							\$-		
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Plan Types Reference

Click here to go t	he Instructions	
Click here to go t	o the "Plan Design" V	Vorksheet
Plan Type	🚽 Line of Business	Description
C-DHMO	Commercial	Dental Health Maintenance Organization
C-DPOS	Commercial	Dental Point of Service
C-DPPO	Commercial	Dental Preferred Provider Organization
C-EPO	Commercial	Exclusive Provider Organization
C-HDHP	Commercial	High-Deductible Health Plan
C-HMO	Commercial	Health Maintenance Organization
C-POS	Commercial	Point-of-Service
C-PPO	Commercial	Preferred Provider Organization
MCD-FFS	Medicaid	Fee For Service
MCD-HMO	Medicaid	Health Maintenance Organization
M-DHMO	Medicare	Dental Health Maintenance Organization
M-DPOS	Medicare	Dental Point of Service
M-DPPO	Medicare	Dental Preferred Provider Organization
M-FFS	Medicare	Fee For Service
M-HMO	Medicare	Health Maintenance Organization
M-PABC	Medicare	Parts A, B and C
M-PD	Medicare	Part D
M-PPO	Medicare	Preferred Provider Organization
M-SNP	Medicare	Special Needs Plan
NA	NA	Not Applicable
Other	Other	Other Plan Type
Note: C = "Comm	nercial", MCD = "Med	icaid", and M = "Medicare"



Agenda item: Board review of data sets and OAR 925-200-0010 criteria for upcoming affordability reviews

Click on the <u>Prescription Drug Affordability Board data web page</u> to access the data in Excel format. Here are the file names:

- <u>Carrier 2023 Preliminary aggregated information v01</u>
- Insulin 2023 Preliminary aggregated information based on APAC phar macy data v01
- mfr-2023-annual-increase-v01.xlsx
- mfr-2023-new-specialty-v01.xlsx

Location on the PDAB website: <u>https://dfr.oregon.gov/pdab/Pages/data.aspx</u>





Prescription Drug Affordability Board

Affordability review

Cortnee Whitlock, senior policy analyst Jan. 15, 2025

Agenda

Review of past affordability review decisions

Updated affordability review process

Goals and purpose



Oregon Prescription Drug Affordability Board



Decisions from first affordability review

Decisions made:

- Focus on carrier data
- No review of the Mfr Rx lists due to challenges of the review
- Price increase list would have had a lot of work to get through
- New specialty Rx would be projected information based off assumptions of the impact the drug has on the system and outof-pocket costs



• Most Costly identified as key data point

Identified preliminary list in

- Removed Most Prescribed Rx list type from review
- Focus on Top Drugs to Review list
- Look at Rx that are on more than one type lists

Identified subset list in September:

- Add all the DPT reported Most Costly drugs into the Top Drug list
- Compare CCO top reported Rx against Top Drug list
- Filter based on Total Costs, and
- Pick no more than 30 drugs, including insulin products, for the board to review





Affordability review process

Phase 1: Identify eligible prescription drugs for affordability review

- Carrier top 25 reported Rx provided under ORS 743.025
- Manufacturer reported information for annual increase and quarterly new specialty prescription drugs provided under ORS 646A.689 (2) & (6)
- Insulin (APAC)

Phase 2: Select prescription drugs for affordability review

- OAR 925-200-0010
- Select subset list of drugs to have health carriers provide additional information on

Phase 3: Data call and supplemental info

- Data call of subset lists (Rx and insulin)
- APAC compare claims against subset list
- Compile data and prepare subset list information for affordability review

Phase 4: Conducting the affordability review

- ORS 925-200-0020
- Affordability review material packets

Phase 5: Select prescription drugs and insulin products that may create affordability challenges to healthcare system or out-of-pocket costs

• Senate Bill 844





Phase 1: Identify eligible prescription drugs for affordability review

- Insurer reported provided under ORS 743.025:
 - Top 25 most frequently prescribed drugs;
 - The 25 most costly drugs as a portion of total annual spending;
 - The 25 drugs that have caused the greatest increase in total plan spending from one year to the next
- Manufacturer reported drugs provided under ORS 646A.689 (2) & (6):
 - Annual increase report:
 - Rx with \$100 or more for a one-month supply or for a course of treatment lasting less than one month and
 - A net increase of 10 percent or more in the price of the prescription drug from the previous calendar year
 - Monthly reporting for new specialty Rx
- Insulin products
 - APAC





 DPT carrier lists Drug Price Transparency (DPT) program collects health insurances carrier's top 25 greatest price increase, most costly, and most prescribed drugs (Rx) under ORS743.025. The DPT aggregates the information and provides it to PDAB's data analyst to setup for the board to review. 	OAR 925-200-0010
 Any carrier Rx on mfr. new drug report or price increase report DPT collects information from manufacturers under ORS 646A.689. Data submitted under is give to PDAB data analyst quarterly and provided to the board to review. Section (2) under ORS 646A.689 is provided annual from DPT and shown to the board for 	
 Historical & current mfr. Rx price increases, based on wholesale acquisition cost (WAC) Rx on list for affordability review will be looked up in Medi-Span to current WAC price. For drugs with multiple national drug codes (NDC), a measure of ce price comparison. 	
 PDAB staff will look up expedited approvals of fast approval, and breakthrough therapy designation. PDAB staff will use Medi-Span to look up brand-na whether there are any approved and marketed ger 	me drugs and biological products, and
Are therapeutic alternatives available? • PDAB staff will review Rx un there are therapeutic altern available?	natives and if cost and
Phase 2: Select prescription drugs for affordability review	• PDAB staff will review Rx under review and research if there are patent or data exclusivity expirations within 18 months of affordability review.
	Dregon Prescription Drug

1859

Phase 2: Select prescription drugs for affordability review (continued)

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





Phase 3: Data call and supplemental information

- Data call of subset lists (Rx and insulin)
- APAC compare claims against subset list
- Compile data and prepare subset list information for affordability review

Phase 4: Conducting the affordability review

- OAR 925-200-0020
- Affordability review material packet

Phase 5: Select 9 prescription drugs and at least one insulin product that may create affordability challenges to the healthcare system or out-of-pocket costs

- Senate Bill 844 reporting requirements
 - Section 2
 - Section 5





Goal of PDAB

To make prescription drugs affordable in Oregon for patients and the healthcare system

- How: apply criteria set up under Senate Bill 844, OAR 925-200-0010 and 0020.
- What determines if an Rx *may* create an affordability challenge or high out of pocket costs for patients?
 - Rx that led to health inequities
 - Number of residents prescribed Rx
 - Price of Rx
 - Price concessions, discount or rebates the manufacturer provides health plans and PBMs
 - Price of therapeutic alternative
 - Patient access considering benefit designs
 - Financial impacts to health, medical or social services costs compared to therapeutic alternative
 - Average patient copayment or other cost-sharing





Purpose of reviews

To improve the accessibility and affordability of prescription medications (Rx) to patients and the health system

How:

- **Cost analysis**: compare Rx to therapeutic benefits. Helps determine if the price of the Rx is justified based on clinical value and the outcome.
- Identifying high-cost drugs: Is the Rx disproportionately expensive compared to other treatments?
- Informed decision making: access to Rx pricing in the supply chain helps board members determine the cost and access to Rx.
- **Transparent pricing**: Can foster competition and incentivize manufacturers to have fair pricing strategies.
- Value-based pricing: aligns the cost of medications with the health outcomes they provide.
- Ensure access and affordability to patients.





What creates an affordability challenge to the health system?

- Cost of the drug
- Therapeutic alternative
- The number of patients requiring the Rx
- The frequency of the drug
- Insurance coverage
- Reimbursement of Rx

- Clinical value
- Health outcomes
- Market dynamics
- Regulatory factors
- Patient populations
- Health equities





Affordability

The ability to pay for medications without experiencing financial challenges

- Cost of medication
- Insurance coverage
- Level of financial stability or income
- Discounts or programs
- Market competition







Insulin Data Process

PDAB Staff January 2025

Table of Contents

Document History	2
Overview	2
Data Sources	2
Assumptions and Constraints	3
Process – Preliminary Aggregated Insulin Data	3
Calculations	6
Definitions	8
Tools	11
Conclusion	11

Document History

Version	Date	Description	Author
v01		Original draft	PDAB Staff

Overview

The following methodology was used to develop the preliminary list for insulin drugs for the 2025 Oregon Prescription Drug Affordability Board (PDAB) affordability review. The data used to produce the list is from the calendar year 2023.

Data Sources

- 1. **APAC Database** "The Oregon All Payer All Claims Database (APAC) is a large database that houses administrative health care data for Oregon's insured populations. In particular, APAC includes medical and pharmacy claims, non-claims payment summaries, member enrollment data, billed premium information, and provider information for Oregonians who receive coverage through commercial insurers as well as through public payers such as Medicaid and Medicare."¹ The APAC Database is maintained by the Oregon Health Authority (OHA) and was the source of the 2023 pharmacy claim data for these outputs. Medical claims were not utilized for these lists. APAC information is gross and not net of rebate.
- Centers for Medicare & Medicaid Services (CMS) The "Selected Drug List" for the Medicare Drug Price Negotiation was used as a resource to verify if an insulin drug was present or absent from the current drug price negotiation list.²
- 3. **Federal Drug Administration** (FDA) The administration is part of the U.S. Department of Health and Human Services. Information published by the FDA was used to gather information relevant to NDC values of interest for insulin.³

¹ <u>https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx</u>; See also <u>https://www.oregon.gov/oha/HPA/ANALYTICS/APAC%20Page%20Docs/APAC-Overview.pdf</u>

² https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation

³ <u>https://open.fda.gov/data/ndc/;</u> See also <u>https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory</u>; See also <u>https://dps.fda.gov/ndc</u>; See also <u>Search Orphan Drug Designations and Approvals</u>

- 4. Medi-Span This Wolters Kluwer drug database was the primary source for NDC information.⁴
- 5. **Contracted Clinician** This resource provided assistance and validation for, insulin therapeutic class level (Medi-Span classification), naming conventions, insulin subclass categorization, and the presence and number of therapeutic alternatives.
- 6. National Institute of Health, National Library of Medicine (NIH) The NIH was used as a secondary source for NDC information throughout the process.⁵

Assumptions and Constraints

- 1. Data provided or acquired by all listed sources is true, accurate, and as complete as possible.
- 2. Due to confidentiality constraints and data use agreements, the analysis outputs must be deidentified and in aggregated form. No individual claim data can be represented.
- 3. The APAC Database "does not include data on uninsured individuals or other populations who pay out-of-pocket for their health care; nor does it include data on individuals insured through certain federal programs such as Tricare, the Federal Employees Health Benefits Program, the Indian Health Service, or the Department of Veterans Affairs. The database also does not collect data on members of small commercial health plans with fewer than 5,000 covered lives. The database does not include information on other types of insurance, such as workers' compensation or stand-alone dental or vision coverage. Additionally, claims related to alcohol and drug treatment are also masked in APAC."⁶

Process – Preliminary Aggregated Insulin Data

- 1. Request and received data from the APAC Database from OHA
 - a. A formal request was submitted to OHA for the release of the 2023 data based on specified fields of interest.
 - b. The 2023 APAC data was received from OHA. Main data files are in text (.txt) format.
 - c. Analytic software was used to read the text files for further analysis.

⁴ <u>https://www.wolterskluwer.com/en/solutions/medi-span/medi-span/drug-pricing-data</u>

⁵ <u>https://www.dailymed.nlm.nih.gov/dailymed/index.cfm</u>

⁶ APAC-FAQ.pdf

2. Insulin NDC values

- a. Medi-span was used to identify all active insulin NDC values and their associated data within the database. The Medi-span therapeutic class level of GPI04 for "Insulin" was used to filter NDC values relevant to insulin based on clinician direction.
- b. Any information that could not be identified for specific insulin NDCs via Medi-span was researched across additional resources (see Data Sources, page 3) and added to the insulin NDC list.
- c. Due to the variety of sources used to gather information pertaining to insulin NDCs, standardization was required for analysis. This included using a uniform format for numbers and text so that the analysis software was able to recognize like and differing values. No data values were altered in this process.
- d. Medi-Span naming convention was used for proprietary names. A summarized naming convention was used for the non-proprietary naming and is denoted with an (*) next to the column name in the Excel workbook.

3. Identification of insulin related claims

- a. Using analytic software, the resulting NDC list was queried against the APAC pharmacy data to extract all claims associated with the NDC values.
 - i. Not all active insulin NDC values from Medi-span were represented in the APAC pharmacy data (no matching claim data for a given NDC).
 - ii. NDCs that were not represented in the APAC pharmacy data were removed from the insulin NDC list.
- b. The result of the query in 3(a) above represents the raw data for 2023 for APAC pharmacy claims for insulin.
 - i. The APAC database contains some claims that have no associated unique person. This was validated with the Oregon Health Authority.
 - ii. The abovementioned value is important to accurately calculate values related to an individual (e.g. amount paid per patient). Those claims with no identifiable unique person were removed from the dataset to avoid skewing the calculations.

4. Aggregation of insulin data

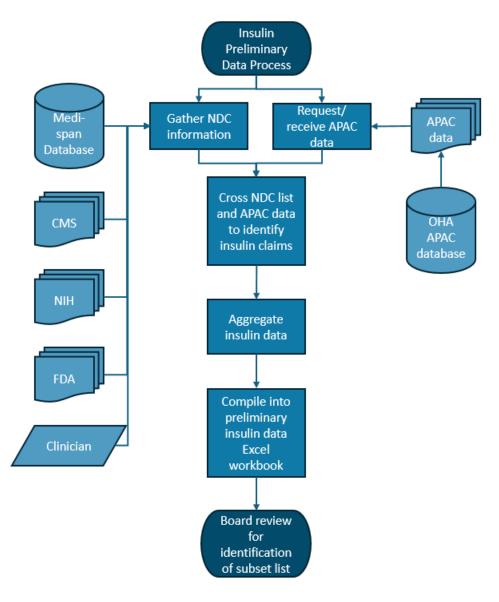
- a. Using the raw data produced in section 3, a programming code was created to select claim data from the raw file for aggregation.
- b. Mathematical functions were used to calculate sums and averages of the values represented. (See Calculations Section)
- c. The resulting information was exported to an Excel workbook with multiple tabs representing the functional aggregated data for insulin.

- d. The data was represented from differing parameters (or pivots) including data by NDC, proprietary name, non-proprietary name, and insulin subclass.
 - i. Note: A unique individual can be represented more than once based on the parameter of analysis. For example, an individual who is prescribed more than one insulin drug that spans more than one insulin subclass, would be represented more than once in the "data by insulin subclass" tab in the Excel workbook. This can happen with any parameter of aggregation.
 - ii. The number of claims is fixed and does not change throughout the data regardless of the parameter of analysis (proprietary name, insulin subclass, etc.).

5. Spreadsheet tabs

- a. The Excel workbook, generated in step 4c, was formatted for aesthetics.
 - i. Additional tabs were created for a cover page, document history, notes, definitions, and sources for continuity of information.
 - ii. Links were created from the cover page to each related page within the Excel workbook.
- b. Workbook tabs are as follows:
 - i. Cover
 - ii. Document history
 - iii. Notes
 - iv. Definitions
 - v. Sources
 - vi. NDC Information
 - vii. Data by NDC
 - viii. Data by Proprietary Name
 - ix. Data by Non-Proprietary Name
 - x. Data by Insulin Subclass

Figure 1 - Insulin Preliminary Data Process Overview



Calculations

The below calculations were performed to create the insulin lists for 2023. The tab representing the location of where each calculated value can be found in the Excel workbook is denoted in parentheses next to the name of the calculation. Fields in the Excel workbook that are not represented below are not calculated measures.

1. **Percent Change in WAC** (NDC information tab) – End of year package (or unit) price minus the beginning of year package (or unit) price the result of which is divided by the beginning of year package (or unit) price. This value is formatted as a percentage.

- Average Percent Change in WAC Over 7 Years (NDC Information tab)- This calculation is an average of the year over year percentage change in WAC. From each year, over 7 years (1/1/2017 – 12/31/2023), the percentage change is calculated for each year. Next, all percentages are averaged to arrive at the average percent change in WAC over 7 years. This value is formatted as a percentage.
- Number of WAC Changes Over 7 Years (NDC Information tab) This value is a sum of the number of changes identified in Medi-span for a given NDC over 7 years (1/1/2017 – 12/31/2023). This field is numeric.
- 4. **Total Payer Paid** (All data tabs) This is the sum of all payer paid amounts based on a particular parameter (e.g. NDC, proprietary name, etc.). This value is formatted as currency in U.S. dollars.
- 5. **Total Patient Paid** (All data tabs) This sum represents all patient paid amounts based on a particular parameter. This includes patient copay, deductible, and coinsurance amounts. This value is formatted as currency in U.S. dollars.
- 6. **Overall Spend** (All data tabs) This calculated value is the sum of the Total Payer Paid and the Total Patient Paid amounts for a specific parameter of interest. This value is formatted as currency in U.S. dollars.
- 7. **Payer Paid per Patient** (All data tabs) This value is calculated by dividing the Total Payer Paid amount by the Total Unique Patients. This value is formatted as currency in U.S. dollars.
- 8. **Paid per Patient** (All data tabs) This value is calculated by dividing the Total Patient Paid amount by the Total Unique Patients. This value is formatted as currency in U.S. dollars.
- 9. **Payer Paid per Prescription** (All data tabs) This value is calculated by dividing the Total Payer Paid amount by the Total Prescriptions Filled. This value is formatted as currency in U.S. dollars.
- Patient Paid per Prescription (All data tabs) This value is calculated by dividing the Total Patient Paid amount by the Total Prescriptions Filled. This value is formatted as currency in U.S. dollars.

- 11. **Total Prescriptions Filled** The total prescriptions for a given parameter (e.g. NDC) based on the claim identifier in the APAC database.
- 12. **Total Unique Patients** The unique person (or patient) is based upon the "uniquepersonID" APAC field and identifies a person by identifying them with a unique identifier. "Total Unique Patients" is a sum of all unique patients based on a specific parameter (e.g. NDC). For example, all uniquely identifiable patients related to an NDC are counted once for that NDC. More than one claim can exist for that patient for that NDC but the unique person is counted only once.⁷

Definitions

- Bioequivalence "Bioequivalence is, in pertinent part: the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study."⁸
- 2. Biosimilar "A biosimilar is a biologic medication. It is highly similar to a biologic medication already approved by FDA the original biologic (also called the reference product). Biosimilars also have no clinically meaningful differences from the reference product. This means you can expect the same safety and effectiveness from the biosimilar over the course of treatment as you would the reference product. Biosimilars are made from the same types of sources (e.g., living cells or microorganisms) and are just as safe and effective as their reference products."⁹
- 3. **Brand Name Drug** A drug sold by a drug company under a specific name or trademark and that is protected by a patent.¹⁰ Brand name drugs may be available by prescription or over the counter.
- 4. **Generic Drug** A generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.¹¹

⁷ https://www.oregon.gov/oha/HPA/ANALYTICS/APAC%20Page%20Docs/APAC-Data-User-Guide.pdf

⁸ <u>https://www.fda.gov/media/160054/</u>

⁹ <u>https://www.fda.gov/drugs/biosimilars/</u>

¹⁰ Drugs@FDA Glossary of Terms | FDA

¹¹ Generic Drugs: Questions & Answers | FDA

- 5. **Insulin mix** A combination of insulin products with a duration of up to 24 hours. Typically given twice daily before meals.¹²
- 6. Intermediate Acting (NPH) Insulin Human insulin with an onset of about 90 minutes and a duration of up to 24 hours. Typically given once or twice daily.¹³
- 7. Long Acting Insulin Human insulin analog with a duration of ~24 hours (up to 42 hours with insulin degludec). Typically given once daily.¹⁴
- 8. National Drug Code (NDC) This code is a unique identifier for drug products.¹⁵
- 9. Non-proprietary name The chemical name for a drug.¹⁶
- 10. **Orphan designation** A drug designated by the FDA as a treatment for a rare disease and when the drug has been granted exclusive marketing rights for a seven-year period to treat rare diseases.¹⁷
- 11. Patient (aka enrollee) Individual enrolled for coverage under a health benefit plan.¹⁸
- 12. **Payer (aka carrier)** Any person or entity that provides health benefit plans in the state that include but are not limited to licensed insurance companies, health care service contractors, health maintenance organizations, and any other corporation responsible for the payment of benefits or provisions of services.¹⁹
- 13. **Pharmaceutical equivalence** Drug products that have "identical dosage form and route(s) of administration; contain identical amounts of the identical active drug ingredient, i.e., the same salt or ester of the same therapeutic moiety, or, in the case of modified-release dosage forms that require a reservoir or overage or such forms as prefilled syringes where residual volume may vary, that deliver identical amounts of the active drug ingredient over the identical dosing period; do not necessarily contain the same inactive ingredients; and meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates."²⁰

¹² Provided by the Contracted Clinician

¹³ Ibid.

¹⁴ Ibid.

¹⁵ <u>https://open.fda.gov/data/ndc/</u>

¹⁶ <u>https://medical-dictionary.thefreedictionary.com/nonproprietary+name</u>

¹⁷ <u>https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions</u>

¹⁸ <u>https://oregon.public.law/statutes/ors_743b.005</u>

¹⁹ Ibid.

²⁰ https://www.fda.gov/media/160054

- 14. **Priority review** Priority review status for a drug application indicates that the FDA will review the drug within 6 months (at a faster rate than the 10 month standard review).²¹
- 15. **Proprietary name** "The protected brand name or trademark, registered with the U.S. Patent Office, under which a manufacturer markets its product. It is written with a capital initial letter and is often further distinguished by a superscript R in a circle ([®])." ²² The Medispan designated proprietary name was used throughout this analysis.
- 16. **Rapid Acting Insulin** Prandial human insulin analogs with an onset of 10 to 30 minutes and duration of 3 to 5 hours. Given with meals.²³
- 17. **Short-acting insulin** Regular human insulin with an onset of about 30 minutes. Longer time to onset and longer duration (~8 hours) than rapid-acting.²⁴
- 18. **Therapeutic alternative** A "drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved, compendia-recognized as off-label use for the same indication, or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose."²⁵
- 19. **Therapeutic equivalence** "The scientific and regulatory foundation for the evaluation of therapeutic equivalence of prescription drug products involves pharmaceutical equivalence, bioequivalence, and the same clinical effect and safety profile for the conditions of use specified in the labeling."²⁶
- 20. **Total prescription filled** The total prescriptions for a given parameter (e.g. NDC) based on the claim identifier in the APAC database.
- 21. Total Unique Patients The unique person (or patient) is based upon the "uniquepersonID" APAC field and identifies a person by identifying them with a unique identifier. "Total Unique Patients" is a sum of all unique patients based on a specific parameter (e.g. NDC). For example, all uniquely identifiable patients related to an NDC are counted once for that NDC. More than one claim can exist for that patient for that NDC but the unique person is counted only once.

²¹ https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review

²² <u>https://medical-dictionary.thefreedictionary.com/proprietary+name</u>

²³ Provided by the Contracted Clinician

²⁴ Provided by the Contracted Clinician

²⁵ PDAB Administrative Rule 925-200-0020

²⁶ <u>www.FDA.gov</u>

22. Wholesale Acquisition Cost (WAC) - The price paid by a wholesaler to purchase drugs from a supplier, typically the manufacturer.²⁷

Tools

- 1. **Microsoft Excel** This tool is the industry leading spreadsheet software program, data visualization and analysis tool.
- 2. **RStudio** RStudio is programming software used to import, clean, organize, query, and analyze data that comes from a variety of sources, including insurance carriers. R has the versatility to process large amounts of data and read the multiple file formats that are encountered in the prescription drug affordability program enabling flexibility in data modeling.
- 3. **SQL** (Structured Query Language) SQL is a standardized programming language used for searching, manipulating, and combining data from relational databases. SQL enables efficiency in retrieving and analyzing data as well as generating reports to inform business decisions.

Conclusion

This document is a living document and will be updated as needed as the affordability review process progresses. The above information is pertinent to the development of the preliminary insulin list. Additional processes will be required for the subset list once the drugs listed for review are selected

²⁷ https://prescriptionanalytics.com/white-paper/key-terms-in-pharmaceutical-government-pricing/



Oregon Prescription Drug Affordability Board

Preliminary Drug List Data Process

PDAB Staff January 2025

Table of Contents

Document History	2
Overview	2
Data Sources	2
Assumptions and Constraints	3
Process – Preliminary Aggregated Drug Data	3
Calculations	5
Definitions	6
Tools	9
Conclusion	9

Document History

Version	Date	Description	Author
v01		Original draft	PDAB Staff

Overview

The following methodology was used to develop the preliminary drug lists from health insurance carriers reported under ORS 743.025 for the 2025 Oregon Prescription Drug Affordability Board (PDAB) affordability review. The data used to produce the lists is from the calendar year 2023.

Data Sources

- Drug Price Transparency Oregon's Drug Price Transparency (DPT) program is responsible for collecting various health care data under ORS 743.025 from health insurance companies offering a health benefit plan in Oregon. Primarily, the data that is collected are the top 25 drugs from each plan of the health insurance companies that qualify for the greatest increase, most costly, and most prescribed lists. Other information include national drug codes (NDC), plan type, number of prescriptions, number of enrollees, and total annual spend. The information collected by DPT is aggregated and calculated net of rebate.
- Centers for Medicare & Medicaid Services (CMS) The "Selected Drug List" for the Medicare Drug Price Negotiation was used as a resource to verify if a drug was present or absent from the current drug price negotiation list.¹
- 3. Federal Drug Administration (FDA) The administration is part of the U.S. Department of Health and Human Services. The FDA was used to determine Orphan drug designation of drugs by proprietary and non-proprietary name, as well as a source for patents, approvals, exclusivity, and bioequivalents of drugs. Information published by the FDA was used to as a secondary source for general information relevant to NDC values of interest.²

¹ <u>https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation</u>

² <u>Search Orphan Drug Designations and Approvals</u>; <u>See also Approved Drug Products with Therapeutic Equivalence</u> <u>Evaluations | Orange Book | FDA</u>; <u>See also https://open.fda.gov/data/ndc/</u>

- 4. **Medi-Span** This Wolters Kluwer drug database was the primary source for NDC and wholesale acquisition cost (WAC) information.³
- 5. **Contracted Clinician** This resource provided assistance and validation for, insulin therapeutic class level (Medi-Span classification), naming conventions, insulin subclass categorization, and the presence and number of therapeutic alternatives.

Assumptions and Constraints

- 1. Data provided or acquired by all listed sources is true, accurate, and as complete as possible.
- 2. Due to confidentiality constraints, the analysis outputs must be deidentified and in aggregated form. No individual claim data can be represented.
- 3. The carrier data does not provide information on patients paying out-of-pocket for their medical and pharmaceutical expenses and are not included in the aggregated analysis.

Process – Preliminary Aggregated Drug Data

1. Request and received data from the healthcare carriers

- a. The 2023 drug data was reported by the health insurance carriers to the DPT program as required under ORS 743.025.
- b. DPT received, validated, and aggregated the data that was submitted in Excel format by the health insurance carriers.
- c. The PDAB staff received the aggregated information from the DPT program in various Excel workbooks and combined the information into one singular Excel sheet.

2. Standardizing drug names and carrier codes.

- a. A proprietary naming convention was created in order to unify drug names that differ slightly according to the reporting. A new column of "Proprietary Name Summarized" was created based off of the proprietary names given by carriers.
- b. Each healthcare carrier was given an unique carrier code to identify the individual entries of drugs. A new column of "carrier_id" was created and other columns were added as well to further distinguish the reporting such as "carrier_group_type".

3. Identification of preliminary drugs for investigation

a. Using the pivots in Excel, all drugs reported by healthcare carriers were identified and sorted by the number of Top 25 lists (Greatest Increase, Most Costly, and Most

³ https://www.wolterskluwer.com/en/solutions/medi-span/medi-span/drug-pricing-data

Prescribed) they were on. If a drug was reported by 5 or more carriers for the Greatest Increase and Most Costly lists they were included in the preliminary drug list. The drugs were identified by their "Proprietary Name Summarized".

b. Precursory edits of the list resulted in insulin products and medical devices being removed from the preliminary drug list.

4. Aggregation of drug data

- a. An unique ID for each entry of the drugs were created from carrier id, carrier type, and proprietary drug name summarized. Based on the unique ID, duplicate entries were removed from the raw data in the Excel workbook.
- b. Mathematical functions were used to calculate sums and averages of the values represented. (See Calculations Section.)
- c. The resulting information was exported to an Excel workbook with multiple tabs representing the functional aggregated data.
- d. The WAC data was calculated using Medi-Span as the source. Using the NDC's provided by the carriers, PDAB staff used SQL and Medi-Span to pull WAC information on the drugs on the preliminary list.

5. Spreadsheet tabs

- a. The Excel workbook, generated in step 4c, was formatted for aesthetics.
 - i. Additional tabs were created for terms and sources for continuity of information.
- b. Workbook tabs are as follows:
 - i. Terms
 - ii. Sources
 - iii. Carrier Prelim Rx List 2024-2025

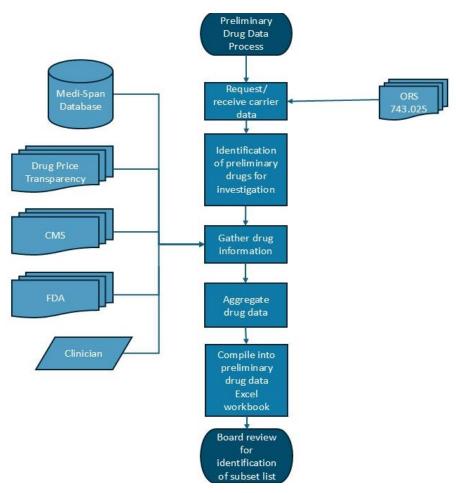


Figure 1 - Preliminary Drug Data Process Overview

Calculations

The below calculations were performed to create the preliminary drug lists for 2023.

- 1. **Total Annual Net of Rebate Spend Per Enrollee** This calculation is the Total Annual Net of Rebate Spend divided by the Number of Enrollees. The annual net is the total aggregated amount spent per enrollee from all reporting health insurance carriers. This value is formatted as currency in U.S. dollars.
- 2. Average Cost Net of Rebate Per Prescription This calculation is the Total Annual Net of Rebate Spend divided by the Number of Prescriptions. The average cost is the amount spent that included rebates or other discounts per prescription. This value is formatted as currency in U.S. dollars.

- 3. WAC Price Change Percentage in 2023 End of year package (or unit) price minus the beginning of year package (or unit) price the result of which is divided by the beginning of year package (or unit) price. This value is formatted as a percentage.
- 4. **Greatest Increase (GI) Rank** Carriers are required to report the prescription drugs causing greatest increase in total plan spending from the current experience period to the previous experience period. This list must consider total annual spending including the net impact of any rebates or other price concessions. Drugs are ranked beginning with the drug causing the largest year over year increase, when factoring in the impact of rebates and price concessions. The value is formatted as a whole number.
- 5. **Most Costly (MC) Rank** The most costly drugs are required to be reported by prescription drug products, from both pharmacy and medical benefits. This list considers the net impact of any rebates or other price concessions that have or will impact the total annual spending for the year reported. Drugs are ranked beginning with the drug causing the largest cost to total annual spending, when factoring in the impact of rebates and price concessions. The value is formatted as a whole number.
- 6. **Most Prescribed (MP) Rank** The most prescribed drugs are required to be reported by the number of claims received. This includes prescription drugs covered under both the pharmacy and medical benefits. Drugs are ranked beginning with highest numbers of prescription drug claims. The value is formatted as a whole number.
- 7. Most Expensive (ME) Rank The most expensive drugs are calculated by PDAB staff and are identified by calculating the cost per enrollee, including the impact of rebates and price concessions. Total Annual Net of Rebate Spend is divided by the Number of Enrollees using RStudio to determine the most expensive drugs. Drugs are ranked beginning with the drug causing the most cost per enrollee, when factoring in the impact of rebates and price concessions. The value is formatted as a whole number.

Definitions

1. **Bioequivalence** – "Bioequivalence is, in pertinent part: the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site

of drug action when administered at the same molar dose under similar conditions in an appropriately designed study."⁴

- 2. Biosimilar "A biosimilar is a biologic medication. It is highly similar to a biologic medication already approved by FDA the original biologic (also called the reference product). Biosimilars also have no clinically meaningful differences from the reference product. This means you can expect the same safety and effectiveness from the biosimilar over the course of treatment as you would the reference product. Biosimilars are made from the same types of sources (e.g., living cells or microorganisms) and are just as safe and effective as their reference products."⁵
- 3. **Brand-name drug** A drug sold by a drug company under a specific name or trademark and that is protected by a patent.⁶ Brand name drugs may be available by prescription or over the counter.
- 4. **Carrier (aka payer)** Any person or entity that provides health benefit plans in the state that include but are not limited to licensed insurance companies, health care service contractors, health maintenance organizations, and any other corporation responsible for the payment of benefits or provisions of services.⁷
- 5. Enrollee (aka patient) Individual enrolled for coverage under a health benefit plan.⁸
- Generic Drug A generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.⁹
- 7. National Drug Code (NDC) This code is a unique identifier for drug products.¹⁰
- 8. Non-proprietary name The chemical name for a drug.¹¹

⁴ https://www.fda.gov/media/160054/

⁵ <u>https://www.fda.gov/drugs/biosimilars/</u>

⁶ Drugs@FDA Glossary of Terms | FDA

⁷ https://oregon.public.law/statutes/ors_743b.005

⁸ Ibid

⁹ Generic Drugs: Questions & Answers | FDA

¹⁰ <u>https://open.fda.gov/data/ndc/</u>

¹¹ <u>https://medical-dictionary.thefreedictionary.com/nonproprietary+name</u>

- 9. **Number of Enrollees** The number of enrollees who filed claims for the prescription drugs in the reporting year.
- 10. **Number of Prescriptions** The number of claims received for the prescription drug in the reporting year.
- 11. **Orphan designation** A drug designated by the FDA as a treatment for a rare disease and when the drug has been granted exclusive marketing rights for a seven-year period to treat rare diseases.¹²
- 12. **Pharmaceutical equivalence** Drug products that have "identical dosage form and route(s) of administration; contain identical amounts of the identical active drug ingredient, i.e., the same salt or ester of the same therapeutic moiety, or, in the case of modified-release dosage forms that require a reservoir or overage or such forms as prefilled syringes where residual volume may vary, that deliver identical amounts of the active drug ingredient over the identical dosing period; do not necessarily contain the same inactive ingredients; and meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates."¹³
- 13. **Priority review** Priority review status for a drug application indicates that the FDA will review the drug within 6 months (at a faster rate than the 10 month standard review).¹⁴
- 14. **Proprietary name** "The protected brand name or trademark, registered with the U.S. Patent Office, under which a manufacturer markets its product. It is written with a capital initial letter and is often further distinguished by a superscript R in a circle (®)." ¹⁵ The Medispan designated proprietary name was used throughout this analysis.
- 15. **Therapeutic alternative** A "drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved, compendia-recognized as off-label use for the same indication, or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety

¹² <u>https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions</u>

¹³ <u>https://www.fda.gov/media/160054</u>

¹⁴ <u>https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review</u>

¹⁵ <u>https://medical-dictionary.thefreedictionary.com/proprietary+name</u>

profile, and expected outcome when administered to patients in a therapeutically equivalent dose."¹⁶

- 16. Therapeutic equivalence "The scientific and regulatory foundation for the evaluation of therapeutic equivalence of prescription drug products involves pharmaceutical equivalence, bioequivalence, and the same clinical effect and safety profile for the conditions of use specified in the labeling."¹⁷
- 17. Wholesale Acquisition Cost (WAC) The price paid by a wholesaler to purchase drugs from a supplier, typically the manufacturer.¹⁸

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¹⁶ PDAB Administrative Rule 925-200-0020

¹⁷ www.FDA.gov

¹⁸ <u>https://prescriptionanalytics.com/white-paper/key-terms-in-pharmaceutical-government-pricing/</u>