Oregon Prescription Drug Affordability Board

350 Winter Street NE, Salem, OR 97301 | 971-374-3724 | pdab@dcbs.oregon.gov | dfr.oregon.gov/pdab

Agenda

Date: **October 19, 2022** | *Time*: **9:30 – 11:30 a.m.**

Meeting name	**Prescription Drug Affordability Board**
Meeting location	Virtual
Zoom link	Click here to register for the meeting

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

*(A) denotes Alternate Member

Staff: Ralph Magrish, executive director; Cortnee Whitlock, policy analyst; Stephen Kooyman, project manager; Yasu Tanaka, data analyst; Melissa Stiles, administrative specialist; Joanna Tucker Davis, counsel; Pramela Reddi, counsel

Subject	Presenter	Time Allotted
☐ Call to order, roll call, and approval of minutes	Chair Patterson	5 minutes
☐ Executive Director's program update	Ralph Magrish	5 minutes
☐ Presentation on upper payment limits	Lila Cummings, Colorado Prescription Drug Affordability Director, and Andrew York, Executive Director, Maryland PDAB	20 minutes
☐ Questions from the PDAB Board	Lila Cummings and Andrew York	15 minutes
☐ Presentation on pharmacy benefit manager (PBM)	Cassie Soucy and Numi Griffith, senior policy advisors, Division of Financial Regulation	20 minutes
☐ Questions from the PDAB Board	Cassie Soucy and Numi Griffith	15 minutes

☐	Discussion of Report Timeline: Rx Generic Drugs Report Rx Distribution and Payment System Report Price Trends for List of Rx Recommendations from Rx List	Cortnee Whitlock	10 minutes
☐	Announcements: 2023 board calendar	Ralph Magrish	10 minutes
☐	Public comment	Chair Patterson	10 minutes
☐	Adjournment	Chair Patterson	5 minutes

Next Meeting

November 16, 2022, 9:30 a.m.

Accessibility

The meeting is accessible to persons with disabilities. Closed captions are available for virtual meetings. A request for hearing impaired assistance and accommodations for persons with disabilities may be made to Melissa Stiles by email at pdab@dcbs.oregon.gov or by phone at 971-374-3724, with at least 48 hours' notice.

Public Comment

Oral Testimony

For oral comments, please submit the PDAB Public Comment Form no later than 24 hours before the PDAB meeting. The form is located on the Oregon Prescription Drug Affordability Board website here: https://dfr.oregon.gov/pdab/Pages/public-comment.aspx For assistance, call the PDAB office at 971-374-3724 or send an email to pdab@dcbs.oregon.gov.

Written Testimony

For written comments, please submit the PDAB Public Comment Form no later than 72 hours before the PDAB meeting. The form is located on the Oregon Prescription Drug Affordability Board website here: https://dfr.oregon.gov/pdab/Pages/public-comment.aspx For assistance, call the PDAB office at 971-374-3724 or send an email to pdab@dcbs.oregon.gov.

Open and Closed Sessions

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

Oregon Prescription Drug Affordability Board

Oregon Prescription Drug Affordability Board Meeting
Wednesday, September 21, 2022
Draft Minutes

Call to Order and Roll Call
Chair Akil Patterson called the meeting to order at 9:32 a.m. and asked for the roll call.

Board Members and Alternate Members Present: Shelley Bailey, Richard Bruno, Daniel Hartung, Akil Patterson, Robert Judge (alternate), Rebecca Spain (alternate).
Board Members Absent: None

Appointing Alternate Member for Voting
The chair appointed Robert Judge to be the alternate voting member for the duration of this meeting due to the current board vacancy.

Approval of the Minutes
Chair Akil Patterson asked if board members had any changes to the August 17, 2022 minutes on Pages 3-7 in the packet posted online: https://dfr.oregon.gov/pdab/Documents/20220921-PDAB-document-package.pdf. Hearing none, the chair asked for a motion to approve the minutes. Dr. Bruno moved to approve, and Vice Chair Shelley Bailey provided a second. The chair asked for a voice vote.

MOTION by Richard Bruno to approve the August 17, 2022, minutes.
Board Voice Vote:
Yea: Richard Bruno, Daniel Hartung, Robert Judge, Shelley Bailey, Akil Patterson.
Nay: None.
Motion passed.

Program Update
Executive Director Ralph Magrish gave a presentation to the Cost Growth Target Benchmark's Advisory Committee on September 9. The presentation was well received, and he looks forward to collaborating with the Oregon Health Authority on shared analysis. PDAB has a legislatively-mandated reporting requirement to this program.

Ralph Magrish gave a presentation at the National Academy of State Health Policy's (NASHP) annual conference in Seattle last week. He participated in a preconference discussion on "How States are Addressing Rising Health Care Costs," spotlighting progressive programs in the Northwest. He talked about the PDAB launch and synergy with the Drug Pricing Transparency Program. Also, during the conference, he met with the NASHP pharmacy team and with representatives from the Program on Regulation, Therapeutics, and Law (PORTAL) at the Harvard Medical School. PORTAL received a contract from NASHP to provide technical assistance to PDABs, including the Oregon PDAB. PORTAL also supports the Colorado PDAB in helping develop their affordability review criteria.

Staff is contracting with Institute for Clinical and Economic Review (ICER) for access to information. ICER provides fair analysis of medical treatments and evidence reviews of effectiveness. Staff is also contracting with SSR Health Data, a proprietary net price database for affordability reviews. Colorado and Maryland also plan to use both data sources.

The rulemaking advisory committee for the Oregon PDAB model rules was held Aug. 25. The rulemaking public hearing is scheduled for Oct. 25 from 1-2 pm, with a public comment deadline of Nov. 1. The rules take effect Dec. 1, 2022.

Ralph Magrish and Chair Patterson will give a presentation during the Oregon Senate Interim Committee on Health Care hearing Sept. 22.

Ralph Magrish introduced Yasu Tanaka, board data analyst. Yasu Tanaka joins the team from Oregon Health Authority, where he worked in the public health division as an injury data analyst. He has a master's degree in advanced statistics and quantitative analysis from the University of Oregon. Ralph Magrish announced two new board members: Amy Burns, director of pharmacy in Grants Pass; and John Murray, pharmacist from Heppner. They will join the PDAB for the October meeting.

Board members have been requesting presentations on topics they want to learn more about. Today, the board was scheduled to hear about drug patent law, presented by Tahir Amin, from The Initiative for Medicines, Access, and Knowledge (I-MAK). Due to a scheduling conflict for the October board meeting, Tahir Amen will speak at the Nov. 16 board meeting. I-MAK recently released a report, "Overpatented, Overpriced – Curbing patent abuse: Tackling the root of the drug pricing crisis." https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf. The report has been covered by major news outlets, including NBC news: https://www.nbcnews.com/health/health-news/gaming-us-patent-system-keeping-drug-prices-sky-high-report-says-rcna47507.

At the Oct. 19 board meeting, Maryland and Colorado prescription drug affordability program directors will talk about their authority to implement upper payment limits. Cassandra Soucy, senior policy advisor at the Division of Financial Regulation, will give a presentation on PBM rebates and transparency at the Oct. 19 meeting. Cassandra Soucy was the lead staffer at the Legislative Policy and Research Office. She developed the report "Transparency Strategies for the Pharmaceutical Supply Chain" for the Joint Interim Task Force on Fair Pricing of Prescription Drugs, pursuant to House Bill 4005 of 2018.

Oregon Health Authority Presentation: Dr. Trevor Douglass, OPDP & Pharmacy Purchasing Director, gave a presentation on "Medicaid Pharmacy Fundamentals & Primer on Bulk Purchasing," located on Pages 8-33 of the board packet posted online: https://dfr.oregon.gov/pdab/Documents/20220921-PDAB-document-package.pdf . He discussed state bulk purchasing and leveraging the purchasing power of Oregon and other states.

Questions and Answers from the Board:
Vice Chair Shelley Bailey asked about the meaning of "most favored nation" from slide 10. Trevor Douglass said the contractor is obligated to ensure ArrayRx has the best terms the contractor offers any other entity working with them. From slides 24-25, Shelley Bailey asked if the Oregon Health Authority tracks a claim at claim-level detail, the amount paid to pharmacy, and the amount reimbursed to the PBM. Under fee-for-service, the process is transparent. Under the MCO model, how is transparency achieved, she asked. Trevor Douglass said there are many players in the PBM and CCO worlds. The PBM contract readiness provision mandates that Oregon Health Authority ensures PBM contracts be set up in such a manner that pass through occurs, he said. Spread was not allowed in PBM relationships serving the managed Medicaid lives in the state. Shelley Bailey asked about an audit requesting claims details from the pharmacy versus claims details from the PBM. Trevor Douglass said the Oregon Secretary of State's office is currently conducting a PBM audit of the managed contracts.

Robert Judge said he wanted to state for the public record that he is very familiar with Array Rx because Moda Health, his employer, is the administrator for this program. He said Slide 11 looks at how Oregon could leverage itself to get the best use of taxpayer money. He asked where is the $142 million in savings coming from. Is it coming from pharmacies? Does the state pay pharmacies less, knowing the challenges faced by pharmacies in Oregon, he asked? Trevor Douglass said yes, that savings is the difference in the guaranteed amount and the amount the pharmacy benefit manager was able to negotiate. Robert Judge asked if that would otherwise be captured as spread. Trevor Douglass said traditionally, one would not see a slide like 11. It would be a straight line. Robert Judge said this is all about aggregation, the economy of scale, making taxpayer dollars go further. He asked how governmental payers join, whether they are required to join, and if not, why not? Trevor Douglass said, in the state of Washington, governments are required to use the prescription drug programs and consortium. But in Oregon it is not mandated. Robert Judge asked if it would be advantageous for the state to mandate it. Trevor Douglass said it seems advantageous for Oregon to pursue a similar statute to Washington's.

Robert Judge said right now, Washington, Oregon, and Nevada are part of ArrayRx. What does a state have to do to join? Trevor Douglass said the Northwest Consortium started with an intergovernmental agreement. Nevada signed an adjoining agreement. Most states have options to join intergovernmental agreements and there is a lot of alignment over prescription drugs costs, he said. Robert Judge asked if there is value for Oregon taxpayers when more states join ArrayRx? Trevor Douglass said, as the program grows across state lines, it mutually benefits every entity inside the consortium. As ArrayRx leverages purchasing for another 1 million lives, the economy of scale becomes effective, along with the ability to leverage purchasing inside pharmacy networks, he said.

Rebecca Spain, said the board's task is to focus on high priced drugs, including physician administered drugs. She asked about successes or struggles in addressing them. Trevor Douglass said many of the participating programs have moved these drugs to be paid as a pharmacy benefit. On the medical claim side, retrospective comes after the fact. By putting it through the pharmacy benefit, they have eyes on what is being spent now. Many are high investment medications, costing millions of dollars for one course of treatment. All it takes is one of those inside a small group to have significant fiscal interruptions, he said. The steering committee is working with contracted vendors on options to address cost issues, such as stop-loss insurance. They also want to explore options for high investment drugs that might look like or sound like value-based, outcome-based agreements, he said. They have also looked at site of care for some of these medications. It can make a big cost difference, whether it is performed in the hospital, as an outpatient, or in a medical office, he said.

Shelley Bailey said it is important to mention most pharmacy claims are paid for through the CCO channel as opposed to a fee for service. In the secretary of state audit, are any of the PBMs that provide services on behalf of the CCOs able to do effective rate adjustments, she asked? She defined it as adjustments to pharmacies for reimbursement based on a myriad of factors, including brand to generic purchasing ratios. Many of those adjustments are posted up to one year after a drug has been dispensed, she said. Are those adjustments allowed with the PBM partners for the CCOs, she asked? Trevor Douglass said no. He said he cannot answer on behalf of the Secretary of State's office what is included or not included as part of their audit but encouraged the vice chair to ask. Shelley Bailey said the reimbursement side is also a cost driver to generic medications. She requested the board invite a speaker experienced in contracting directly with PBMs, outside of the ArrayRx model, possibly the leader of a pharmacy association. She thinks it would be a meaningful discussion. She also requested the board hear about the new Ohio model, which is transparent and different from what Oregon is doing now, she said.

Chair Patterson asked the vice chair to send the speaker requests to staff. Ralph Magrish said they would look into scheduling those presentations in 2023. He thanked Dr. Douglass for speaking today, especially when he is

under the weather. He said part of the board's mandate is to know what's going on in group purchasing in the state, especially Medicaid drug rebates, since that was a specific topic request by the board.

Presentation of First Drafts Reports: Cortnee Whitlock, board policy analyst, presented the first drafts reports on Pages 34-47, posted online: https://dfr.oregon.gov/pdab/Documents/20220921-PDAB-document-package.pdf. She thanked board members for their time and contributions to the reports and encouraged them to continue sending information. She hopes to get first drafts to board members soon for their review.

Chair Patterson said the board needs to approve extending the meeting time. He asked for a motion and a second. Dr. Richard Bruno made the motion and Shelley Bailey provided a second.

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

Public Comment
The chair asked people to submit the public comment form no later than 24 hours before the meeting or 72 hours for written comment. The form is located on the PDAB website or send an email to pdab@dcbs.oregon.gov if assistance is needed. The chair allocated three minutes of time for public comments. He called on the person who signed up in advance to speak, Thomas Busse, treasurer of the Libertarian Party of Multnomah County, who presented comments to the board.

Adjournment
There being no further business before the board, the chair asked for a motion and second to adjourn the meeting at 11:08 am. Shelley Bailey made the motion and Robert Judge provided the second. The chair asked for a roll call.

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

Oregon Prescription Drug
Affordability Board

Board Member Welcome Packet

Contents

Oregon Prescription Drug Affordability Board

Board Members

Akil Patterson JD, MLS, PCM, Board Chair, was involved in advocacy for the creation of PDABs in Oregon as a member of the Oregon Coalition for Affordable Prescriptions (OCAP) and in Maryland, where he previously resided. He is passionate in his advocacy that the poor and people of color have access to the same lifesaving medications as others. Mr. Patterson is former political organizer for the Oregon Nurses Association, where he led trainings around diversity and inclusion, and efforts to address the social determinants of health in health policy reforms. Currently Mr. Patterson serves as the City of Portland Social Equity and Educational Development Coordinator for the Cannabis Program. Mr. Patterson was awarded a Presidential Service Award in 2016 by President Barrack Obama for being a champion of social justice and racial equity issues. He has served in a number of leadership roles including the Maryland State Medical Society's Sugar-Free Kids Project and Aids Healthcare Foundation

Shelley Bailey, Board Vice Chair, served as the CEO and co-owner of Central Drugs Pharmacy. Shelley is currently the CEO of Famlee, the nation's first and only 50-state virtual fertility care and treatment option (combining at-home labs with fertility telehealth and Rx delivery). Shelley has been involved in healthcare since she was a young girl and her grandparents owned a small, independent pharmacy in Portland's Mt. Tabor neighborhood. Under her leadership, Central Drugs was the largest contractor for the state's AIDS Drug Assistance Program (ADAP), serving Oregonians living with HIV and Hepatitis C. Shelley has experience with specialty pharmacy, wholesaler price negotiations, manufacturer negotiations, PBM contract negotiations, and 340B arrangements. Previously, Shelley served on the Oregon 2012 Pharmacy Benefit Manager Legislative Committee (HB 4122), the McKesson National Independent Advisory Board, and on state and national pharmacy advocacy committees. Shelley brings direct pharmacy knowledge into broader discussions on effectively saving money on prescription drug costs for the State and all Oregonians.

Richard Bruno, MD, MPH, is a double-boarded Family & Preventive medicine physician, practicing as the Senior Medical Director at Central City Concern, a federally-qualified health center in Portland that has an integrated 340B pharmacy. His main clinical focuses are on houselessness, HIV, gender-affirming care, obesity, and opioids, with involvement in community public health interventions and policies, including cooking classes for kids/seniors and legislation expanding access to medication for opioid use disorder. Dr. Bruno passionately believes no one should have to choose between life-saving medications and other necessities. As a primary care physician, he often runs into barriers trying to get his patients access to the medications they need and states it would be an honor to serve on the PDAB to look at drug pricing and make improvements for all Oregonians.

Dan Hartung PharmD, MPH, is a tenured professor of Pharmacy Practice in the College of Pharmacy at Oregon State University. Over the last two decades, he has conducted pharmaceutical health services research with an emphasis on substance use disorders and prescription drug policy. Dr. Hartung's work has been supported by CDC, AHRQ, and NIH (NIDA). He has published more than 100 papers in peer-reviewed medical literature. His research involves investigating the causes and consequences of rising prescription drug costs, with an emphasis on medications for multiple sclerosis (MS). He has developed a deep understanding about how the dysfunctional pharmaceutical ecosystem has contributed to rising prescription drug prices and expenditures. As a researcher and pharmacist, he is well positioned to serve on this board to help develop policy to address prescription drug affordability challenges for Oregonians.

Amy Burns, PharmD, is the Vice President of Benefit Management and Pharmacy Services at AllCare Health, a Coordinated Care Organization (CCO) and Medicare Advantage plan serving Southern Oregon. Amy received a doctor of pharmacy degree from the College of Pharmacy at Oregon State University in 2011 and holds a board certification in pharmacology. Dr. Burns has spent her career as a pharmacist looking at ways to control rising prescription costs on a limited budget while providing the best care possible for Oregon Health Plan members and Medicare beneficiaries. She understands the challenges in making prescriptions more affordable and available and how access is a barrier to more affordable medications. Dr. Burns notes that as many rural Oregonians live in areas that are pharmacy "deserts," others may have access to pharmacies close to their home, but the pharmacies do not speak their language or understand their cultural needs.

Alternate Members

Robert Judge is the Director of Pharmacy Services at Moda. In this role, Robert is responsible for managing Moda Health's pharmacy account services and data analytics teams for the company's fully insured, ASO and MCO clients. Robert also manages pharmacy programs, services and analytics for Moda Health's government clients and individuals enrolled in ArrayRx (formerly the Northwest Prescription Drug Consortium), a collaboration between the States of Oregon, Washington and Nevada to provide pharmacy solutions and affordable medications to residents in member states. He has expertise in payer pharmaceutical acquisition pricing, pharmacy benefit management services, pharmaceutical distribution, supply chain and public health service 340B program management.

Rebecca Spain MD, MSPH, is an Associate Professor in the Department of Neurology at OHSU, Associate Director of Clinical Care for the, Multiple Sclerosis (MS) VA Center of Excellence West, and MS Regional Director for the VA Portland Health Care System. As a neurologist specializing in MS, she sees first-hand the devastating effects of high cost prescription drugs on patients and their families. Noting these effects result in poorer health outcomes, economic devastation, and a loss of social cohesion, Dr. Spain hopes to contribute to the PDAB with her knowledge, experience, and advocacy.

John Murray, RPh, is a licensed pharmacist and co-owner of Murray's Drug with his wife Ann who is also a pharmacist. John also has 2 adult children who are pharmacist and involved in the business. Murray's Drug started in 1959 and operates three rural pharmacies, also known as critical access or frontier pharmacies in Heppner, Condon, and Boardman, Ore., serving more than 3,000 square miles as the only local pharmacy providers. John has been a board member of the Morrow County Health District (MCHD) for 19 years, serving as board chair the past eight years. Murray's Drug in Heppner has provided contracted pharmacy services to MCHD's Pioneer Memorial Hospital for the past 40 years and is the contracted pharmacy for the district's 340B program. John oversees the day to day pharmacy operations of filling 200-300 prescriptions per day and the delivery of clinical services, including vaccinations. He sees first-hand the impact of high cost, unaffordable medications and how it affects the patients that need them. John is committed to preserving the rural way of life for the next generation, including access to affordable, equitable, and quality health care.

Counsel

Joanna Tucker Davis
Senior Assistant Attorney General
Oregon Department of Justice

Pramela Reddi
Assistant Attorney General
Oregon Department of Justice

Board Staff

Ralph Magrish, Executive Director
ralph.m.magrish@dcbs.oregon.gov

Cortnee Whitlock, Board Policy Analyst
cortnee.whitlock@dcbs.oregon.gov

Stephen Kooyman, Project Manager
stephen.w.kooyman@dcbs.oregon.gov

Yasu Tanaka, Board Data Analyst
yasu.tanaka@dcbs.oregon.gov

Melissa Stiles, Board Administrative Specialist
melissa.g.stiles@dcbs.oregon.gov

Board Purpose

The Prescription Drug Affordability Board (PDAB) was established under Senate Bill 844 and supported by the Department of Consumer and Business Services (DCBS). The PDAB aims to protect residents of the State of Oregon, state and local governments, commercial health plans, health care providers, pharmacies licensed in the state, and other stakeholders within the health care system of Oregon from the high costs of prescription drugs.

PDAB is a board with five members and three alternate members with expertise in health care economics and clinical medicine. The Senate appointed the Board in June 2022. The Board will conduct affordability reviews to determine whether a drug presents affordability challenges to Oregon residents, health systems, and health inequities for communities of color in Oregon.

The members of the Board will elect one member to serve as the Chair and one member to serve as the 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 offers strategic planning to help the Board comply with its statutory duties and responsibilities. The Vice-Chair presides over a Board meeting in the absence of the Chair. The Chair works with Board staff to develop Board meeting agendas and ensures member compliance.

Member term durations will be determined based on the election of the Board chairperson and member interest in term durations. Pending member choice, terms to the first appointed Board will be determined as follows:

1. One member and one alternate shall serve for a term ending December 31, 2024.
2. Two members and one alternate shall serve for a term ending December 31, 2025.
3. Two members, including the chairperson and one alternate, shall serve for a term ending December 31, 2026.

Board members and alternate appointees are expected to make every effort to attend monthly Board meetings. Members may participate in a meeting in person, by telephone, or by any other means of electronic communication by which all persons participating in the meeting can hear each simultaneously. If a member is unable to attend a meeting, the member must notify the Chair and Executive Director prior to the meeting.

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 DCBS to the Board;
2. The prescription drugs reviewed for the affordability reviews; and
3. Any recommendations for legislative changes are 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 the program and Board administration costs.

PDAB Public Website

https://dfr.oregon.gov/pdab/Pages/index.aspx

Questions about PDAB: pdab@dcbs.oregon.gov

Telephone: 971-374-3724

Oregon Prescription Drug
Affordability Board

2023 Calendar

Prescription Drug Affordability Board

Meeting 1	Wednesday, January 18	9:30 – 11:30 a.m.
Meeting 2	Wednesday, February 15	9:30 – 11:30 a.m.
Meeting 3	Wednesday, March 15	9:30 – 11:30 a.m.
Meeting 4	Wednesday, April 19	9:30 – 11:30 a.m.
Meeting 5	Wednesday, May 17	9:30 – 11:30 a.m.
Meeting 6	Wednesday, June 21	9:30 – 11:30 a.m.
Meeting 7	Wednesday, July 19	9:30 – 11:30 a.m.
Meeting 8	Wednesday, August 23	9:30 – 11:30 a.m.
Meeting 9	Wednesday, September 20	9:30 – 11:30 a.m.
Meeting 10	Wednesday, October 18	9:30 – 11:30 a.m.
Meeting 11	Wednesday, November 15	9:30 – 11:30 a.m.
Meeting 12	Wednesday, December 13	9:30 – 11:30 a.m.

Maryland Prescription Drug Affordability Board Overview

October 19, 202

Andrew York, Executive Director

Maryland Prescription Drug Affordability Board

MARYLAND
Prescription Drug Affordability Board

Agenda

- History and Overview of the Maryland Prescription Drug Affordability Board
- Overview of Prescription Drug Affordability Board
- Overview of Prescription Drug Affordability Stakeholder Council
- Summary of Work

House Bill 768 / Senate Bill 759

- During the 2019 Session, the General Assembly introduced and enacted HB768/SB759, “Health - Prescription Drug Affordability Board”
- The Maryland Prescription Drug Affordability Board came into effect in July 2019 as an independent agency
- Its purpose is to “protect State residents, State and local governments, commercial health plans, health care providers, pharmacies licensed in the State, and other stakeholders within the health care system from the high costs of prescription drug products”

PDAB Overview

- Membership: Five members appointed by the Governor, Senate President, Speaker, and Attorney General, and three alternate members appointed by the Governor, Senate President, and the Speaker

- Term: Five years (Sitting & Alternate)

- Board members must possess expertise in health care economics and/or clinical medicine

PDAB Overview

Current Roster:

- **Van Mitchell**, Chair (Appointed by the Senate President and Speaker)
- **Joe Levy, PhD** (Appointed by the Governor)
- **VACANT** (Appointed by the Senate President)
- **Ebere Onukwugha, PhD** (Appointed by the Speaker of the House of Delegates)
- **Jerry Anderson, PhD** (Appointed by the Attorney General)

Board Authority and Required Reports

Under its enabling statute, the Board is authorized to:

- Assess an annual fee to fund the work of the Board;
- Conduct a one-time study and report on:
  - The entire pharmaceutical distribution and payment system in Maryland;
  - Policy options used in other states to lower Rx costs, including upper payment limits, reverse auction marketplace, and bulk purchasing; and
- Collect and review data on drug utilization and pricing data, from public sources or directly from stakeholders;

Board Authority and Required Reports (cont'd)

- Provide annual report to the General Assembly on price trends and legislation;
- Identify drug products that meet certain statutorily-defined pricing thresholds;
- Identify circumstances where a cost review of a prescription drug product is warranted; and
- Determine whether it is in the best interest of the State to establish a process for setting upper payment limits for drug products that create affordability challenges, and, if so, an action plan to implement it.

Many of these tasks are to be performed in consultation with the Stakeholder Council.

Pharmaceutical Distribution and Payment System Report

- In consultation with the Stakeholder Council:
  - Study the entire pharmaceutical distribution and payment system in the State; and
  - Identify policy options being used in other states and countries to lower the list price of pharmaceuticals, including:
    - Setting upper payment limits;
    - Using a reverse auction marketplace; and
    - Implementing a bulk purchasing process; and
- Report findings and recommendations to Senate Finance and House Health & Government Operations Committees.

Upper Payment Limits

- If the Board determines that its in the best interest of the State to establish upper payment limits (UPL), then in conjunction with the Stakeholder Council, it shall draft an action plan to implement UPLs

- On or before December 1, 2023, the Board, in consultation with the Stakeholder Council, shall report to SFC and HGO the legality, obstacles, and benefits of UPLs on all purchases and reimbursements of prescription drug products in MD, and any recommendations on additional legislation.

Stakeholder Council Overview

- Membership: Twenty-six members appointed by the Governor, Senate President, and Speaker of the House
- Term: Three years (Staggered for initial terms)
- Meetings: Bi-monthly
- Leadership: The Chair will select two members of the Stakeholder Council to serve as co-Chairs
- Board staff works with the PDAB Chair and Stakeholder Council co-Chairs to create agendas, administer meetings, coordinate with presenters, etc.

Council Current Membership (1/3)

Name	Representation
Mandi Poplawski, Pharm.D.	Nonprofit Insurance Carriers
Glenn Schneider, MPH	Statewide Health Care Advocacy Coalition
Allison Ciborowski	Statewide Advocacy Organization for Seniors
Jacqueline Allsup	Statewide Organization for Diverse Communities
Shaun O'Brien	Labor Union
Sean Tunis, MD, MSc	Health Services Researcher Specializing in Prescription Drugs
Shawn Brown	Generic Drug Corporations
Thea Williams	Public Member

Council Current Membership (2/3)

Name	Representation
Deron Johnson	Brand Name Drug Corporations
Stephen Rockower, MD	Physicians
Lorraine Diana	Nurses
Nicole Stallings	Hospitals
Eric Morse, DDS	Dentists
Hayley Park, Pharm. D.	Managed Care Organizations
Marc Nicole	Department of Budget and Management
Sherita Hill Golden, MD, MHS	Clinical Researchers
James Gutman	Public Member

Council Current Membership (3/3)

Name	Representation
Beth Rada	Brand Name Drug Corporations
John Elliott	Generic Drug Corporations
Martin Rosendale	Biotechnology Companies
Joseph Winn	For-Profit Health Insurance Carriers
Greta E. Kessler	Employers
Kimberly Robinson	Pharmacy Benefit Managers
Babette Edgar, Pharm.D.	Pharmacies
Joey Mattingly, Pharm. D., MBA, PhD	Pharmacologists
Barry N. Lipsy	Public Member

Council Purpose

- Provide input that will assist the Board in making decisions to protect the State, its residents, and other stakeholders in the Maryland health care system

- Serves in an advisory role including
  - Consults with Board as the Board prepares certain studies and reports, adopts certain regulations, recommends certain statutory changes, and, possibly, identifies drug products that may create affordability challenges
  - The Board may request that the Stakeholder Council to review and discuss certain issues or policies on an ad hoc basis

Ongoing Work

- Published Generics Report on June 1, 2022
- Publishing Pharmaceutical Distribution and Payment System Report and Implementing Recommendations
- Cost Review Process
- Upper Payment Limit Action Plan

2022 Recommendations from Pharmaceutical Distribution and Payment System Report

- Develop and Submit Upper Payment Limit Action Plan
- Transparency Program
- Insulin Affordability Program

Colorado's Prescription Drug Affordability Board

Lila Cummings, Prescription Drug Affordability Director

COLORADO
Prescription Drug Affordability Board
Division of Insurance

PDAB Overview – Board Members

The Governor appointed the following PDAB Members on Sept. 27,2021:

Gail Mizner, MD, FAACP, AAHIVS from Snowmass Village – Board Chair

Sami Diab, MD from Greenwood Village

Amarylis “Amy” Gutierrez, PharmD from Aurora

Catherine Harshbarger from Holyoke

James Justin VandenBerg, PharmD, BCPS from Denver

COLORADO
Prescription Drug Affordability Board
Division of Insurance

PDAB Overview - Responsibilities

Collect and evaluate data on the cost of prescription drugs for Colorado consumers

Perform affordability reviews when a drug meets certain triggers outlined in statute

May set upper payment limit (UPL) on drugs the Board has deemed unaffordable

**Maximum of 12/year for the first 3 years*

Make policy recommendations to the General Assembly

Beginning July 2023, report annually to the Governor and General Assembly about drug prices, Board activity, and impacts on providers and pharmacies

COLORADO
Prescription Drug Affordability Board
Division of Insurance

PDAAC Overview – Advisory Council Members

The Prescription Drug Affordability Advisory Council consists of 15 members:

Kim Bimestefer HCPF Executive Director	**Maria Fenwick** Labor Union	**Brett McQueen** Research Organization
Sabrina Walker Healthcare Consumers	**Nathan Wilkes** Employers	**Katelin Lucariello** Brand-Name Manufacturer
Gail deVore Healthcare Consumers	**Chad Friday** Carriers	**Neal Miller** Generic Manufacturer
Edward Dauer Consumer Advocacy Organization	**Marc Reece** Pharmacy Benefit Managers	**Andrew Gonzales** Pharmacist
Kimberley Jackson Consumers with Chronic Diseases	**Thomas Tobin** Prescribers	**Jason Atlas** Wholesalers

PDAAC Overview - Duties

The Advisory Council provides strategic recommendations, information, materials, and/or analysis necessary for the Board to have sufficient information to make more informed decisions.

Two main Advisory Council roles are outlined in statute, which are to provide:

- Stakeholder input to the Board regarding the affordability of prescription drugs (10-16-1409(1)(a) C.R.S.); and
- Input regarding specific prescription drugs when the Board is selecting drugs for affordability reviews (10-16-1406(2)(c) C.R.S).

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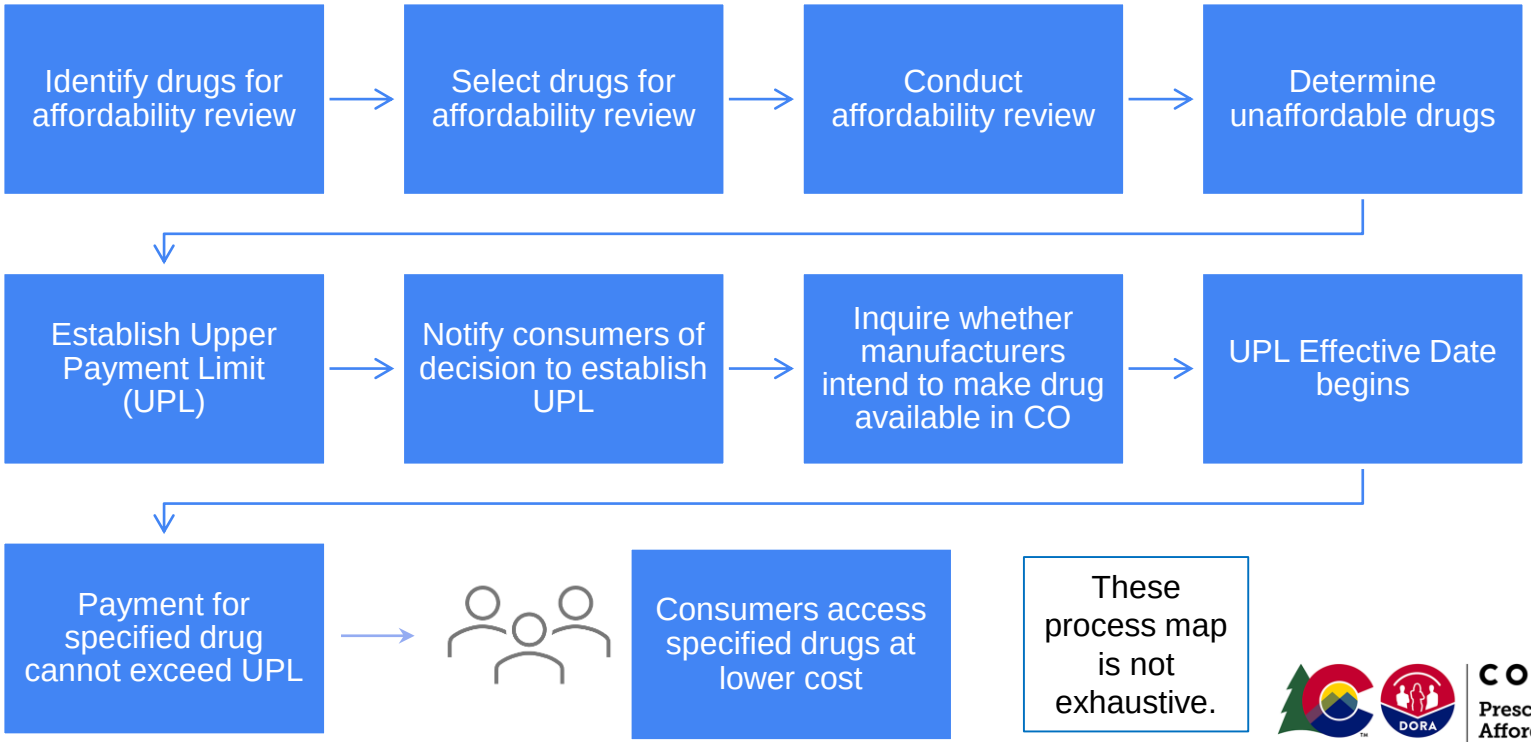
PDAB Overview – Process



These process map is not exhaustive.

COLORADO
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Division of Insurance

PDAB Overview - Process

Board Duties - Procedural

- Promulgate rules to establish methodologies and processes
- Establish Board policies and norms
- Establish engagement style and scope with Advisory Council, stakeholders

Board Duties - Substantive

- Conduct prescription drug affordability review program work:
  - Collect and evaluate data
  - Conduct affordability review work
  - Conduct upper payment limit work
  - Make policy recommendations (including reports)
- Engage with Advisory Council and stakeholders
- Monitor and revise work, rules as needed

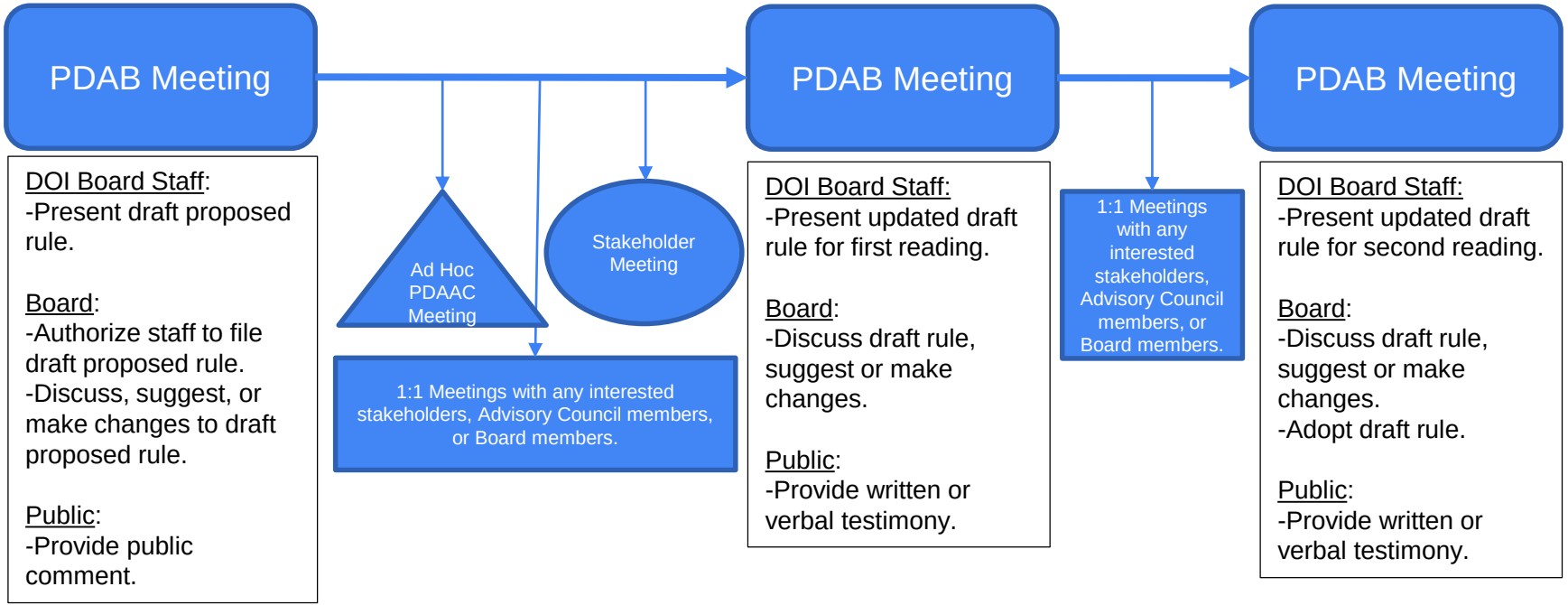
PDAB Overview - Rulemaking

The Board's rules are contained within 3 C.C.R. 702-9:

3 C.C.R. 702-9	
Part 1	General Provisions
Part 2	Appeals
Part 3	Affordability Review
Part 4	Upper Payment Limit Methodology
Part 5	Reporting Requirements for Use of Savings

PDAB Overview - Rulemaking

Generally each rule is presented at three PDAB meetings:



PDAB Overview - Rulemaking

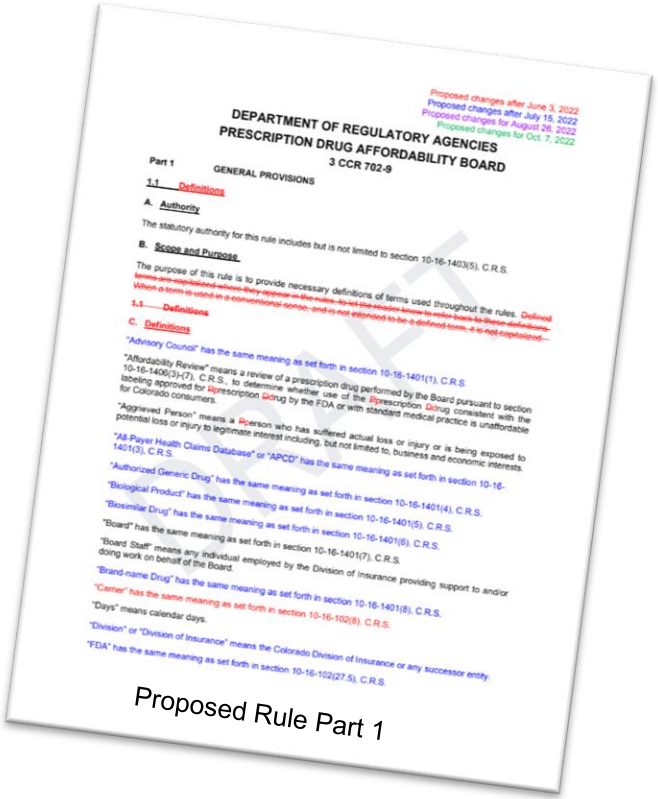
PDAB Meeting
Stakeholder Meeting
Ad Hoc PDAAC Meeting

	June 3 PDAB Meeting	June 22 Stake-holder Meeting	July 15 PDAB Meeting	July 28 PDAAC Ad Hoc	Aug. 10 Stake-holder Meeting	Aug. 18 PDAAC Meeting	Aug 26 PDAB Meeting	Sept 15 PDAAC Ad Hoc	Sept 21 Stake-holder Meeting	Oct. 7 PDAB Meeting	Nov. 18 PDAB Meeting
Part 1 - General Provisions	Draft Presented		1st Reading				2nd Reading			Anticipated Additional Reading	Anticipated Final Reading
Part 5 - Use of Savings	Draft Presented	Stakeholder Meeting	1st Reading				2nd Reading				
Part 3 - Affordability Review			Draft Presented	Ad Hoc PDAAC Meeting	Stakeholder Meeting		1st Reading			2nd Reading	Staff Recommended 3rd Reading
Part 4 - Upper Payment Limit							Draft Presented	Ad Hoc PDAAC Meeting	Stakeholder Meeting	1st Reading	2nd Reading

Proposed Rule Part 1 – General Provisions

Proposed Rule Part 1 – General Provisions includes:

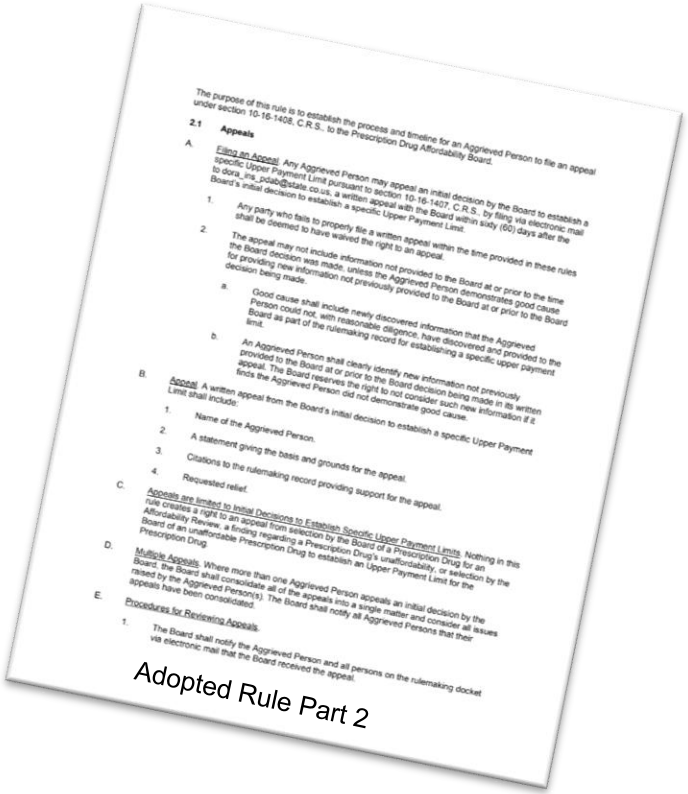
- 1.1 – Definitions
- 1.2 – Severability
- 1.3 – Declaratory Orders



Adopted Rule Part 2 – Appeals

Adopted Rule Part 2 – Prescription Drug Affordability Board Appeals includes:

- 2.1.A – Filing an Appeal
- 2.1.B – Appeal
- 2.1.C – Appeals are limited to Initial Decisions to Establish Specific UPLs
- 2.1.D – Multiple Appeals
- 2.1.E – Procedures for Reviewing Appeals
- 2.1.F – Final Decision by the Board
- 2.1.G – Judicial Review



Proposed Rule Part 3 – Affordability Reviews

Proposed Rule Part 3 – Affordability Review includes:

- 3.1.A – Authority
- 3.1.B – Scope and Purpose
- 3.1.C – Identifying Prescription Drugs for Affordability Reviews
- 3.1.D – Selecting Prescription Drugs for Affordability Reviews
- 3.1.E – Conducting Affordability Reviews

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Proposed Rule Part 3 – Affordability Reviews

The Board will annually adopt the list of prescription drugs eligible for review prior to selecting a drug for review. Per 10-16-1406(1) C.R.S the Board will identify:

Brand Name Drug or Biological Product

- Initial WAC ≥$30K for a 12-month supply or course of treatment
- Increase in WAC ≥10% in the preceding 12 months or course of treatment

Biosimilar Product

- Initial WAC not at least 15% lower than its corresponding biological product

Generic Drug

- Increase in WAC ≥200% during the preceding 12 months & WAC ≥$100 for:
  - 30-day supply
  - Supply that lasts less than 30 days
  - One dose of the generic drug if the FDA does not recommend a finite dose

Proposed Rule Part 3 – Affordability Reviews

For prescription drugs identified as eligible for affordability review, per 10-16-1406(2) C.R.S., the Board will consider:

Evaluating the class of the drug and whether there are therapeutically equivalent drugs for sale in the state.	Evaluating aggregated data.	Seeking and considering input from the PDAAC about the prescription drug.	Considering the average patient's out of pocket cost for the drug.
Determine if there are therapeutic equivalents for the drug Cost & availability of therapeutic equivalent	Historical & current pricing Expenditure and utilization of the drug Health inequity impact	Board will consider input from PDAAC before selecting drugs for affordability review	May include copayment, cost sharing, and other relevant information

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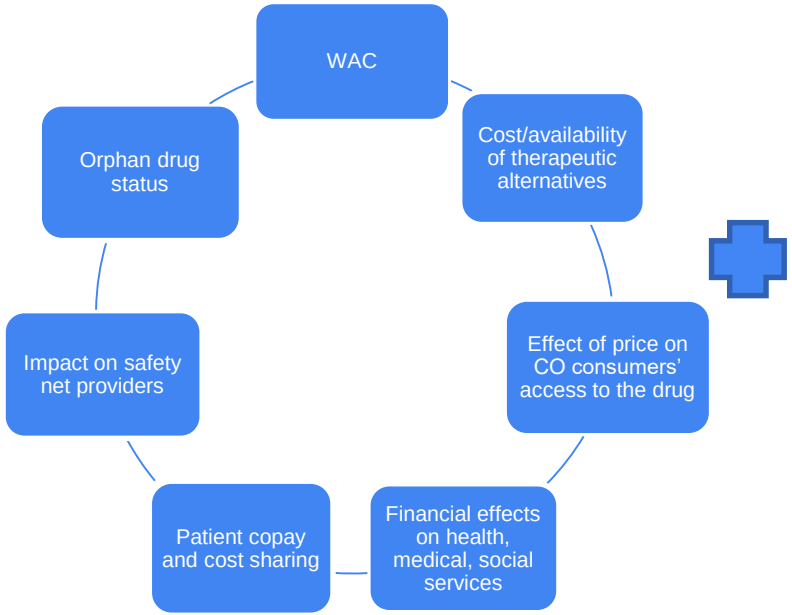
Division of Insurance

Proposed Rule Part 3 – Affordability Reviews

Per 10-16-1406(3)-(7) C.R.S., in performing an affordability review, to the extent practicable, the Board shall consider the following to determine if a drug is unaffordable:



Input from:
- Patients and caregivers
- Individuals with relevant scientific or medical training

Any other information a manufacturer, carrier, PBM, or other entity chooses to provide.

Any other factors as determined by the Board in rule.

Rebates, Discounts, and Price Concessions

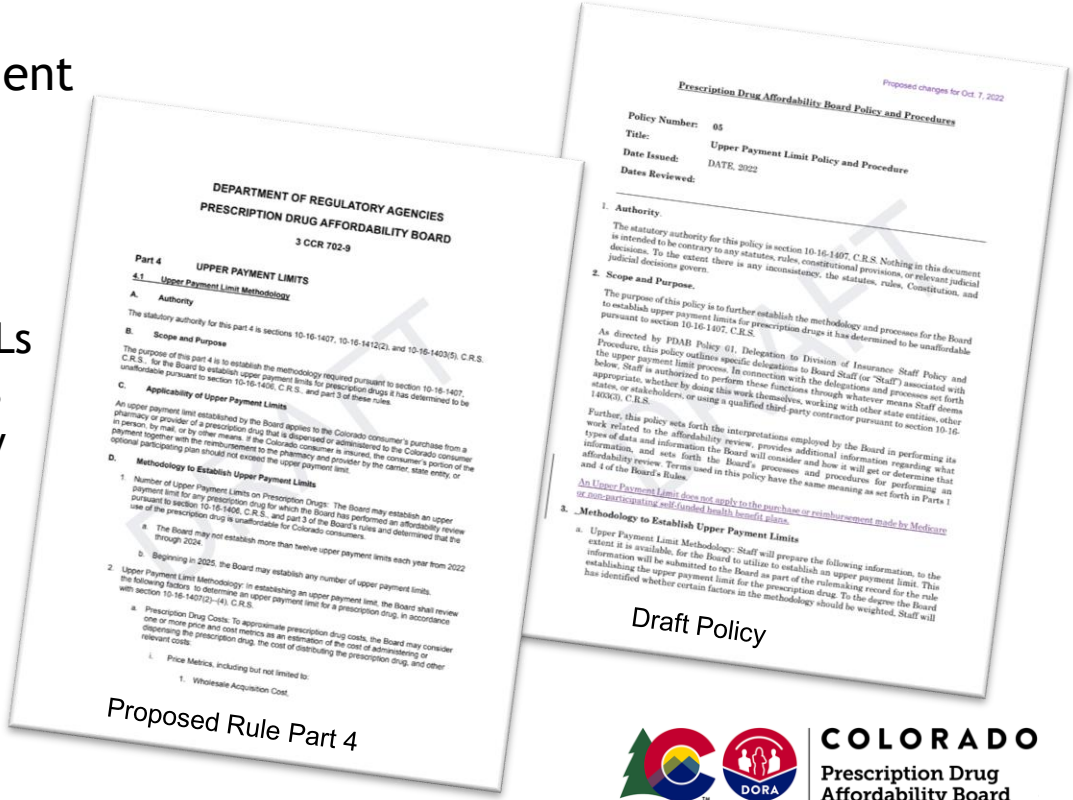
Health Inequity Impacts

Information from HCPF

Proposed Rule Part 4 - Upper Payment Limits (UPLs)

Proposed Rule Part 4 – Upper Payment Limit Methodology includes:

- 4.1.A – Authority
- 4.1.B – Scope and Purpose
- 4.1.C – Applicability of UPLs
- 4.1.D – Methodology to Establish UPLs
- 4.1.E – Process for Establishing UPLs
- 4.1.F – Prescription Drug Availability Inquiries and Reporting
- 4.1.G - Confidentiality



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Proposed Rule Part 4 - UPLs

The Board must promulgate by rule the methodology for establishing a UPL to protect consumers from the excessive cost of prescription drugs and ensure they can access necessary prescription drugs. The proposed methodology considers:

- Prescription Drug Costs
- Drug Shortage List
- Impact to Older Adults and Persons with Disabilities
- Reasonable Pharmacy Fees
- Research and Methods that Employ a Dollars-per-Quality Adjusted Life Year (QALY)
- Stakeholder Input

Proposed Rule Part 4 - UPLs

Prescription Drug Costs

- Wholesale Acquisition Cost (WAC)
- Average Sales Price (ASP)
- National Average Drug Acquisition Cost (NADAC)
- Out-of-pocket spending
- Carrier paid amounts
- Public program fee schedules
- Net-cost estimates
- Medicare's Maximum Fair Price
- Cost information voluntarily provided by wholesalers, pharmacists, and providers

Drug Shortage List

- Whether the drug is listed on the Drug Shortage List or subject to a resolved or discontinued shortage
- Availability and estimated shortage duration
- Shortage reason
- Therapeutic classification
- Other related information

Reasonable Pharmacy Fees

- UPLs established by the Board do not preclude a pharmacy licensed by the State Board of Pharmacy to charge reasonable fees, to be paid by the providing health benefit plan of the consumer, for dispensing or delivering a prescription drug for which the Board has established a UPL.

Proposed Rule Part 4 - UPLs

Impact to Older Adults

- Utilization of the Rx drug,
- Cost of the Rx drug,
- Insurance coverage type for individuals utilizing the Rx drug, and
- Qualitative or quantitative analyses and information submitted by stakeholders with lived experience or expertise of the prescription drug's impact to older adults.

Impact to Persons with Disabilities

- Therapeutic classification of the Rx drug, including the drug's therapeutic purpose and any conditions/diseases the drug may treat,
- To the extent it is known that any conditions or diseases the prescription drug may treat are considered disabilities, the Board may consider: Utilization, Cost, and Insurance coverage type for individuals utilizing the drug.
- Qualitative or quantitative analyses and information submitted by stakeholders with lived experience or expertise of the prescription drug's impact to persons with disabilities.

Proposed Rule Part 4 - UPLs

Research Methods

- The Board shall **not** consider any research or methods that employ a dollars-per-QALY or similar measure in estimating impact to older adults and persons with disabilities, or in any other upper payment limit methodology considerations.

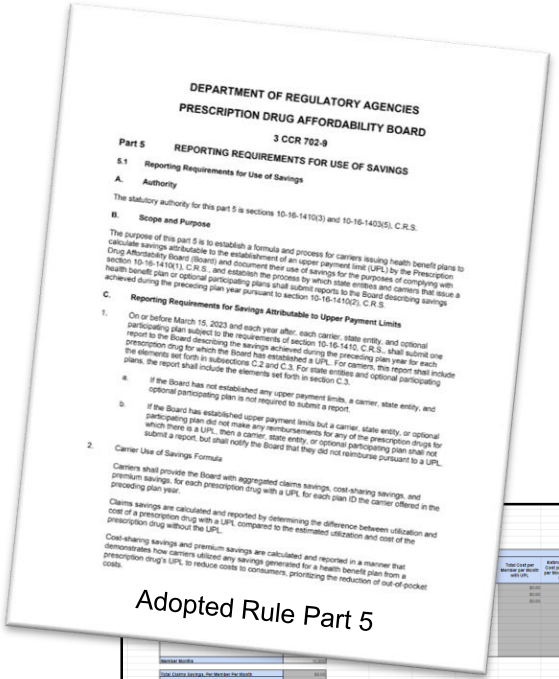
Stakeholder Input

- The Board shall receive stakeholder information submitted through a UPL rulemaking.

Adopted Rule Part 5 – Reporting Requirements for Use of Savings

Adopted Rule Part 5 –Reporting Requirements for Use of Savings includes:

- 5.1.A – Authority
- 5.1.B – Scope and Purpose
- 5.1.C – Reporting Requirements for Savings Attributable to UPL
- 5.1.D - Confidentiality



DEPARTMENT OF REGULATORY AGENCIES

PRESCRIPTION DRUG AFFORDABILITY BOARD

3 CCR 702-9

Part 5 REPORTING REQUIREMENTS FOR USE OF SAVINGS

5.1 Reporting Requirements for Use of Savings

A. Authority

The statutory authority for this part 5 is sections 10-16-1410(3) and 10-16-1403(5), C.R.S.

B. Scope and Purpose

The purpose of this part 5 is to establish a formula and process for carriers issuing health benefit plans to calculate savings attributable to the establishment of an upper payment limit (UPL) by the Prescription Drug Affordability Board (Board) and document their use of savings for the purposes of complying with section 10-16-1410(1), C.R.S., and establish the process by which state entities and carriers that issue a health benefit plan or optional participating plans shall submit reports to the Board describing savings achieved during the preceding plan year pursuant to section 10-16-1410(2), C.R.S.

C. Reporting Requirements for Savings Attributable to Upper Payment Limits

1. On or before March 15, 2023 and each year after, each carrier, state entity, and optional participating plan subject to the requirements of section 10-16-1410, C.R.S., shall submit one report to the Board describing the savings achieved during the preceding plan year for each prescription drug for which the Board has established a UPL. For carriers, this report shall include the elements set forth in subsections C.2 and C.3. For state entities and optional participating plans, the report shall include the elements set forth in section C.3.

a. If the Board has not established any upper payment limits, a carrier, state entity, and optional participating plan is not required to submit a report.

b. If the Board has established upper payment limits but a carrier, state entity, or optional participating plan did not make any reimbursements for any of the prescription drugs for which there is a UPL, then a carrier, state entity, or optional participating plan shall not submit a report, but shall notify the Board that they did not reimburse pursuant to a UPL.

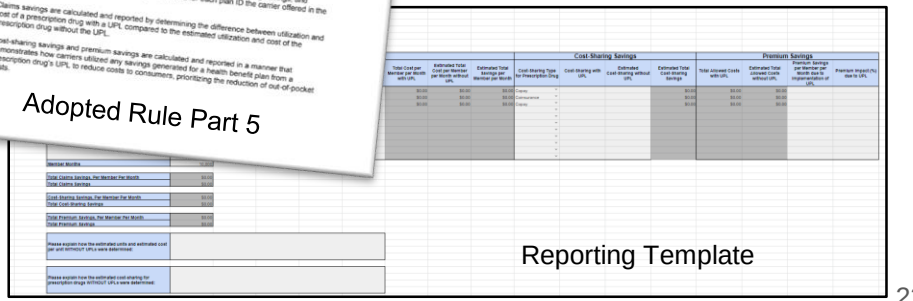
2. Carrier Use of Savings Formula

Carriers shall provide the Board with aggregated claims savings, cost-sharing savings, and premium savings, for each prescription drug with a UPL for each plan ID the carrier offered in the preceding plan year.

Claims savings are calculated and reported by determining the difference between utilization and cost of a prescription drug with a UPL compared to the estimated utilization and cost of the prescription drug without the UPL.

Cost-sharing savings and premium savings are calculated and reported in a manner that demonstrates how carriers utilized any savings generated for a health benefit plan from a prescription drug's UPL to reduce costs to consumers, prioritizing the reduction of out-of-pocket costs.

Adopted Rule Part 5



Reporting Template

Adopted Rule Part 5 – Reporting Requirements for Use of Savings

5.1.C – Reporting Requirements for Savings Attributable to Upper Payment Limits (UPL)

1. High-level reporting requirements and timing
2. Carrier Use of Savings Formula
3. Savings Description report

5.1.C.2 - Carrier Use of Savings Formula

Looking Ahead: 2023 PDAB Meeting Schedule & Timeline

The tentative, high-level 2023 Board meeting schedule is:

January	February	March	April	May	June
Jan. 13, 2023 • Draft identified list	**Feb. 17, 2023** • Final identified list.	**March 31, 2023** • Selection of Rx drugs.	No meeting.	**May 12, 2023** • Prelim AR results.	**June 23, 2023** • Final AR results.

July	August	September	October	November	December
No meeting.	**Aug. 4, 2023** • Selection of Rx drugs for UPL.	**Sep. 15, 2023** • UPL established via rule.	**Oct. 27, 2023**	No meeting.	**Dec. 8, 2023**

Q&A

For meeting minutes, agendas, and general information about PDAB, visit

https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board

Questions about the Prescription Drug Affordability Board and Advisory Council can be sent to dora_ins_pdab@state.co.us.

COLORADO
Prescription Drug Affordability Board
Division of Insurance

MARYLAND
Prescription Drug Affordability Board

support.pdab@maryland.gov
pdab.maryland.gov

Pharmacy Benefit Manager Overview

Numi Rehfield-Griffith, Senior Policy Advisor
Cassie Soucy, Senior Policy Advisor
Division of Financial Regulation

DFR | Division of Financial Regulation
Department of Consumer and Business Services

Pharmaceutical Supply Chain

- Primary stakeholders within the pharmaceutical supply chain:
  - Manufacturers – brand, generic, biopharmaceutical
  - Wholesale distributors
  - Pharmacies – retail, independent, mail-order, specialty
  - Pharmacy benefit managers
  - Insurance companies
  - Medical providers
  - Consumers
  - Other entities – government agencies, group purchasing organization, and pharmacy services administration organization

Pharmaceutical Supply Chain

All direct transactions between different entities in the pharmaceutical supply chain.

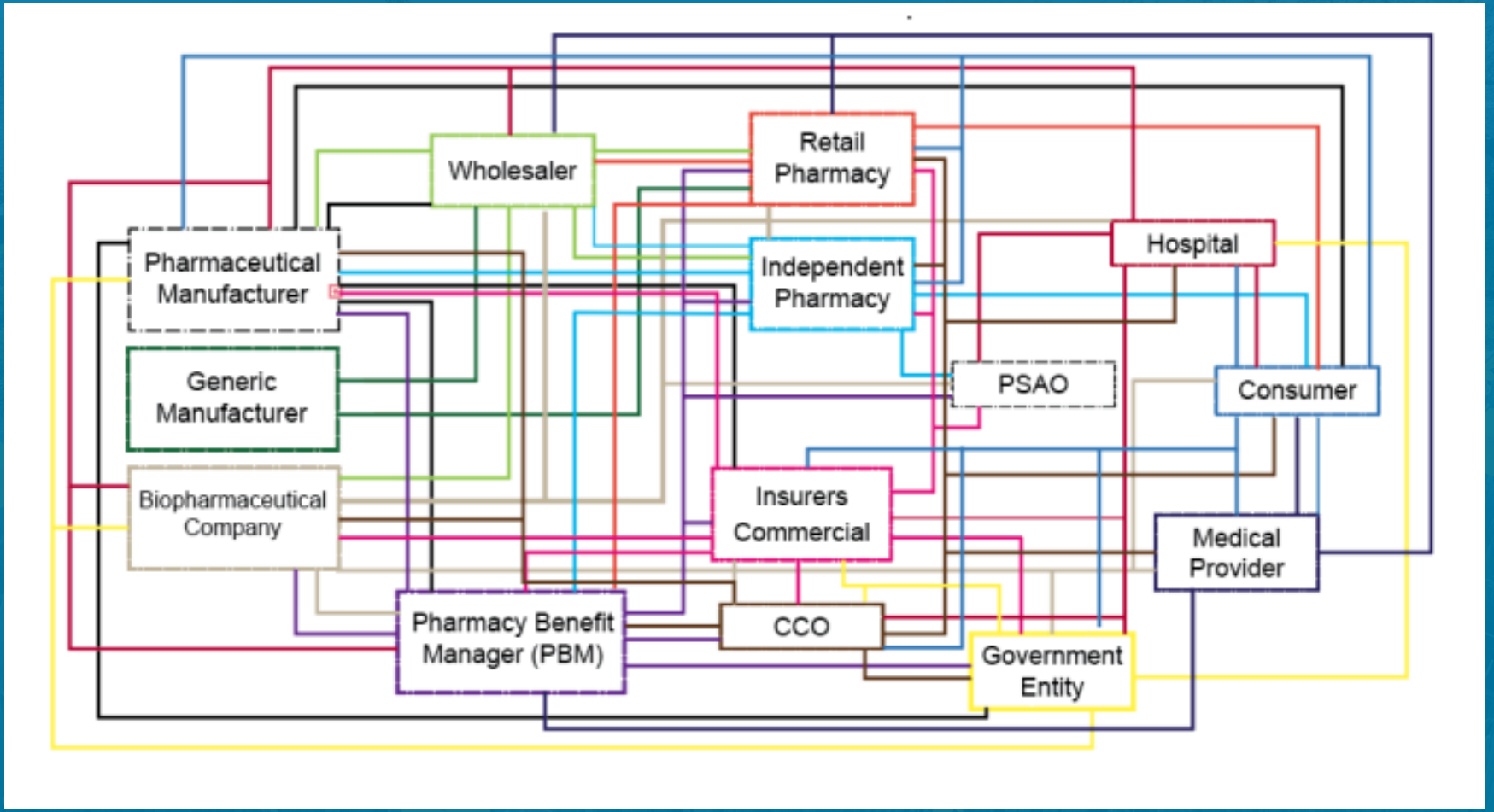
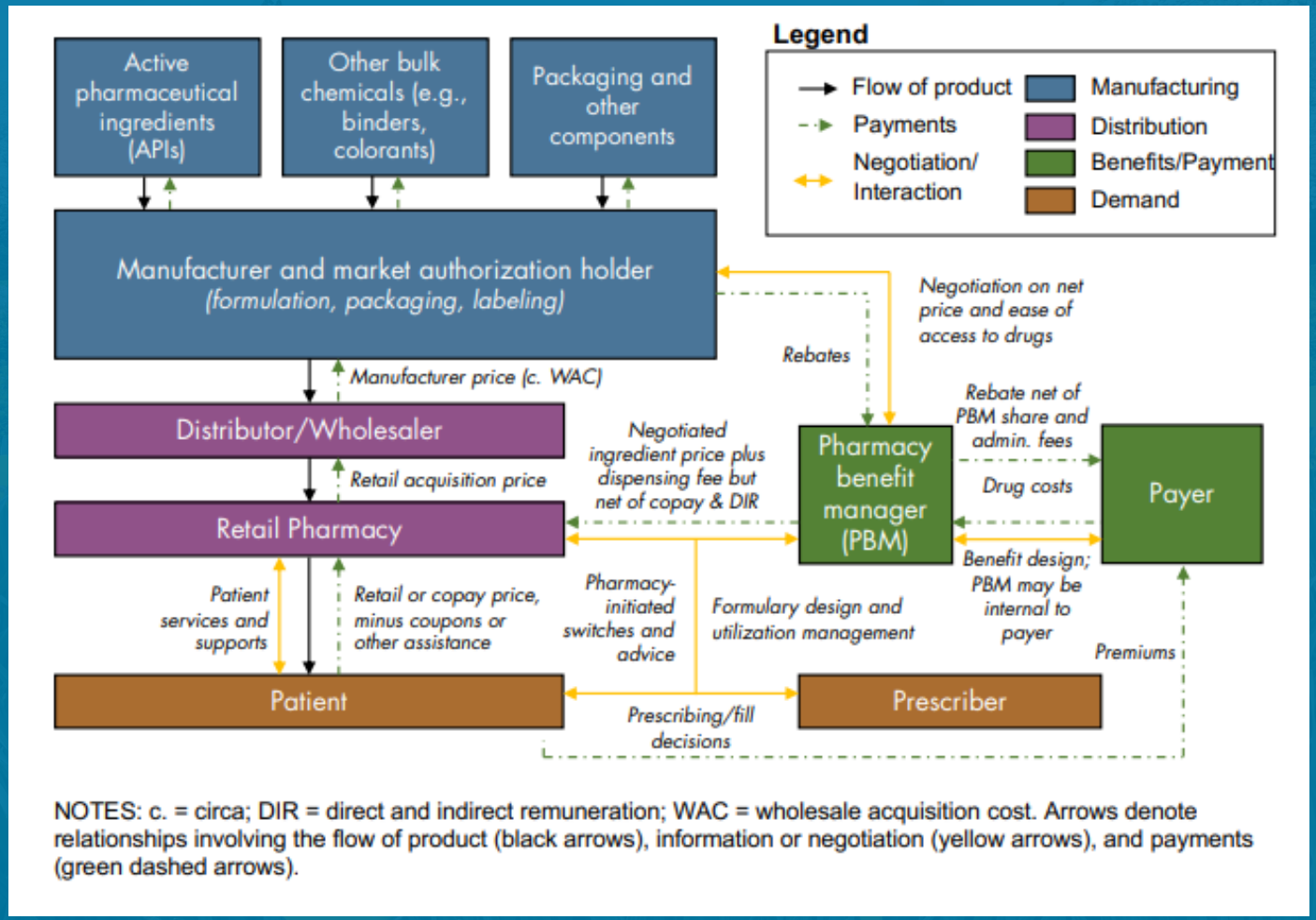


Figure from Oregon Legislative Policy and Research Office, 2018.

Pharmaceutical Supply Chain

Typical supply for brand-name drugs dispensed through retail pharmacies.



NOTES: c. = circa; DIR = direct and indirect remuneration; WAC = wholesale acquisition cost. Arrows denote relationships involving the flow of product (black arrows), information or negotiation (yellow arrows), and payments (green dashed arrows).

Figure from RAND Corporation funded by U.S. Department of Health and Human Services, 2021.

Pharmacy Benefit Managers (PBMs)

Pharmacy benefit managers (PBMs) are intermediaries between health insurers, pharmacies, wholesalers, and manufacturers.

- Services can include claims processing, formulary and benefit design (tiers, utilization management, cost-sharing), pharmacy network contracting, and rebate negotiation with manufacturers.
- Three companies make up approximately 80% of the market.
- 55 companies are registered in Oregon.

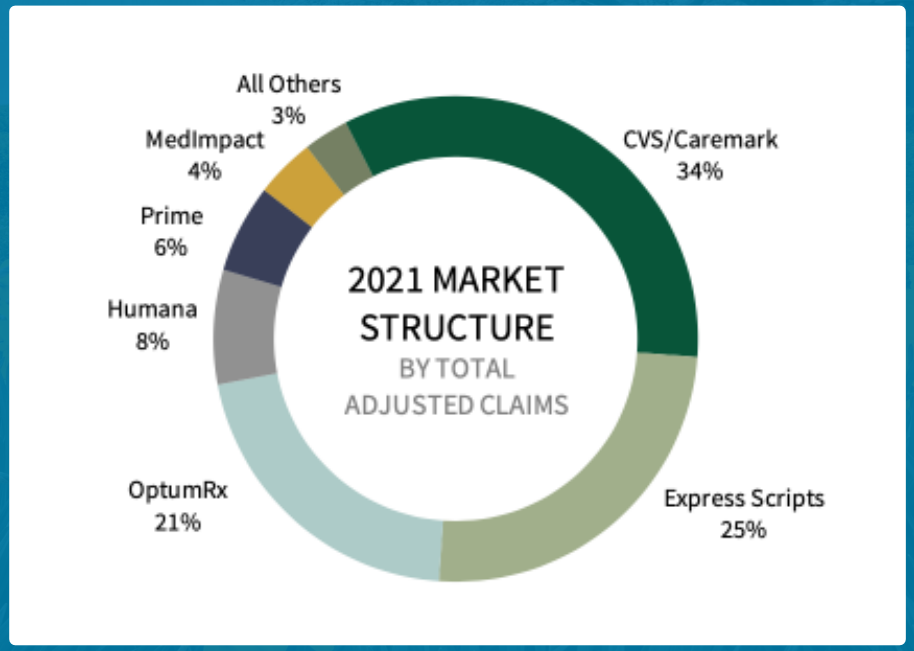


Figure from Health Industries Research Company, 2022.

Rebates

Typically based on the ability of a purchaser to move market share for the manufacturer's product.

Rebates are confidential and are based on the volume of dispensed drug as well as other factors and are paid by a manufacturer after a drug has been dispensed.

Strategies used to shift volume include tiered formularies, requirements to use mail-order pharmacy, and other utilization management techniques such as prior authorization.

Oregon's PBM Laws and Regulations

Oregon Laws

- 2013 Oregon Laws Chapter 570 (HB 2123)
- 2017 Oregon Laws Chapter 73 (HB 2388)
- 2019 Oregon Laws Chapter 526 (HB 2185)

Code Sections

- ORS 735.530 – ORS 735.552

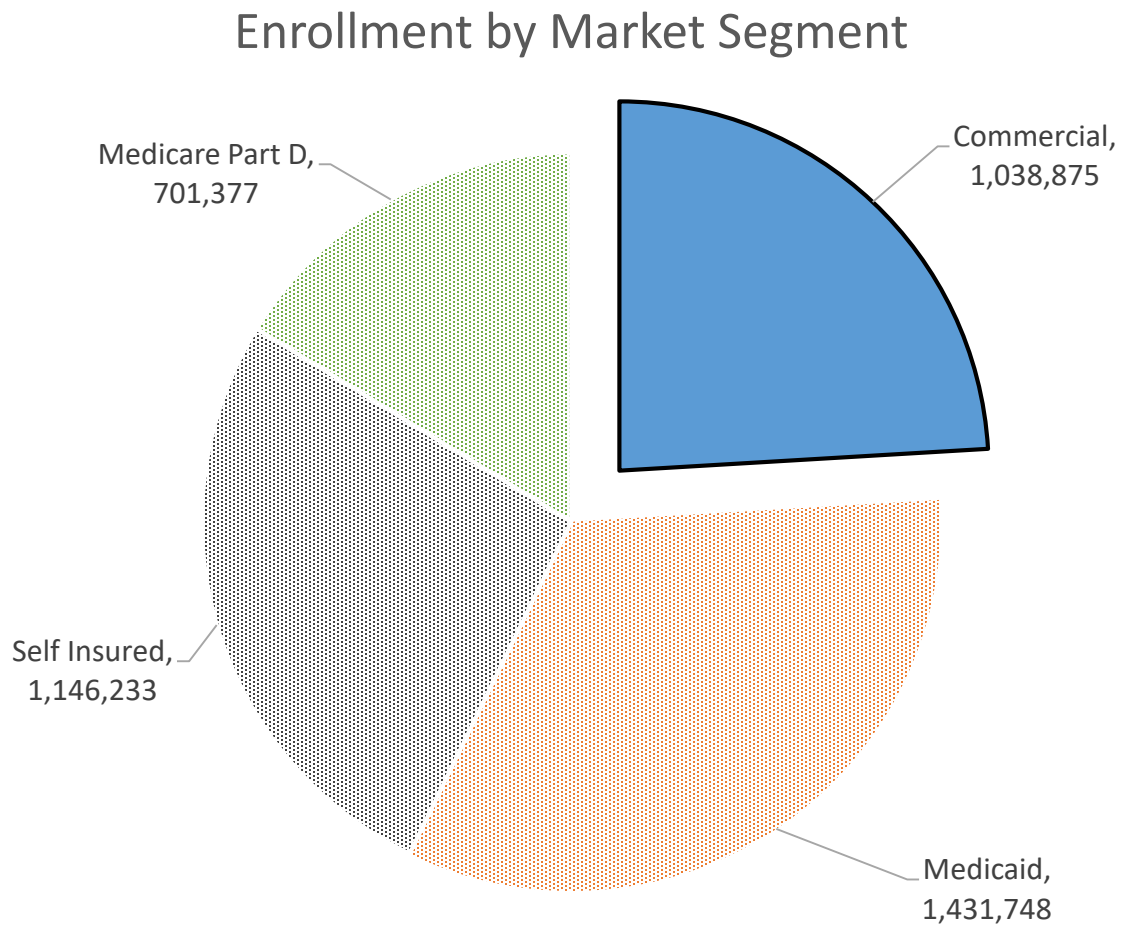
Regulations

- OAR 836-200-0401 – OAR 836-200-0440

Scope of Oregon's PBM Law

ORS 735.530(11): "a person that contracts with pharmacies on behalf of an insurer offering a health benefit plan, a third party administrator, or the Oregon Prescription Drug Program."

Includes: Commercial, OPDP
Excludes: Self-insured, Medicare Part D, some Medicaid



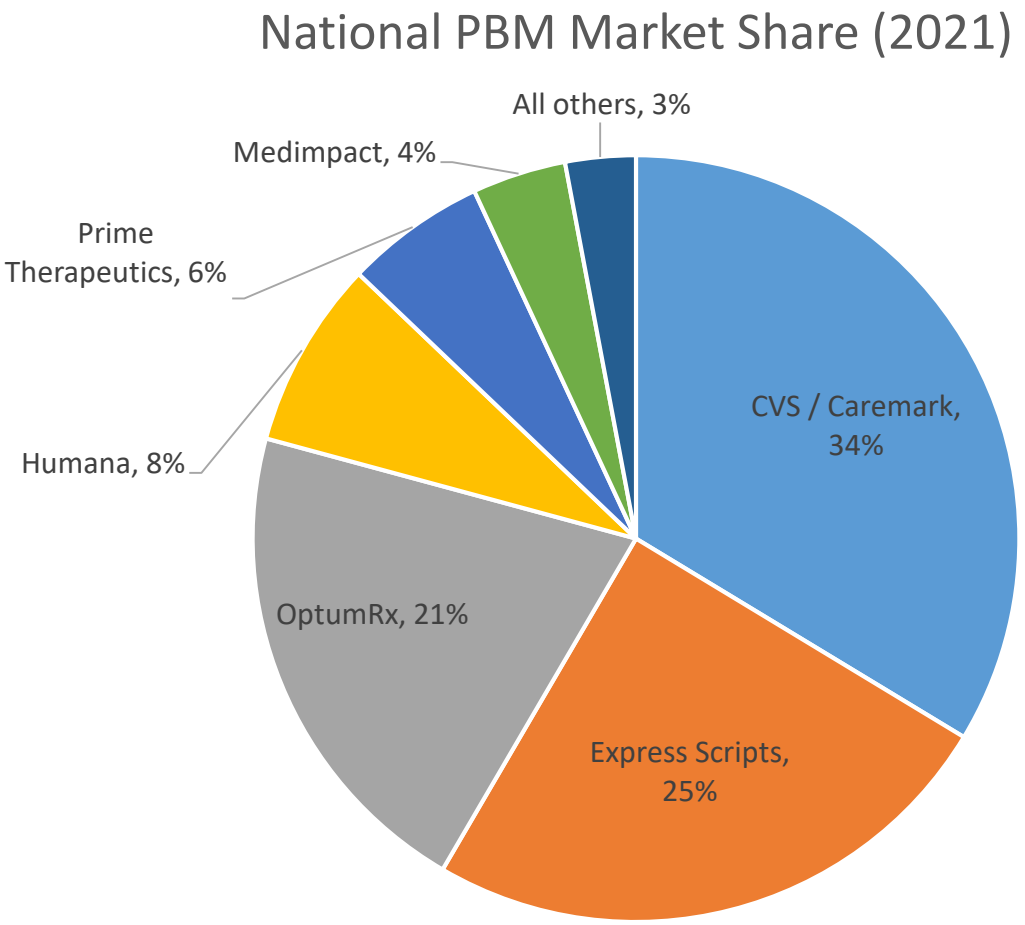
Commercial and Self insured enrollment figures from DFR quarterly insurance enrollment report for Q2 2022. Medicaid enrollment from OHA. Medicare Part D enrollment from Kaiser Family Foundation.

Scope of Oregon's PBM Law

PBM Market Landscape

The PBM Market is highly consolidated, with 80% of the market controlled by three companies: CVS/Caremark, Express Scripts, and OptumRx. The five largest PBMs, covering 97% of market share, are all registered with DCBS. This suggests that despite the limitations on what market segments we can regulate, PBMs that serve the vast majority of covered lives in the state are registered.

However, our ability to regulate registered PBM conduct with respect to Medicare, Medicaid, and self-insured plans remains untested.



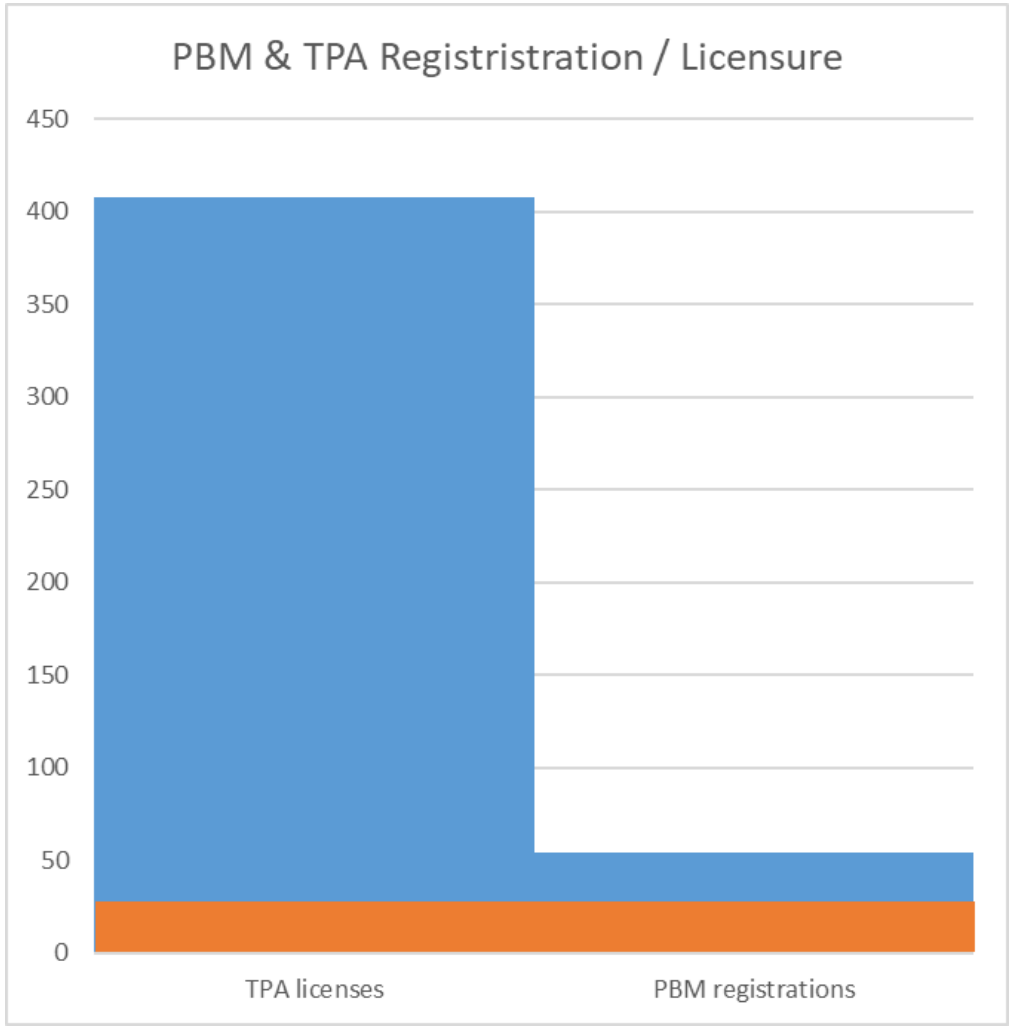
Data Source: Pharmacy Benefit Managers: market Landscape and Strategic Imperatives, HIRC (2021)

Scope of Oregon's PBM Law

Overlap with TPA Licensure

PBMs, by their very nature, also qualify as Third-Party Administrators (TPAs) under ORS 744.702. However, of the 54 PBMs currently registered with Oregon, only 25 also hold a TPA license, likely in violation of Oregon law (note that TPAs that only serve self-funded plans are exempt from the licensure requirement).

The Orange area represents registered PBMs who also hold a TPA license.



Data Source: DCBS

PBM Market Conduct Requirements: MAC

Maximum Allowable Cost (MAC) Requirements: a PBM may not reimburse a pharmacy for less than the pharmacy's acquisition cost.

- A PBM must update its MAC lists to account for manufacturer price changes at least once every seven days, provide its lists to a network pharmacy upon request, and provide the sources used to determine MAC.
- A PBM may not set MAC for a drug unless it has multiple sources or a generic equivalent generally available.
- A PBM must have an appeals process for pharmacies to contest below-cost reimbursement under MAC. If an appeal is denied, the PBM must provide the pharmacy with a source for the drug at a cost at or below the MAC price.
- A PBM may not include pharmacy dispensing fees in MAC.

Other PBM Market Conduct Requirements

Clawback: a PBM may not retroactively deny or reduce reimbursement for a claim for the cost of services after the claim has been adjudicated (except in cases of fraud or error).

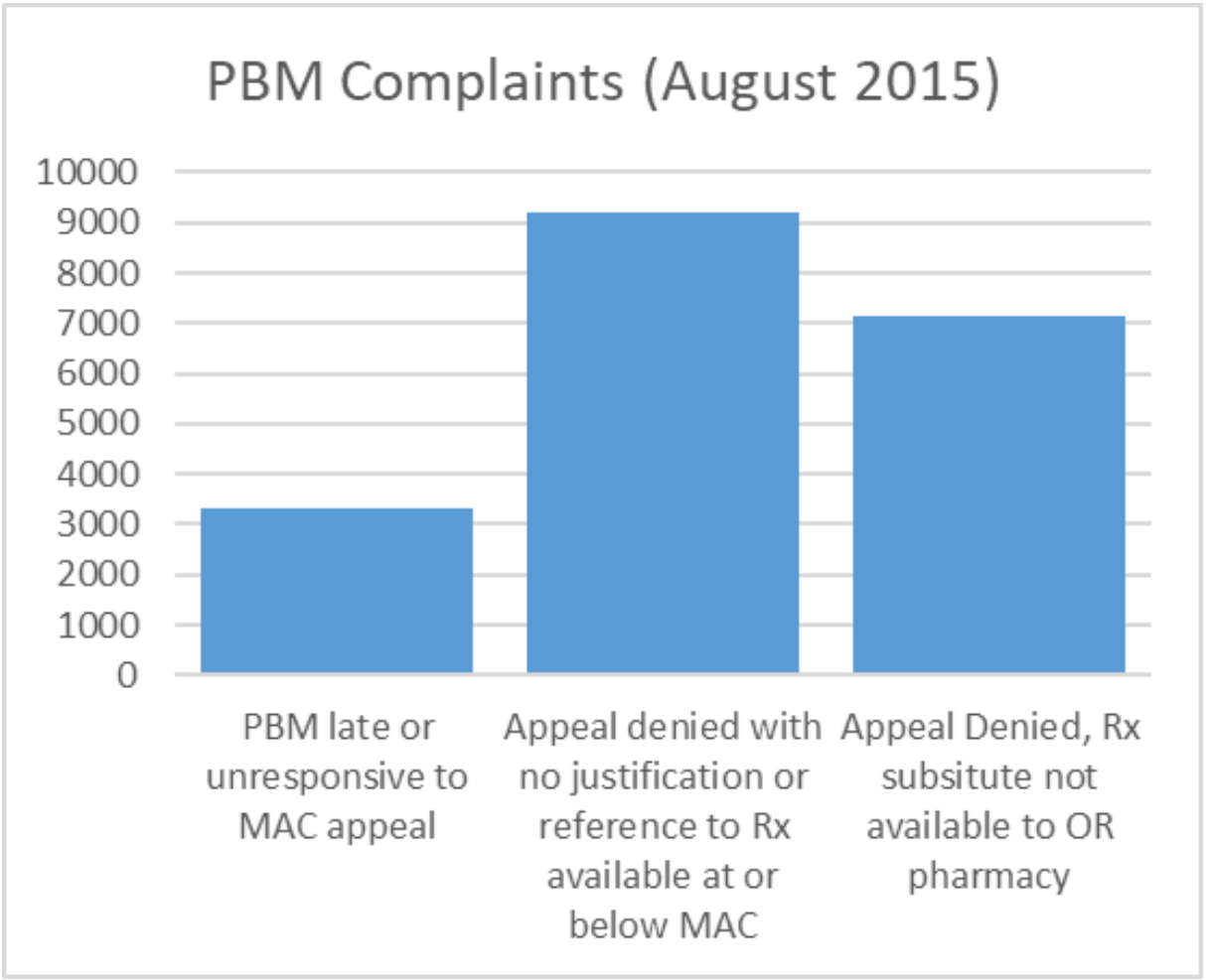
Mail Order (2019): a PBM may not require that a prescription be filled by a mail-order pharmacy as a condition of reimbursement.

Gag Clause Ban (2019): a PBM may not penalize a pharmacy for notifying a patient that the "cash" price of a drug would be less than the co-pay required under their coverage.

Pharmacy Claims Audits: ORS 735.542-735.552 set out a variety of restrictions on the scope and frequency of claims audits by PBMs.

PBM Complaints – Early Implementation

In August 2015, a DCBS analyst performed a comprehensive review of pharmacy complaints against PBMs during the first seven months of the statute's implementation. During that period, pharmacies submitted almost 20,000 complaints related to MAC appeals, suggesting widespread non-compliance with the law.



Data Source: DCBS

PBM Complaints – Recent

While the total volume of PBM complaints since the last major change to our statute went into effect (1/1/2021), they suggest that at least some PBMs remain non-compliant with Oregon's requirements. Some examples of likely non-compliance include:

- Providing out-of-date or unresponsive contact information to pharmacies, including disconnected phone numbers.
- Failure to adjust payment after a successful MAC appeal.
- Requiring pharmacies to use the services of a PSAO to submit MAC appeals.
- Not updating MAC lists or failing to provide lists upon request.
- Requiring a patient to fill prescriptions by mail order.

Enforcement Authority over PBMs

- **ORS 735.533**: denial, suspension or revocation of registration as a Pharmacy Benefit Manager.
- **ORS 731.988:** civil penalty of up to $10,000 per violation of the insurance code.

Questions?

Oregon Prescription Drug
Affordability Board

Prescription Drug Affordability Board

Update on SB 844 Reports

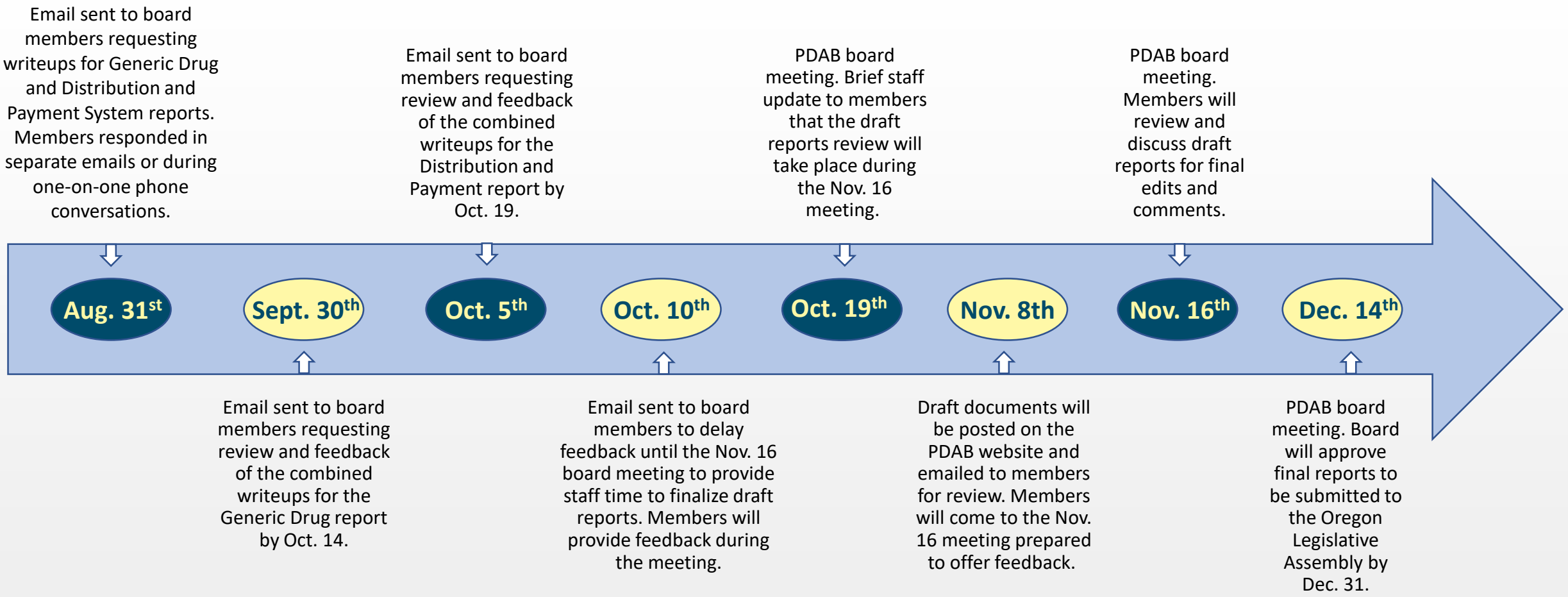
Board Meetings and Topics

TOPICS	July 20 PDAB Meeting ✓	Aug. 3 PDAB Meeting ✓	Aug. 17 PDAB Meeting ✓	Sept. 21 PDAB Meeting ✓	Oct. 19 PDAB Meeting	Nov. 16 PDAB Meeting	Dec. 14 PDAB Meeting	Report Due Date
Work Plan	Presentation to Board	Formal Approval						
Review Rx Report from DPT				Presentation for Board Review				
Rx Generic Drugs Report[1]			Presentation of Outline to Board	Presentation of First Draft to Board	Update to Presentation Timeline to Extend Draft Review to November Meeting	Presentation of Draft Reports to Board	Board Approval of Final Draft	12/31/22
Rx Distribution and Payment System Report								12/31/22
Price Trends for List of Rx								12/31/22
Recommendations from Rx List								12/31/22
Report of Affordability Reviews Conducted by the Board[2]								06/01/23

[1] *Originally due June 1, now December 31, 2022*

[2] *Originally due December 31, 2022, now due June 1, 2023*

Timeline of SB 844 Reports



Oregon Prescription Drug Affordability Board

3

Section 5 vs Section 7 Recommendations

Section 5 (3)

PDAB to provide recommendations if any, for legislative changes necessary to make prescription drug products more affordable in this state.

Section 7 (2)

Recommendations for policies to lower the list prices of prescription drugs sold in this state and for legislative changes necessary to implement the policies.

4

Rx Generic Drugs Report (SB 844, Section 6 (2))

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

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

For 2022 reporting, Section 6 (2) will be submitted to the Legislative Assembly by 12/31/2022.

5

Rx Distribution and Payment System Report (SB 844, Section 7)

(1) Study of the entire prescription drug distribution and payment system in Oregon and polices adopted by other states and countries that are designed to lower the list price of prescription drugs including but not limited to the following options:

(a) Establishing upper payment limits for all financial transactions in this state involving a drug and specifying the methodology used to determine the upper payment limit that does not undermine the viability of any part of the prescription drug supply chain;

(b) Using a reverse auction marketplace for the purchase of prescription drugs by state and local governments;

(c) Implementing a bulk purchasing process for state and local governments to purchase prescription drugs.

(2) No later than December 31, 2022, PDAB shall report to the interim committees of the Legislative Assembly:

(a) The board's findings including findings for each option described in subsection (1) of this section; and

(b) Recommendations for policies to lower the list prices of prescription drugs sold in this state and for legislative changes necessary to implement the policies.

SB 844, Section 5 (1) & (3)

By December 31 of each year, the PDAB shall report to the Health Care Cost Growth Target program and to the interim committees of the Legislative Assembly.

For 2022, Section 5 (1) and (3) will be reported by 12/31/2022. Section 5 (2), for the prescription drugs that were reviewed under Section 2 of SB 844, will be reported by 06/01/2023.

(1) Price trends for the list of prescription drugs provided to the board by the Department of Consumer and Business Services

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

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Oregon Prescription Drug Affordability Board

2023 Calendar

Prescription Drug Affordability Board

Meeting 1	Wednesday, January 18	9:30 – 11:30 a.m.
Meeting 2	Wednesday, February 15	9:30 – 11:30 a.m.
Meeting 3	Wednesday, March 15	9:30 – 11:30 a.m.
Meeting 4	Wednesday, April 19	9:30 – 11:30 a.m.
Meeting 5	Wednesday, May 17	9:30 – 11:30 a.m.
Meeting 6	Wednesday, June 21	9:30 – 11:30 a.m.
Meeting 7	Wednesday, July 19	9:30 – 11:30 a.m.
Meeting 8	Wednesday, August 23	9:30 – 11:30 a.m.
Meeting 9	Wednesday, September 20	9:30 – 11:30 a.m.
Meeting 10	Wednesday, October 18	9:30 – 11:30 a.m.
Meeting 11	Wednesday, November 15	9:30 – 11:30 a.m.
Meeting 12	Wednesday, December 13	9:30 – 11:30 a.m.

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