Oregon Prescription Drug Affordability Board

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Agenda

This is a regular meeting. *Date*: **August 21, 2024** | *Time*: **9:30 a.m.**

This agenda is subject to change.

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

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

Staff: Ralph Magrish, executive director; Cortnee Whitlock, senior policy analyst; Stephen Kooyman, project manager, Heather Doyle, data analyst; Pei-Chen Choo, research analyst; Melissa Stiles, administrative specialist; Jake Gill, counsel; Pramela Reddi, counsel

Purpose	Subject	Presenter	Estimated Time Allotted
Informational and vote	Call to order and roll call	Chair Bailey	2 minutes
Informational	Board declaration of conflict of interest	Chair Bailey	2 minutes
Discussion and vote	Board approval of **07/24/2024 minutes**	Chair Bailey	2 minutes
Informational	Executive director's program update	Ralph Magrish	5 minutes
Informational and discussion	**SB 192 Upper payment limit deliverable presentation**	Myers and Stauffer	60 minutes
Discussion	Board discussion: **Affordability review process**	Chair Bailey	60 minutes
Informational	Announcements	Chair Bailey	2 minutes
Informational	General public comment *Comments will be limited to 3 minutes per person or organization. Written comments are reviewed by the board prior to the meeting.*	Chair Bailey	10 minutes
Informational	Adjournment	Chair Bailey	2 minutes

Next meeting

September 18, 2024, at 9:30 a.m.

Accessibility

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

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 PDAB public comment form no later than 24 hours before the PDAB meeting. **Written:** to provide written comments to the board, please submit the PDAB public comment form 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

Oregon Prescription Drug Affordability Board (PDAB) Regular Meeting
Wednesday, July 24, 2024
Draft Minutes

Web link to the meeting video: https://youtu.be/VntX-UHodJ0
Web link to the meeting materials: https://dfr.oregon.gov/pdab/Documents/20240724-PDAB-document-package.pdf

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Call to order and roll call: Chair Shelley Bailey called the meeting to order at 9:33 am and roll was called.
Board members present: Chair Shelley Bailey, Vice Chair Amy Burns, Dan Hartung, Robert Judge, Dan Kennedy, Chris Laman,
Absent: John Murray, Akil Patterson

Declaration of conflict of interest: Robert Judge disclosed potential conflicts of interest, real or perceived. View at video minute 00:00:45.

Approval of board minutes: Chair Bailey asked for a motion and second to approve the board minutes as shown on Pages 3-4 of the agenda materials, with any amendments. Dan Kennedy made a motion to approve the minutes and Robert Judge provided a second. View at video minute 00:01:31.

MOTION to approve the June 26, 2024, minutes
Board Vote:
Yes: Dan Hartung, Robert Judge, Dan Kennedy, Chris Laman, Vice Chair Amy Burns, Chair Shelley Bailey
No: None
Absent: John Murray, Akil Patterson
Motion passed 6-0

Executive director's program update: Ralph Magrish provided a program update. View the video at minute 00:02:27.

Constituent Panels: Chair Bailey stated the board is hosting seven constituent panels with a question-and-answer format moderated by the board chair. This is a follow up to the focus groups and community forums the board held recently to hear feedback about upper payment limits. An upper payment limit, or UPL, limits what purchasers in Oregon will pay for specific drugs. She thanked everyone who participated. View at video minute 00:05:45.

Panel 1 Patients, consumers:

Chair Bailey announced panel member, Mark Sturbois, and invited him to talk about how a UPL would impact him. View at video minute 00:07:47.

Board Member Robert Judge question: "During your therapy, have you ever skipped filling a prescription or rationed medication because of the cost? How has the out-of-pocket costs for your medications affected your household budget." View at video minute 00:13:41.

Panel 2 Pharmacy benefit managers:

Chair Bailey announced panel members, Greg Baker, CEO, BS Pharm, AffirmedRx, Tonia Sorrell Neal, senior director, state affairs, PCMA, and LuGina Mendez-Harper, state government affairs principal, Prime Therapeutics.

Chair Bailey question: "The board's goal is to improve drug affordability for Oregonians. Numerous constituents have suggested pass through models, whereby UPL savings are realized at the point of sale, could help improve affordability for patients. At least one state, West Virginia, has adopted such a model. If Oregon were to pursue such a model, what data or reporting would PBMs be able to provide to demonstrate 100 percent pass-through of the UPL savings for an insured patient?" View at video minute 00:17:57.

Board Member Robert Judge question: "You said you lose negotiating leverage with manufacturers when it's passed through to payers and then down to consumers. What are you exactly referring to?" Follow up questions: "Does it impact the ability to exert influence on formulary placement? In my experience, tier placement for drugs on formulary is used as a lever for negotiating preferred and non-preferred drugs. This is a tool used in negotiating manufacturer rebates. Does the passthrough affect that?" View at video minute 00:25:44.

Board Member Chris Laman question: "I'm still trying to understand, when the rebate gets passed on to the consumer, how the PBM loses leverage. You're still negotiating that rebate but instead of the PBM keeping that money, it's getting passed on to the consumer. I understand how it's affecting the PBM financially, but how is it costing you leverage in terms of the negotiation with the pharmaceutical company?" Follow up question: "How frequently is the data required to be submitted to the state?" View at video minute 00:30:00.

Panel 3 Insurance companies:

Chair Bailey announced panel members, Justin Weiss, VP, pharmacy operations & compliance, Cambia Health Solutions, and Rick Blackwell, PacificSource Health Plans.

Chair Bailey question: "Some constituents have suggested that certain benefit design strategies, for example, carve out, point of sale models, have direct impact on drug affordability for patients. How common are these types of strategies in your benefit design considerations and or plan offerings?" Follow up question: "Related to our previous discussion with PBMs about point-of-sale discounts, how does that impact your plan design decisions?" View at video minute 00:34:20.

Panel 4 Manufacturers:

Chair Bailey announced panel members: Brett Michelin, Senior Director, State Government Affairs, Association for Accessible Medicines (representing generic and biosimilar manufacturers)
Brian Warren, senior director, state government affairs, Biotechnology Innovation Organization
Liisa Bozinovic, executive director, Oregon Bioscience Association, and Dharia McGrew, director, state policy, PhRMA

Chair Bailey question: "We have heard in listening sessions with manufacturers that they are willing to provide certain types of information to the board in a confidential way to help us make some of our decisions. We recognize the importance of data for our affordability reviews and in our efforts to develop associated UPL strategies. What specific protections and structures would be required from manufacturers to share this type of confidential information with the board, for example, statutory protections, regulations, or contractual. We would like to hear from the panelists today on how we might be able to structure something that would give the board confidential information in a mechanism that's agreeable to manufacturers." View at video minute 00:49:53.

Chair Bailey question: "Constituents have suggested the board define affordability in a better way and that is something we have discussed as a board. What factors beyond manufacturer costs for a given drug should the board consider in our definitions? What type of data should be included and from what constituents should we obtain this? What are some additional things the board should think about to help us define affordability?" View at video minute 00:56:27.

Board Member Robert Judge question: "This is a broad question that gets to some of the information I've been listening to over the last two years about upper payment limits and the impact on the industry. From a manufacturer perspective, how would an upper payment limit method impact your pricing strategy for new and existing medications?" View at video minute 01:03:17.

Panel 5 Advocacy Groups:

Chair Bailey announced panel members Leigh Purvis, prescription drug policy principal, AARP Public Policy Institute, Tiffany Westrich-Robertson, chief executive officer, AiArthritis IFFAAA, Madonna McGuire Smith, executive director, Bleeding Disorders Counsel, Kathleen Costello, ANP-BC, MSCN, Chief operating officer, Can Do Multiple Sclerosis, Lorren Sandt, executive director, Caring Ambassadors Program, Corey Greenblatt, director of state policy and advocacy, Global Healthy Living Foundation, Gina Ross Murdoch, president, CEO, Multiple Sclerosis Association of America, Kasey Minnis, executive director, Multiple Sclerosis Foundation, Bill Robie, state government relations director, National Bleeding Disorders Foundation, Seth Greiner, senior manager advocacy, National Multiple Sclerosis Society, Lucy Laube, state government relations manager west, National Psoriasis Foundation, John Mullin, president, Oregon Coalition for Affordable Prescriptions, Charlie Fisher, OSPIRG, and Sara van Geertruyden, executive director, Partnership to Improve Patient Care.

Chair Bailey question: "Advocacy groups have made recommendations to the board. We want to better understand these recommendations and how we might move forward. Advocacy groups here have suggested the board consider a UPL feasibility study. What exactly would this group recommend the board study? Who should be engaged in completing such a study and what types of information or data should the board seek?" View at video minute 01:07:50.

Board Member Robert Judge question: "I have a question for Mr. Greenblatt, a clarification on what he was referring to on pharmacies not being able to stock inventory if an upper payment level is set for a drug that they could not stock. Are you inferring or assuming that an upper payment level would be a reimbursement to a pharmacy of whatever the PDAB establishes as the upper payment limit, as opposed to a rebate on the back end?" View at video minute 01:28:32.

Panel 6 Pharmacies:

Chair Bailey announced panel members, Caitlin Malone, director of procurement, Albertsons, Melanie Maxwell, president, AlignRx LLC, Michael Murphy, senior advisor for state government affairs, American Pharmacists Association, Thad Mick, chief clinical & innovation officer, Ardon Health Holdings, LLC, Priyal N Patel, pharmacist, co-owner, Broadway Pharmacy in North Bend (also a member of the Oregon Board of Pharmacy), Pat Hubbell, RPh, owner, Brooklyn Pharmacy, in Portland, Austin Blakeslee, director of pharmacy, Hi-School Pharmacy, John Covello, Senior Director of Government Relations, Independent Pharmacy Cooperative, Thomas Irby, pharmacist, owner, Irby Pharmacy, in Vernonia, Justin Ramsey, pharmacy director, La Clinica, Medford, Randy Klemm, owner, CEO, Managed Healthcare Pharmacy, in Eugene, Lauren Lyles-Stolz, Pharm.D vice president, reimbursement, innovation, and advocacy, National Association of Chain Drug Stores (NACDS), Kevin Russell, director of ambulatory pharmacy services, St. Charles Health System, Bend, and Brian Mayo, executive director, Oregon State Pharmacy Association.

Chair Bailey question: "Pharmacies have made recommendations to the board. We want to better understand these recommendations and how we might move forward. Pharmacies have suggested that drug importation may be a potential solution for affordability issues. As a pharmacy provider, what challenges would you see related to drug importation, for example, the Drug Supply Chain Security Act may create challenges." View at video minute 01:36:25.

Chair Bailey question: "What suggestions do panelists have for the board to consider related to the UPL model and how would you propose we ensure both patients and providers are protected should a UPL model be implemented." View at video minute 01:51:37.

Board Member Robert Judge question: "The PDAB exists to try to come up with recommendations on how to address the affordability of drugs. It's a burden to everybody and I don't think there's anybody who disagrees with that. We're hearing a lot today from individuals saying how do we protect ourselves or how do we do this? What I'd like to hear are what are your recommendations for affordability? What would you recommend to the board to consider as we think about upper payment limits and affordability? Dr. Lyles-Stolz, do you have a recommendation, because I think you make a very cogent point." View at video minute 01:56:05.

Panel 7: Hospitals, FQHCs, providers

Chair Bailey announced panel members: Robert Trachtenberg, senior director, Health Center Operations, Cascadia Health, Portland, Arsalan Shah, senior director of pharmacy, Central City Concern, Portland, Simon Vismantas, counsel, government relations, Kaiser Permanente, Jay Flesch, clinical pharmacist, La Pine Community Health Center, LaPine, Amanda Cummings, PharmD, director of pharmacy, Dietitians and Cancer Services, Adventist Health Columbia Gorge, The Dalles, Michele Koder, pharmacy director, Multnomah County Health Department, Portland, Shinta Imansjah, Nara Northwest (Native American Rehabilitation Association), Portland, Jennifer McElravey, director of pharmacy, Neighborhood Health Center, Lisa Sandoval, PharmD, BCACP, One Community Health, Hood River, Marty Carty, gov affairs director, Oregon Primary Care Association, Joe Evans, PeaceHealth at River Bend Hospital, Springfield Amy Cervan, senior director of pharmacy, Rogue Community Health, Medford, Cory Rahn, director of pharmacy, Salem Health Hospitals and Clinics, Salem, and Megan Jones, PharmD BCGP, Director of

Outpatient Pharmacies, Samaritan Health Services, Corvallis, April Etheridge-Bosworth, Virginia Garcia Memorial Health Center, Hillsboro, and Russ Heaton, VP of Pharmacy, Yakima Valley Farm Workers Clinic

Chair Bailey question: "Related to specific protections and structure, what would be required for health systems or hospitals to share details regarding exactly any 340B program savings that are used to benefit patients? Are there statutory protections, regulation or contractual, related to anything we may propose related to UPLs and the potential impact on hospitals and FQHC providers?" View at video minute 02:06:30.

Board Member Robert Judge question: "An upper payment limit is a reimbursement on a drug and 340B is an acquisition cost method for a drug. The point you're making is the upper payment limit may use less margin, which is used to fund your underserved responsibilities. Is that the point that you're arguing for exclusions of 340B entities? Would that apply to hospitals as well, making huge monies from cancer medication and infusion centers? View at video minute 02:14:34.

Announcements: Chair Bailey said the next board meeting would be Aug. 21, 2024. View at video minute 02:33:23.

Public comment: Chair Bailey said the board received six public comment letters, which are posted to the PDAB website. No one signed up to speak during the general public comment portion of the agenda. View at video minute 02:33:23.

Adjournment: Chair Bailey adjourned the meeting at 12:30 pm with all board members in agreement. View at view minute 02:34:13.

Constituent Group Engagement Report

Prescription Drug Consulting and Outreach Services

August 21, 2024

MYERS AND STAUFFER LC
CERTIFIED PUBLIC ACCOUNTANTS

AGENDA

- Background
- Approach
- Participation
- Synthesis of Feedback
- Recommendations, Concerns, Obstacles
- Board Considerations

MYERS AND STAUFFER LC
CERTIFIED PUBLIC ACCOUNTANTS

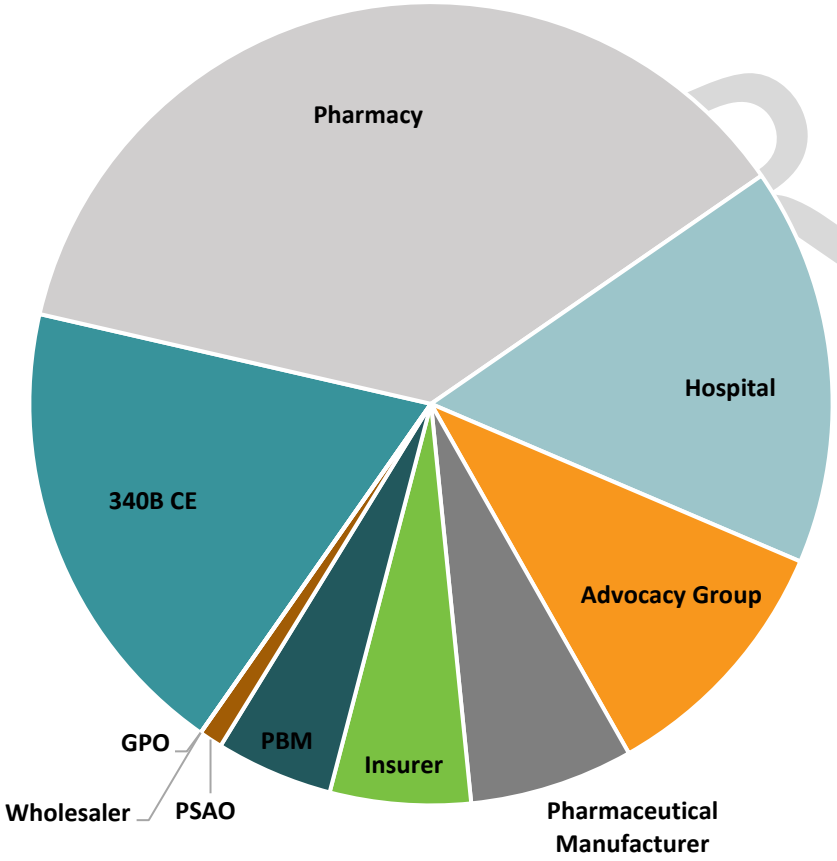
Background

- SB192 tasked the Board with developing a UPL plan
- Myers and Stauffer engaged to support UPL plan development
- Scope of work includes constituent engagement to:
  - Identify concerns, questions, support, or opposition to UPLs
  - Solicit input about UPL process, utilization, and implementation
  - Solicit input about data and alternative approaches

Approach

- Constituent groups
  - 340B Covered Entities (CEs)
  - Carriers
  - Hospitals
  - Patient Advocacy Groups
  - Pharmaceutical Manufacturers
  - Pharmacy Benefit Managers (PBMs)
  - Retail Pharmacies
- Mechanisms for engagement
  - Online Survey
    - Non-mandatory Likert scale and free text questions
      - Affordability, UPL impact, methodology, recommendations
    - Inform focus groups
  - Focus Groups
    - 2 X 1-hour meetings per group
    - Expand on survey responses
    - Solicit additional feedback

Survey Participation



Constituents	Sent	Responses
340B CE	34	20
Advocacy Groups	60	11
Hospital	51	17
Insurer	53	6
Pharmaceutical Manufacturer	56	7
Pharmacy	429	39
PBMs	159	5
PSAOs	6	1
Wholesalers	4	0
GPOs	4	0
Total	**856**	**106**

Focus Group Participation

Constituent Group	Date	Participants	Unique Organizations
Carriers	May 16, 2024	9	5
Retail Pharmacies (Independent Only)	May 16, 2024	8	7
Hospitals	May 20, 2024	11	5
340B CEs	May 22, 2024	20	14
Carriers	May 29, 2024	7	5
Retail Pharmacies (Grocery/Chain Only)	May 29, 2024	4	3
Hospitals	May 30, 2024	7	5
340B CEs	May 30, 2024	17	14
Retail Pharmacies (Grocery/Chain and Wholesalers)	June 5, 2024	2	2
Retail Pharmacies (Independent, GPOs, and PSAOs)	June 12, 2024	4	4
Pharmaceutical Manufacturers	July 1, 2024	18	11
Patient Advocacy Groups	July 1, 2024	7	7
PBMs	July 2, 2024	0	0
Pharmaceutical Manufacturers	July 10, 2024	15	10
Patient Advocacy Groups	July 11, 2024	7	7
PBMs	July 16, 2024	4	4

Synthesis of Feedback: Survey

- Concerned with the cost of drugs to organizations and patients
- Concerned with UPL financial impact on organizations
- Concerned with UPL impact on patient access and costs
- Concerned with increased administrative burden, infrastructure costs, and operational challenges

Synthesis of Feedback: Focus Groups

- Concerned about drug affordability, though no agreement regarding definition or how it should be determined
- Unsure how to assess the impact of a UPL, particularly given the strategy has yet to be implemented in other states
- Expressed concerns regarding loss of revenue, decreased patient access, and increased patient costs

Synthesis of Feedback : Focus Groups

- Concerned with delivery system complexity and limitations of a state-based solution
- Concerned with administrative burden, particularly, effort required to serve patients, perform business operations, and manage contracts
- Frequently requested information regarding how a UPL would be developed, implemented, and enforced

Summary of Recommendations, Concerns, and Obstacles

- Most common recommendations focused on affordability determinations, drug selection for affordability review, PBM reform, and transparency
- Concerns regarding negative impact a on provider revenue, patient access, and supply chain operations
- Concerns regarding lack of information regarding affordability determinations, how a UPL would be established; and how a UPL would be implemented and enforced
- Obstacle to supporting UPL was constituents' desire to fully understand how the UPL would be developed, implemented, enforced, and updated

Constituent Group Recommendations

Constituent Group Recommendations								
Recommendation	**340B CEs**	**Carriers**	**Hospitals**	**Patient Advocacy Groups**	**Pharmaceutical Manufacturers**	**PBMs**	**Retail Pharmacies (Ind./GPO/PSAO)**	**Retail Pharmacies (Grocery/Chain/ Wholesalers)**
Focus UPLs on drug classes, rather than individual drugs, especially those drugs without lower cost alternatives and those representing Oregonians highest percentage of spending		✓	✓	✓			✓	
Incorporate lessons learned from other state PDABs into the Board's affordability reviews and UPL planning processes		✓		✓			✓	
Ensure that the UPL is enforced across the entire supply chain (i.e., that no one pays more than the UPL), that there is transparency to the process, and that savings pass-through to patients in the form of reduced premiums or reduced drug costs is demonstrated	✓	✓		✓		✓		
Ensure transparency in affordability reviews and how UPLs are established (i.e., how the Board arrives at its conclusions); establish a periodic review process for UPLs to adapt to market changes, innovation, and economic conditions, ensuring they remain relevant and effective	✓	✓		✓		✓		
Pursue comprehensive PBM reform (i.e., prohibit clawbacks, spread pricing, mandatory mail order; permit pharmacy choice, including specialty pharmacies, and a shared and common definition of specialty drugs)	✓	✓	✓	✓	✓		✓	
Eliminate the use of rebates in the various levels of the supply chain	✓		✓				✓	
Ensure that pharmacies are paid no less than the UPL and separate the dispensing fee from the cost of the drug; dispensing fees should be adequate to cover the enhanced clinical services required for specialty drugs and the cost of drugs and services in pharmacies in general	✓		✓	✓	✓		✓	

Constituent Group Concerns & Obstacles

Constituent Group Concerns, and Obstacles								
Recommendation	**340B CEs**	**Carriers**	**Hospitals**	**Patient Advocacy Groups**	**Pharmaceutical Manufacturers**	**PBMs**	**Retail Pharmacies (Ind./GPO/PSAO)**	**Retail Pharmacies (Grocery/Chain/ Wholesalers)**
Constituent Group Concerns								
UPL will impact revenue and limit the ability to provide cost sharing support and/or provide non-revenue generating services	✓		✓	✓			✓	
UPL will result in reimbursement below costs	✓		✓	·			✓	
UPL will reduce patient access to medications due to benefit design changes (e.g., preference for more highly rebated drugs when there are multiple therapeutic options)	✓	✓	✓	✓	✓	✓	✓	
UPL will result in increased use of alternative funding programs or encourage manufacturers to withdraw from the state or to stop selling the drug in the state; wholesalers may also choose not to sell in the state if a UPL reduces revenues	✓		✓	✓	✓		✓	
There is not a current mechanism to enforce a UPL throughout the supply chain or to ensure that savings are realized by patients		✓	✓		✓	✓	✓	
National scope of health care, including contracting and length of contract negotiations	·	✓	✓	✓	·	·	✓	✓
Increased administrative burden	✓	✓	✓	·	✓	·	✓	·
Constituent Group Obstacles								
A need to fully understand how the UPL would be developed, implemented, enforced, and updated before constituent group members could commit to supporting a UPL; the concerns related to 340B revenue and adequate pharmacy reimbursement are especially strong	✓	✓	✓	✓	✓	✓	✓	✓

Board Considerations

- Conduct additional constituent outreach and collaboration
- Assess risk to patient access and cost; and develop corresponding mitigation strategies
- Assess pharmacy provider reimbursement protections

Board Considerations

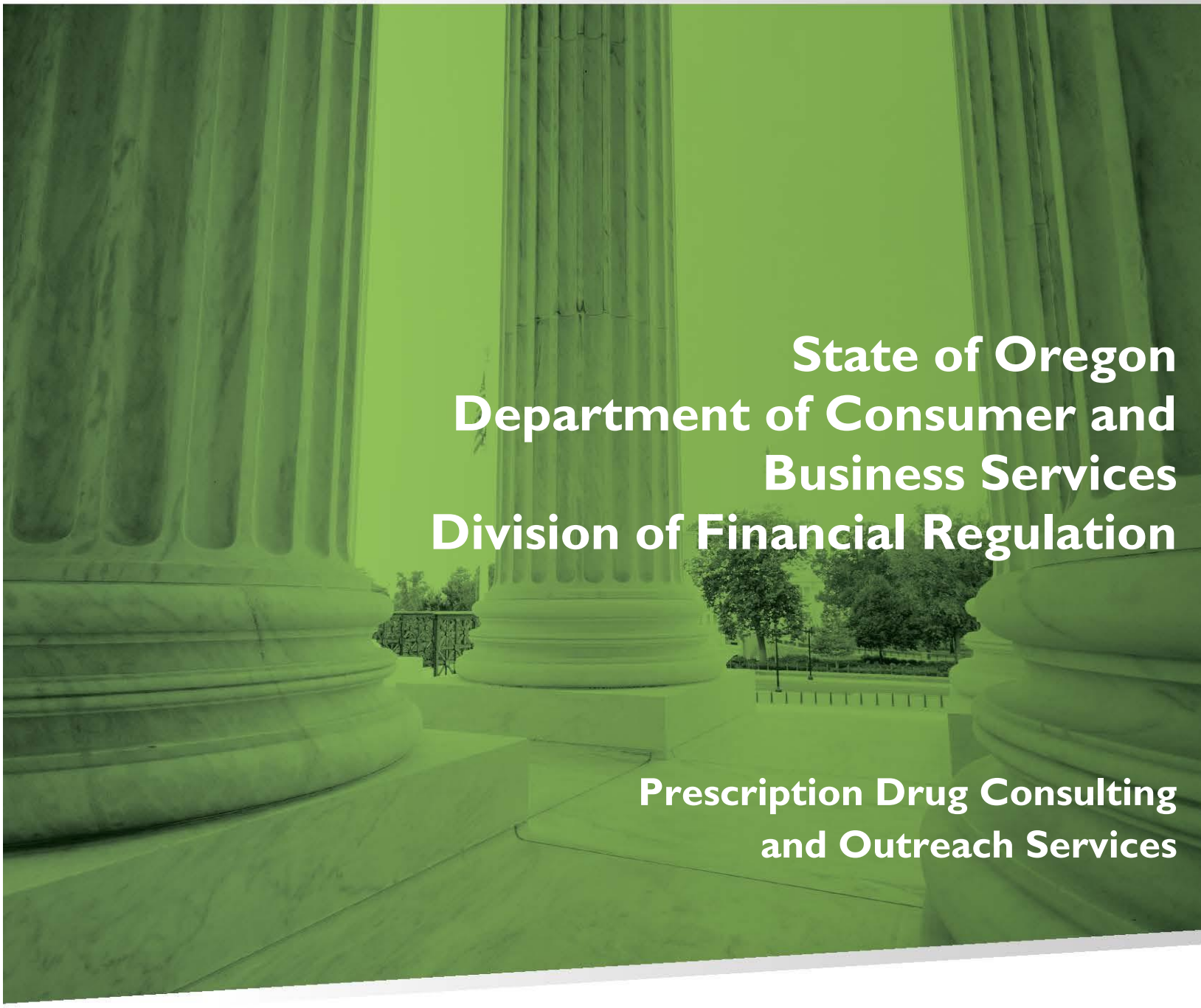
- Assess available data and identify opportunities for enhancement, including confidentiality protections
- Assess financial and administrative impact of system and staffing changes, and assess UPL contract implications
- Assess the feasibility of implementing alternative and/or complementary solutions to improve drug affordability

Discussion

- Engagement Report Questions/Feedback

- Plan for Establishing OR-Specific UPL
  - Methodologies for Establishing a UPL
  - Potential UPL Savings and/or Costs
  - Authorities Necessary for Enforcement of UPL
  - Resources Required for Implementation

MYERS AND STAUFFER LC
CERTIFIED PUBLIC ACCOUNTANTS



State of Oregon Department of Consumer and Business Services Division of Financial Regulation

Prescription Drug Consulting and Outreach Services

PO-44000-00028053

Constituent Group Engagement Report

DRAFT August 14, 2024

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700 W 47th St #1100
Kansas City, MO 64112
www.myersandstauffer.com

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Executive Summary

Background

The Oregon Prescription Drug Affordability Board (Board) was established in 2021, with the goal of protecting Oregonians from high prescription drug costs. The Board's mandate includes annually identifying and reviewing nine drugs, and at least one insulin product, that may present affordability challenges. In June 2023, the Board was also tasked with developing a plan to establish upper payment limits (UPLs). To support this initiative, the Board contracted with Myers and Stauffer LC (Myers and Stauffer) to conduct constituent outreach on the Board's behalf. The purpose of this outreach was to capture the perspectives of constituents throughout the pharmaceutical supply chain regarding a UPL, rather than push a particular model or approach.

Approach

Seven constituent groups were identified for targeted outreach: 340B Covered Entities (CEs), carriers, hospitals, patient advocacy groups, pharmaceutical manufacturers, pharmacy benefit managers (PBMs), and retail pharmacies. Myers and Stauffer then developed and administered an informal survey and facilitated two, one-hour virtual focus group meetings per constituent group, to identify perceptions regarding strengths, weaknesses, opportunities, and threats associated with a UPL methodology. Surveys included a series of non-mandatory Likert scale questions and multiple response questions, as well as free-text questions to allow recipients to provide more detailed information on approaches, recommendations, or concerns. Focus group questions were organized around topics including the impact of drug affordability, impact of a UPL, UPL methodologies, desired state of drug affordability, and recommendations or other strategies. While interrelated with the concept of a UPL, the focus of Myers and Stauffer's outreach was not to solicit feedback regarding the Board's affordability reviews; however, constituents did provide considerable feedback on this topic, which we have incorporated into our analysis where appropriate.

Synthesis of Feedback Provided

Myers and Stauffer sent 856 surveys (recipients were encouraged to forward to colleagues) and collected 106 responses. A review of quantitative survey data found that the majority of respondents were concerned with the cost of drugs on their organizations, patients, and/or members. Despite overall concerns regarding drug affordability, perceptions regarding the impact of a UPL were mixed. For example, 47% of respondents expressed the belief that a UPL would have a negative financial impact on their organization, 32% expressed a neutral impact, 10.5% expressed a positive impact, and 10.5% failed to respond. Similarly, 54% of respondents expressed the belief that a UPL would create challenges to patient access, 22% expressed a neutral impact, 21% expressed a positive impact, and 3% failed to respond. Finally, 47% of respondents expressed the belief that a UPL would have a neutral impact on patients' ability to afford their medications, 26% expressed a negative impact, 23% expressed a positive impact, and 4% failed to respond. An analysis of qualitative survey data found that more than half of respondents did not believe a UPL would result in cost savings, with many expressing concerns regarding loss of revenue, decreased patient access, and increased patient costs. A number of respondents also expressed concern that implementation of a UPL would result in increased administrative burden, infrastructure costs, and operational challenges.

In addition to soliciting input via surveys, Myers and Stauffer sent 675 focus group meeting invitations (recipients were encouraged to forward to colleagues), and 140 constituents participated in 16

meetings. A review of qualitative data found that, across all focus groups, participants were concerned about drug affordability; however, there was not agreement as to the definition of affordability or how it should be determined. Similarly, participants were unsure how to assess the impact of a UPL on drugs dispensed in Oregon, particularly given the strategy has yet to be implemented in other states. Of those who did assess the impact, most expressed concerns regarding loss of revenue, decreased patient access, and increased patient costs. Participants across all focus groups cited delivery system complexity as a concern, with several explicitly stating a state-based solution would not likely have a significant impact on affordability, and that geographic considerations regarding how care is delivered could result in decreased patient access. A number of participants also expressed concerns regarding administrative burden, stating that adding a UPL to existing complex processes, in a highly regulated environment, would increase the level of effort required to serve patients, perform routine business operations, and manage contracts. Lastly, participants found it challenging to discuss UPL methodologies and frequently requested information regarding how a UPL would be developed and implemented. Two key themes emerged from these discussions, specifically how affordability would be defined and how the Board would ensure a UPL was enforced.

Summary of Recommendations, Concerns, and/or Obstacles

Constituent groups were asked in both surveys and focus groups to provide recommendations, concerns, and/or obstacles for the Board to consider. The most common recommendations focused on affordability determinations, drug selection for affordability review, PBM reform, and transparency. Several constituents also recommended strategies beyond the Board's scope of authority that would likely require federal action. The most common concerns focused on the potential negative impact a UPL might have on provider revenue, patient access, and supply chain operations; however, the prevailing concern, expressed across groups, was that constituents did not have enough information to understand how a drug would be deemed to be unaffordable, which was not a focus of this outreach; how a UPL would or should be established; and how a UPL would be implemented and enforced throughout the supply chain. Lastly, the most commonly cited obstacle was constituents' desire to fully understand how the UPL would be developed, implemented, enforced, and updated, before they could commit to supporting a UPL. While comprehensive listings of recommendations, concerns, and obstacles are provided in the body of this report, the table below lists those most frequently cited across constituent groups (i.e., cited by three or more groups).

Table 1. Recommendations, Concerns, and Obstacles

Constituent Group Recommendations, Concerns, and Obstacles								
Recommendation	**340B CEs**	**Carriers**	**Hospitals**	**Patient Advocacy Groups**	**Pharmaceutical Manufacturers**	**PBMs**	**Retail Pharmacies (Ind./GPO/PSAO)**	**Retail Pharmacies (Grocery/Chain/ Wholesalers)**
Constituent Group Recommendations								
Focus UPLs on drug classes, rather than individual drugs, especially those drugs without lower cost alternatives and those representing Oregonians highest percentage of spending		✓	✓	✓			✓	
Incorporate lessons learned from other state PDABs into the Board's affordability reviews and UPL planning processes		✓		✓			✓	
Ensure that the UPL is enforced across the entire supply chain (i.e., that no one pays more than the UPL), that there is transparency to the process, and that savings pass-through to patients in the form of reduced premiums or reduced drug costs is demonstrated	✓	✓		✓		✓		
Ensure transparency in affordability reviews and how UPLs are established (i.e., how the Board arrives at its conclusions); establish a periodic review process for UPLs to adapt to market changes, innovation, and economic conditions, ensuring they remain relevant and effective	✓	✓		✓		✓		
Pursue comprehensive PBM reform (i.e., prohibit clawbacks, spread pricing, mandatory mail order; permit pharmacy choice, including specialty pharmacies, and a shared and common definition of specialty drugs)	✓	✓	✓	✓	✓		✓	
Eliminate the use of rebates in the various levels of the supply chain	✓		✓				✓	
Ensure that pharmacies are paid no less than the UPL and separate the dispensing fee from the cost of the drug; dispensing fees should be adequate to cover the enhanced clinical services required for specialty drugs and the cost of drugs and services in pharmacies in general	✓		✓	✓	✓		✓	
Constituent Group Concerns								
UPL will impact revenue and limit the ability to provide cost sharing support and/or provide non-revenue generating services	✓		✓	✓			✓	
UPL will result in reimbursement below costs	✓		✓				✓	

UPL will reduce patient access to medications due to benefit design changes (e.g., preference for more highly rebated drugs when there are multiple therapeutic options)	✓	✓	✓	✓	✓	✓	✓	
UPL will result in increased use of alternative funding programs or encourage manufacturers to withdraw from the state or to stop selling the drug in the state; wholesalers may also choose not to sell in the state if a UPL reduces revenues	✓		✓	✓	✓		✓	
There is not a current mechanism to enforce a UPL throughout the supply chain or to ensure that savings are realized by patients		✓	✓		✓	✓	✓	
National scope of health care, including contracting and length of contract negotiations		✓	✓	✓			✓	✓
Increased administrative burden	✓	✓	✓		✓		✓	
Constituent Group Obstacles								
A need to fully understand how the UPL would be developed, implemented, enforced, and updated before constituent group members could commit to supporting a UPL; the concerns related to 340B revenue and adequate pharmacy reimbursement are especially strong	✓	✓	✓	✓	✓	✓	✓	✓

Board Considerations

Myers and Stauffer provided a number of considerations for the Board to evaluate as it moves forward. These considerations are not exhaustive and, in many cases, would require the Board to work with legal counsel to understand the implications of certain policies and to identify the appropriate legal authority required to implement them (i.e., statutory and/or regulatory). Specifically, the Board may wish to consider: (1) conducting additional outreach and collaboration with constituents; (2) assessing the risk that a UPL would compromise patient access and that savings would not be realized by patients, and developing corresponding mitigation strategies; (3) assessing whether and to what extent protections could be established that ensure any UPL-generated cost savings are not the result of reductions in payment to providers; (4) working with constituents to assess currently available data and identify opportunities for enhancement, including establishing confidentiality protections for constituents willing to share private data; (5) directly engaging pharmacy providers and other impacted entities to better understand the financial and administrative impact of system and staffing changes, and assess opportunities to make a UPL immediately applicable to current contracts; and (6) assessing the feasibility of implementing alternative and/or complementary solutions to improve drug affordability. Each of these recommendations is outlined in greater detail in the body of this report.

Background

The Oregon Prescription Drug Affordability Board was established in 2021 through Senate Bill 844. The purpose of the Board is to protect residents of Oregon, state and local governments, commercial health plans, health care providers, pharmacies licensed in Oregon, and other stakeholders within the health care system from the high costs of prescription drugs. The Board is responsible for annually identifying and reviewing nine drugs and at least one insulin product that may create affordability challenges for the healthcare systems or high out-of-pocket costs for patients in Oregon. In June 2023, the Oregon Legislature passed Senate Bill 192, which tasked the Board with developing a plan to establish UPLs on drugs sold in the State that are subject to the Board's affordability reviews. The Board must report its plan to the interim committees of the Legislative Assembly related to health in fall 2024. In December 2023, the Board, acting through the Department of Consumer and Business Services, Division of Financial Regulation, contracted with Myers and Stauffer (PO-44000-00028053) to provide prescription drug consulting and outreach services related to the Board's Senate Bill 192 obligations. As part of these services, Myers and Stauffer is responsible for capturing the perspectives of constituents throughout the pharmaceutical supply chain regarding a UPL, and creating a report that includes a table of recommendations, concerns, and obstacles identified, and an executive summary. While interrelated with the concept of a UPL, the focus of Myers and Stauffer's outreach was not to solicit feedback regarding the Board's affordability reviews; however, constituents did provide considerable feedback on this topic, which we have incorporated into our analysis where appropriate. In addition, the Board also hosted in-person and online community forums across Oregon to specifically engage consumers regarding the high cost of prescription drugs and its effect on Oregonians' lives, health, and budgets.[1]

[1] CONSUMER OUTREACH REPORT, PRESCRIPTION DRUG AFFORDABILITY BOARD (June 17, 2024), *available at* https://dfr.oregon.gov/pdab/Documents/reports/PDAB-Consumer-Report-2024.pdf.

Approach

Constituent engagement is a critical component in health systems research, one that can assist in reducing the gap between research and practice. While constituent engagement activities typically occur during the problem identification and goal setting phases of a new initiative, participation in the planning and implementation phases may strengthen constituent capacity and produce unique insights. Given the complexity of the subject matter associated with development of a UPL plan, the unique experiences of constituents, and the potential for unintended consequences associated with a UPL, Myers and Stauffer leveraged the following approach to solicit constituent input.

Constituent Identification

Seven groups were formed to capture perspectives of constituents throughout the pharmaceutical supply chain: CEs, carriers, hospitals, patient advocacy groups, pharmaceutical manufacturers, pharmacy benefit managers (PBMs), and retail pharmacies.[2] The table below provides a brief description of each identified constituent group.

Table 2. Constituent Groups

Constituent Groups	
Constituent Group	**Description**
340B CEs[3]	This constituent group was intended to capture the perspective of organizations participating in the federal 340B Drug Pricing Program, and their affiliated associations. The Program requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to organizations that provide care for uninsured and low-income patients (i.e., statutorily defined CEs). The Program is designed to allow CEs to stretch limited federal resources to reduce the price of outpatient pharmaceuticals for patients and expand health services to the patients and communities they serve.
Carriers	This constituent group was intended to capture the perspective of insurance carriers licensed in Oregon through the Division of Financial Regulation. The Division is responsible for protecting consumers and regulating insurance, depository institutions, trust companies, securities, and consumer financial products and services. This group included carriers providing services for both commercial and government-sponsored health plans.
Hospitals	This constituent group was intended to capture the perspective of hospitals and health systems providing services throughout Oregon. The group included both hospital leadership and pharmacy representatives to provide input regarding inpatient and outpatient pharmacy services.
Patient Advocacy Groups	This constituent group was intended to capture the perspective of both state and national advocacy organizations representing specific diseases or populations. These groups assist patients, their families, and their caregivers in navigating the health care system, working to ensure patients receive appropriate and timely care, education, and financial assistance, when needed.

[2] Pharmaceutical manufacturers and related entities, pharmacy benefit managers, and patient advocacy constituent groups were added through a subsequent contract amendment in May 2024.

[3] Statutorily defined CEs include various provider types such as Federal Qualified Health Centers (FQHCs) and certain hospitals/health systems (e.g., Disproportionate Share Hospitals, children's hospitals, etc.). As such, CEs were often represented in other constituent groups (e.g., Hospitals and pharmacies).

Constituent Groups	
Constituent Group	**Description**
Pharmaceutical Manufacturers	This constituent group was intended to capture the perspective of drug manufacturers and representatives from professional organizations representing manufacturers. In addition to the research, development, manufacturing and distribution of innovator drug products, these companies have direct impacts on drug affordability issues through gross and net pricing approaches, as well as through implementation of patient and co-pay assistance programs.
PBMs	This constituent group was intended to capture the perspective of PBMs and affiliated advocacy organizations. PBMs are responsible for managing drug benefits on behalf of health insurers, government-sponsored benefit plans, large employers, and other payers, and use various approaches to achieve cost savings (e.g., rebates and volume discounts, either fully or partially passed back to plan sponsors; utilization management tools; leveraging of large networks of pharmacies for advantageous pricing; etc.).
Retail Pharmacies	This constituent group was intended to capture the perspective of pharmacies dispensing drugs to Oregonians. Although, originally established as a single group, it was determined to create sub-groups, one for independent pharmacies and one grocery/chain pharmacies, following dissemination of the pre-session surveys. As such, survey results do not differentiate between pharmacy types. In addition, following the first focus group meeting for each of these sub-groups, entities that support pharmacy providers with drug purchasing were also included. The independent pharmacy provider sub-group group was expanded to include group purchasing organizations (GPOs) and pharmacy services administrative organizations (PSAOs), and the grocery/chain pharmacy provider sub-group was expanded to include drug wholesalers.[4]

Mechanisms for Engagement

Once the above structure was finalized, it was determined that Myers and Stauffer would develop and administer an informal survey and facilitate two, one-hour virtual focus group meetings per constituent group, to identify perceptions regarding strengths, weaknesses, opportunities, and threats associated with a UPL methodology. Each of these mechanisms are described in detail below.

Pre-Session Survey[5]

Myers and Stauffer leveraged Qualtrics, a cloud-deployed survey platform that provides distribution, tracking, and response analytics. Emails were sent to targeted constituents that included a link to the survey, a narrative introduction, as well as an attached document describing the Board's purpose, its rationale for engaging constituents, and an overview of the UPL concept describing how it was intended to represent the maximum amount to be paid for a prescription drug throughout the supply chain. The survey leveraged branching or "skip logic" to create individualized paths for survey recipients based on their respective constituent group. In addition, recipients were encouraged to forward the email if they were not the most appropriate person to respond. The surveys were not intended to collect data in a manner that would allow for complex statistical analysis.

[4] Group purchasing organizations represent groups of drug purchasers, and negotiate on behalf their clients for either up-front, on-invoice discounts or back-end rebates. Similar to a GPO, PSAOs negotiate purchasing on behalf of independent pharmacies, but also support drug price negotiations with pharmacy benefit managers and provide a variety of administrative services. In addition, the grocery/chain pharmacy provider sub-group was expanded to include drug wholesalers. Wholesalers purchase drugs directly from manufacturers, then resell either direct to provider-purchasers, or resell to smaller, regional distributors for regional or local distribution.

[5] A sample survey is included as *Appendix A*.

Each survey included four mandatory questions designed to collect respondent demographic information. In addition, each survey included a series of non-mandatory Likert scale questions and multiple response questions designed to measure respondent perspectives toward particular questions or statements, as well as seven free-text questions to allow recipients to provide more detailed information on approaches, recommendations, or concerns. Some multiple choice and free-text response questions included "if applicable" or "not applicable" as a response option.

Surveys were initiated April 24, 2024, and closed June 30, 2024. As previously described, survey responses were intended to inform and support focus group discussions; therefore, data was analyzed throughout the outreach process. While performing this analysis, invalid responses were excluded from review. For example, there were a number of respondents who submitted multiple identical responses. In these instances, only one response was reviewed. Similarly, there were a number of respondents who did not answer questions beyond the initial mandatory questions or who answered some, but not all, non-mandatory questions. In both of these instances only completed questions were reviewed. Lastly, responses to non-mandatory questions that did not contain valid data (e.g., Lorem ipsum or clearly unresponsive text such as "text") were excluded from review.

Focus Group Meetings[6]

Myers and Stauffer conducted two focus group meetings for each constituent group throughout May, June, and July 2024. All meetings were recorded, though attendees were given the option to request that the recording be paused at any time. Further, attendees were informed that meetings were designed to solicit feedback, and facilitators indicated that any questions should be directed to the Board using an email address that was provided or via the Board's website. Meetings were facilitated by Myers and Stauffer subject matter experts, who were supported by scribes and logistics coordinators.

Facilitators began each meeting with a brief presentation describing the Board's purpose, its rationale for engaging constituents, as well as an overview of the UPL concept and how it was intended to represent the maximum amount to be paid for a prescription drug throughout the supply chain. Presentation materials were generally consistent across focus groups, with minor adaptations to address the specific context of each group. Following the presentation, facilitators asked attendees a series of pre-scripted questions designed to solicit their perspectives on the use of UPLs and to gather recommendations for improving drug affordability for Oregonians. Questions, while tailored to each constituent group, were generally organized around the following topics:

- *Impact of Drug Affordability (e.g., what does "affordability" mean to your organization, how do the costs of drugs impact your organization and/or your stakeholders)*
- *Impact of a UPL (e.g., what impact would a UPL have on your organization's finances, what impact would a UPL have on your operations, what impact would a UPL have on patient access)*
- *UPL Methodologies (e.g., what data or other factors should the Board consider when calculating a UPL, how should transparency be demonstrated when calculating a UPL)*

[6] A sample meeting agenda, UPL overview, presentation, script, and list of questions are included as *Appendices B – F*.

- *Desired State of Drug Affordability (e.g., how should a UPL program be evaluated)*
- *Recommendations and Other Strategies (e.g., what recommendations do you have regarding a UPL, what other non-UPL strategies should the Board consider to address drug affordability)*

Synthesis of Feedback

Leveraging the approach described above, Myers and Stauffer collected and analyzed survey responses, along with detailed focus group notes, to produce a high-level synthesis of constituent group feedback. The discussion below is presented by engagement mechanism. Where appropriate, qualitative data from surveys and focus groups are organized around key themes including the impact of drug affordability, the impact of a UPL, implementation of a UPL, UPL methodology, and the desired state of drug affordability.[7] Per contractual requirements, constituent recommendations, concerns, and obstacles are presented as Tables in the Section that follows. Summary reports were developed following each focus group session to provide real-time insight regarding feedback received. These reports are provided as supplements to this report in *Appendix G*.

Survey Analysis: Quantitative Data

Myers and Stauffer reviewed quantitative data collected through non-mandatory Likert scale questions and multiple response questions in constituent group surveys. Survey response data were exported from Qualtrics in a Microsoft Excel file format for analysis. As noted above, invalid responses were excluded from review. A total of 856 surveys were sent approximately 2-3 weeks in advance of the first session for each constituent group. Recipients were encouraged to forward the survey to colleagues. A total of 106 responses were received.

Table 3. Survey Participation

Survey Participation		
Constituent Group	**Surveys Sent**	**Responses Received**
340B CEs	34	20
GPOs	4	0
Hospitals	51	17
Insurers/Carriers	53	6
Patient Advocacy Organizations	60	11
Pharmaceutical Manufacturers	56	7
Pharmacies (Independent, Grocery, and Chain)	429	39
Pharmacy Benefit Managers	159	5
PSAOs	6	1
Wholesalers	4	0
Total	856	106

Survey responses were reviewed at a high level, focusing on response frequency, and were not weighted or analyzed for statistical significance. The following represent key points of feedback:

- *Fifty of 106 survey responses contained answers to every non-mandatory question. Fifty-six survey responses did not contain answers to every non-mandatory question.*

[7] Free text survey questions did not solicit feedback regarding impact of drug affordability nor the desired state of drug affordability.

- *Of the groups that received the question (all constituent groups excluding manufacturers), 81 of 99 responses indicated they were very concerned about the impact of the cost of drugs on their organization. Eleven responses indicated they were somewhat concerned, three responses indicated they were not concerned, and four responses were blank.*

- *Seventy-nine of 106 responses indicated that they were very concerned about the impact of the cost of drugs on their patients or members. Seventeen responses indicated they were somewhat concerned, three responses indicated they were not concerned, and seven responses were blank.*

- *Fifty of 106 responses indicated a UPL would have a negative impact on their organization's spending and budgetary concerns. Thirty-four responses indicated a neutral impact, 11 responses indicated a positive impact, and 11 responses were blank.*

- *Fifty-seven of 106 responses indicated a UPL would create challenges to patient access to medications. Twenty-three responses indicated a neutral impact, 22 responses indicated a positive impact, and four responses were blank.*

- *Fifty of 106 responses indicated a UPL would have a neutral impact on patients' ability to afford their medications. Twenty-eight responses indicated a negative impact, 24 responses indicated a positive impact, and four responses were blank.*

- *Eighteen of 20 responses indicated the implementation of a UPL would have a negative impact on their organization's 340B program. Two responses indicated a neutral impact.*

- *Eleven of 17 hospital responses indicated a UPL would have a negative impact on their drug procurement and supply chain management. Five responses indicated a neutral impact, and one response indicated a positive impact.*

- *Eight of 17 hospital responses indicated a UPL would have no impact on their chargemaster (i.e., comprehensive listing of items billable to a patient or a patient's health plan) prices. Seven responses indicated prices would decrease, and two responses indicated prices would increase.*

- *Nineteen of 39 pharmacy responses indicated a UPL would have a negative impact on their revenue and financial viability. Fifteen responses indicated a neutral impact, and five responses indicated a positive impact.*

- *Three of five PBM responses indicated a UPL would have a neutral impact on their revenue and financial viability. Two responses indicated a negative impact.*

Survey Analysis: Qualitative Data

Myers and Stauffer also reviewed qualitative data collected through free-text responses in constituent group surveys. Again, survey response data were exported from Qualtrics in a Microsoft Excel file format, and invalid responses were excluded from review. We leveraged a systematic, multi-step process to ensure thoroughness and reliability of our analysis. First, multiple subject matter experts (SMEs) reviewed responses to identify key themes present in the responses. Once themes were identified, an initial reviewer examined and categorized all responses into one or more of the identified themes. To ensure accuracy and consistency, a second SME independently reviewed each response to ensure assigned themes were appropriate and to mitigate potential errors or biases that may have existed during the initial review.

Impact of Upper Payment Limit

Respondents were asked two questions about the potential impact of a UPL. First, they were asked whether a UPL would create meaningful cost savings throughout the supply chain. In total, 85 responses to this question were received from pharmacies, patient advocacy groups, hospitals, and pharmaceutical manufacturers. Responses generally failed to answer the specific question asked, and instead referenced revenue, access, and patient cost concerns; however, 14 respondents specifically stated that the believed a UPL would not create meaningful savings. Second, respondents were asked how they would use savings generated from a UPL. In total, 87 responses to this question were received across all constituent groups. Again, responses generally failed to answer the specific question asked, instead referencing revenue concerns; however, approximately 40% specifically stated that they believed a UPL would not result in savings. Note, pharmacies, CEs, and hospitals were more likely to make this statement.

Revenue

Several respondents expressed the belief that a UPL would negatively affect pharmacy revenue and that a UPL plan must ensure fair and equitable ingredient reimbursement, as well as an adequate professional fee or dispensing fee. At least one CE and two manufacturer respondents expressed concern that a UPL would negatively affect 340B revenue, thereby limiting CEs ability to provide costly non-reimbursable services. Few respondents that indicated a UPL would improve revenue; however, those who did suggested that savings would be used to increase drug stock, make facility improvements, increase staffing, and/or expand non-reimbursable service offerings.

Access

Multiple respondents expressed concern that a UPL would limit access to medications. The most commonly cited causes were manufacturer withdrawal from the Oregon market, changes in benefit design as payers or PBMs shift formularies to non-UPL products, and potential exacerbation of pharmacy closures due to revenue loss.

Patient Costs

At least a dozen respondents, across all constituent groups, expressed the belief that a UPL would have no impact on patient costs; however, an almost equal number indicated that a UPL could result in cost savings if implemented with appropriate protections. Regarding the latter, several respondents suggested the Board “pass through” UPL savings to consumers, ensure fair and equitable ingredient reimbursement for providers, and levy penalties against manufacturers who refuse to sell products at or below the UPL. In addition, one respondent noted that a UPL could be particularly helpful to patients on a fixed income, as it would likely result in more predictable out-of-pocket expenses.

Implementation of Upper Payment Limit

Pricing changes to several products (e.g., insulin) in recent years suggest considerable flexibility in the supply chain. As such, respondents were asked about implementation of a UPL, specifically whether they anticipated administrative burdens or operational challenges and, if yes, what could be done to mitigate those challenges. In total, 86 responses were received across all constituent groups. Respondents expressed a variety of concerns largely related to complexity of the supply chain, infrastructure, and contracting; however, at least one also noted that a UPL could increase provider burden if patients need to change therapies due to product availability, formulary changes, or increased utilization management.

Regarding complexity of the supply chain, one respondent expressed the belief that a single UPL would not account for the differences between the types of pharmacies dispensing medications (i.e., independent versus chain), which often have different operating costs. Another respondent noted that some pharmacies have locations in multiple states and, similarly, that many pharmacies leverage wholesalers with operations in multiple states. As a result, the respondent was concerned that pharmacies may need to maintain separate stocks for UPL and non-UPL products and that smaller wholesalers might have difficulty supplying drugs in Oregon.

Numerous respondents expressed concerns regarding infrastructure costs noting that system upgrades would be required to support a new basis for pricing. Respondents further indicated there would be increased administrative burden associated with maintaining multiple pricing lists and new pricing structures within those systems. There was also an associated concern that a UPL would require increased staffing to ensure that wholesalers or manufacturers were providing the appropriate UPL cost of goods and that claims were reimbursed appropriately. Lastly, several respondents cited contracting concerns regarding increased administrative burden associated with managing medication quotas put in place by manufacturers or wholesalers, maintaining multiple supplier contracts for UPL and non-UPL products, and aligning contract terms with UPL implementation schedules.

Upper Payment Limit Methodologies

Respondents were asked what specific factors the Board should consider when developing a UPL methodology. In total, 71 responses were received across all constituent groups. While the majority of respondents continued to express concerns regarding transparency, ensuring adequate reimbursement, and maintaining access, several specifically suggested that the Board ensure it had a thorough understanding of the drug supply chain before establishing a UPL methodology. Specifically, respondents noted that the Board should carefully account for the flow of revenue through the supply chain, consider the possibility that manufacturers would increase costs on non-UPL affected drugs to make up for any UPL-related losses, and evaluate the potential for lost pharmacy revenue should reimbursement not cover costs or should PBMs implement additional fees or clawbacks in response to a UPL.

Focus Group Analysis

As previously described, Myers and Stauffer conducted two engagement sessions for each constituent group throughout May, June, and July 2024. A total of 675 invitations were sent, and recipients were encouraged to forward the invitation to colleagues. A breakdown of attendance by constituent group, including unique organizations represented, is provided in the table below.

Table 4. Meeting Participation

Meeting Participation			
Constituent Group	**Date**	**Participants**	**Unique Organizations**
Carriers	May 16, 2024	9	5
Retail Pharmacies (Independent Only)	May 16, 2024	8	7
Hospitals	May 20, 2024	11	5
340B Covered Entities (CEs)	May 22, 2024	20	14
Carriers	May 29, 2024	7	5
Retail Pharmacies (Grocery/Chain Only)	May 29, 2024	4	3
Hospitals	May 30, 2024	7	5
340B Covered Entities (CEs)	May 30, 2024	17	14
Retail Pharmacies (Grocery/Chain and Wholesalers)	June 5, 2024	2	2
Retail Pharmacies (Independent, GPOs, and PSAOs)	June 12, 2024	4	4
Pharmaceutical Manufacturers	July 1, 2024	18	11
Patient Advocacy Groups	July 1, 2024	7	7
PBMs	July 2, 2024	0	0
Pharmaceutical Manufacturers	July 10, 2024	15	10
Patient Advocacy Groups	July 11, 2024	7	7
PBMs	July 16, 2024	4	4

Interaction during each of the above meetings varied. For example, some meetings were highly interactive with participants freely engaging one another and facilitators, offering to provide additional information, as well as asking questions and/or making recommendations. During other meetings, however, participants were silent and did not respond to any of the facilitators' questions.[8] What follows are high-level areas of feedback from discussions.

Impact of Drug Affordability

The impact of drug affordability on participants and their stakeholders was cited as a concern throughout all constituent group meetings, but generated considerably less feedback than other topics, such as the impact or implementation of a UPL. Generally, participants agreed that certain drugs created affordability challenges for many consumers; however, there was not an agreement as to the definition of affordability or how it should be determined. Specific challenges included high insurance premiums due to corresponding high-cost drugs, high co-payments, and benefit designs that required the use of branded drugs. With respect to co-payments, one participant representing an FQHC in a CE session suggested that affordability for their patients was defined as "a cost of $4 or less" and that, in their experience, "the FQHC's patient population was extremely sensitive to changes in cost-sharing."

[8] There was no feedback provided during June 5th meeting with grocery/chain pharmacies, and little feedback provided during the May 29th meeting with carriers. Further, while six participants registered for the July 2nd PBM meeting, none attended.

While manufacturer participants did not provide specific feedback on the impact of affordability on consumers, they did highlight their collective efforts to address these challenges. For example, one manufacturer participant noted that the industry collectively offers over 900 patient assistance programs (PAPs) designed to provide free or low-cost drugs to low-income consumers who do not qualify for government-sponsored health care programs such as Medicare or Medicaid, and cost-sharing assistance programs designed to provide financial support for consumer deductibles, co-payments and co-insurance to those with private health insurance. In addition, another manufacturer participant cited price concessions provided through various programs (e.g., 340B), as well as contractual rebates and discounts offered to insurers and PBMs, as evidence of their efforts to improve drug affordability. When asked if these amounts could be quantified, manufacturer participants cited contractual confidentiality requirements, yet stated that on average rebates account for cost savings of approximately 50% for branded products and as much as 80% on highly rebated products.

Impact of Upper Payment Limit

Across all focus groups, participants frequently indicated that drug affordability was a concern, though they were unsure how to assess the impact of a UPL on drugs dispensed in Oregon, particularly given the strategy remains theoretical (i.e., no state has implemented and consequences are unknown). Many also stated that it was challenging to respond to focus group questions without understanding how a UPL would be developed or implemented in Oregon. Of those who directly addressed the impact of UPL, many expressed concerns regarding loss of revenue and decreased access to much needed drugs. These concerns are further detailed below.

Revenue

Though a distinct constituent group, 340B CEs also attended other group meetings (e.g., hospital and retail pharmacy). Many spoke at length during these meetings about the use of 340B program savings to enhance their missions, and expressed concerns that a UPL would have a negative impact on their communities. For example, CE participants indicated that 340B savings were used to support critical providers and services that would otherwise not be available including, but not limited to, clinical pharmacists, reduced co-pays, mobile clinics, community health workers, behavioral health providers, nutritionists, and food pantries, all of which are generally non-billable/reimbursable. Further, CE participants noted that the loss of revenue would require additional state investments to support continued operations. Finally, CE participants expressed concerns that pending changes to the Medicare program, specifically implementation of the Medicare Drug Price Negotiation Program, would intersect with state UPLs and/or further erode 340B program savings.[9]

A number of CE participants also spoke at length about the differences between hospital CEs (i.e., children's, critical access, disproportionate share, free standing cancer, rural referral, and sole community) and non-hospital entities, otherwise known as "340B grantees" (i.e., federally qualified health centers, Ryan White HIV/AIDS programs, and five types of specialized clinics). Unlike most hospital CEs, 340B grantees are not required to meet a threshold of underserved patients, rather they qualify for the program based on their status as federal grantees. Additionally, 340B grantees are statutorily required to redirect program savings into programs and services for patients, whereas

[9] The Inflation Reduction Act permits Medicare to negotiate the price of certain high expenditure, single source drugs covered under Part B or Part D. For manufacturers of selected drugs, CMS will establish maximum fair price (MFP), taking into account a variety of factors including the value of the medication and the availability of therapeutic alternatives. Inflation Reduction Act of 2022 (P.L. 117-169).

hospital CEs are not. Participant CEs indicated that, given this distinction between CEs, a UPL could have a disproportionate impact on 340B grantees.

Additionally, several constituent groups including CEs, independent non-340B pharmacies, and patient advocacy groups expressed concerns that a UPL could have a negative impact on their revenue should PBMs and payers not be required to reimburse providers, minimally, at the UPL rate. This is of particular concern for pharmacies reimbursed outside of the Medicaid fee-for-service program, as these amounts are highly dependent on contractual terms established between providers and PBMs. These contracts may be negotiated independently or, as is common for independent pharmacies, through PSAOs. Further, reimbursement is typically based upon a price for the drug, generally a discount from published prices such as wholesale acquisition cost (WAC), average wholesale price (AWP), or maximum allowable cost (MAC), plus a dispensing fee. Prescriptions covered by insurance also include a cost-sharing amount, often in the form of a co-payment.

Access

Several pharmacy, carrier, CE, PBM, and manufacturer participants expressed concern regarding a UPL, particularly if applied to a single-agent drug in a class with multiple competitors. Specifically, participants suggested that this could result in a shift of utilization to a non-UPL drug, thereby neutralizing any savings and creating challenges for patient access to certain drugs and/or established therapy options. For example, multiple biologic agents (e.g., Humira®, Enbrel®, Orencia®, and Cimzia®) are approved for use in rheumatoid arthritis. Participants were concerned that a UPL on one of these drugs could prompt plan administrators to require that patients switch to a non-UPL agent, or that the drug with the UPL would become unavailable to them as a treatment option.

Similarly, a number of patient advocacy organization participants referenced the rise in alternative funding programs (AFPs), which are marketed to, and used by, employer-sponsored health plans to control the cost of high-cost drugs. When leveraging an AFP, health plans exclude pharmacy benefit coverage for select high-cost drugs and AFP administrators redirect members to manufacturer PAPs. Participants suggest that AFPs negatively impact patient access due to income-based eligibility requirements, limited coverage of provider administered specialty medications, and interruptions in coverage. Given the untested impacts of a UPL, participants expressed concern whether a UPL would resolve or exacerbate the concerns raised by the use of AFPs.

In addition to changes in benefit design, a number of participants across constituent groups expressed concern that a UPL program could disrupt certain supply chain transactions, having a negative impact on patient access to medications. For example, patient advocacy organization, hospital, and pharmacy participants suggested that, in an effort to protect revenue, manufactures might refuse to sell certain UPL-affected products in the State. Likewise, hospital participants expressed concern that wholesalers might be unwilling to purchase drugs from manufacturers if their contracted acquisition cost is above a state UPL, thereby making it difficult for in-state pharmacies to acquire UPL-affected drugs.

Lastly, while not a dominant topic of discussion, several constituent group participants expressed concern that a UPL could directly impact “best price” provisions in the Medicaid Drug Rebate Program (MDRP), and thereby limit access to UPL-affected drugs in the State. The MDRP, authorized by Section 1927 of the Social Security Act, requires that drug manufactures enter into a rebate agreement with the Department of Health and Human Services in exchange for state Medicaid coverage of most of the

manufacturer's drugs.[10] The rebate amount is set in statute and is designed to ensure that the Medicaid program receives the "best price" available in the marketplace (i.e., the lowest price offered to any U.S. purchaser during a rebate period). In effect, if a manufacturer offers a discount in excess of this rebate amount, for example a UPL lower than the current national best price, the manufacturer's rebate liability would increase in all 50 states. Participants suggest that this would likely dis-incentivize manufactures to do business in Oregon.

Patient Costs

Pharmacy, patient advocacy organization, and manufacturer participants expressed the belief that insurers would likely adjust formulary management practices in response to a UPL, thereby increasing patient costs. Formularies are lists of drugs covered by an individual health plan. Typically, these lists are divided into categories or tiers based on the type of drug (i.e., generic, preferred brand, non-preferred brand, and specialty), with lower tiers having the lowest consumer out-of-pocket costs and higher tiers having the highest. Although the goal of health plans is to provide cost-effective care management, participants suggested that health plans are often incentivized to prefer higher-priced brand drugs over less expensive alternatives, because the latter may offer greater manufacturer price concessions via rebates. Similarly, participants noted that specialty drug coverage varies between health plans' medical and pharmacy benefits and, while health plans often shift coverage between benefits to control spending, they have different implications for consumer out-of-pocket costs (i.e., placement of a drug on the medical benefit creates coinsurance cost-sharing, whereas keeping a drug on the pharmacy benefit creates co-payments). Though not related to benefit design, patient advocacy organization participants also expressed concern that a UPL might result in manufacturers reducing funding for PAPs. Lastly, participants across nearly every constituent group expressed the need for transparency regarding implementation of a UPL, with many explicitly stating that all savings should be returned to consumers, and not result in additional revenue for other supply chain entities.

Implementation of Upper Payment Limit

Constituent groups rarely agreed on specific points regarding the development and implementation of a UPL; however, delivery system complexity and administrative burden were most frequently cited as concerns. Regarding the former, several constituent group participants expressed the belief that a state-based solution, particularly a UPL, was not likely to have a significant impact on drug affordability and that due to the complexity of the drug supply chain, with its interconnected web of rebates, contracts, and intermediaries, a national solution was required.

Similarly, geographic considerations regarding how care is delivered and accessed may result in unintended consequences. For example, participants noted that consumers frequently access health care across state lines and that Washington, Idaho, Nevada, and California would not be subject to Oregon-specific UPL requirements. Patient advocacy group participants cited specialty drugs with limited distribution (e.g., cell and gene therapies) as a primary concern, given these drugs are often administered in regional centers of excellence outside of Oregon. These participants also noted that buying groups often include members from other states, and that a UPL could create administrative challenges. For example, the buying group would be responsible for applying varied contract terms and

[10] State Medicaid coverage is also contingent upon drug manufacturers entering agreements with the Health Resources and Services Administration for the 340B Program and the Secretary of Veterans Affairs for the Federal Supply Schedule.

controlling who receives a UPL discount. Further, participants suggested that extracting Oregon utilization from a buying group contract could negatively affect members outside of the State.

Several participants expressed concerns regarding administrative burden stating that adding a UPL to existing complex processes, in a highly regulated environment, would increase the level of effort required to serve patients and perform routine business operations. For example, hospital participants suggested that a UPL would impact transactions in pharmacies with both in-state and out-of-state locations, as well as in-state pharmacies using out-of-state central fill locations and, conversely, out-of-state pharmacies using in-state central fill locations. Hospital participants also cited the level of effort associated with updating and maintaining chargemasters and billing algorithms to implement a UPL. While it is not uncommon for hospitals and other providers to account for different reimbursement methodologies, it was unclear to respondents as to how the UPL would be implemented, and therefore, how they would address the challenges of implementation. Similarly, pharmacy participants noted that point-of-sale systems changes could require in excess of six months to implement a UPL. Lastly, carrier and pharmacy participants highlighted the complexities and time associated with contracting, which takes in excess of twelve and six months, respectively.

Upper Payment Limit Methodologies

Across all constituent groups, participants found it challenging to discuss UPL methodologies and frequently requested information regarding how a UPL would be developed and implemented. Two key themes emerged from these discussions, specifically how affordability would be defined and how the Board would ensure a UPL was enforced. Regarding the former, which was not intended as the focus of this outreach, patient advocacy and manufacturer participants felt that it was important for the Board to clarify whether improved affordability would be demonstrated through system or consumer-level cost savings (i.e., reductions in co-payment, out-of-pocket, or premiums). Further, manufacturer participants mentioned a need to include “cost-avoidance” in the evaluation of any drug for affordability (i.e., the cost of avoiding future health care expenditures), particularly as it relates to therapies that may be curative or mitigate the severe impacts of a disease (e.g., cell and gene therapies). Regarding UPL enforcement, participants in virtually all constituent groups expressed a strong desire to understand how the Board would enforce a UPL throughout the supply chain, with recommendations including increased transparency of affordability reviews and public reporting to demonstrate UPL compliance and that savings were realized by consumers.

Desired State of Affordability

Respondents were asked about the desired state of affordability, what an ideal affordability or UPL program might look like, and the outcomes needed for a program to be considered successful. This discussion generated very little specific feedback, likely due to participant hesitancy to comment on a program that they admittedly don’t understand. There was a suggestion in the independent pharmacy session that a desired state would be ensuring that the program accomplishes the goal of increasing access to medications for patients. Conversely, there must be an understanding and anticipation of potential unintended consequences. For example, if manufacturers eliminate or reduce PAPs in response to the UPL, and the potential for such changes is not considered when calculating a UPL, then a new affordability challenge could be created where one didn’t exist before.

Table of Recommendations

In addition to soliciting input regarding the impact of drug affordability, the impact of a UPL, implementation of a UPL, UPL methodology, and the desired state of drug affordability, constituent groups were asked in both surveys and focus groups to provide recommendations for the Board to consider regarding a UPL and/or other strategies that might be leveraged to address issues of drug affordability in Oregon. Though not intended as a focus of this outreach, numerous recommendations focused on affordability determinations and drug selection for affordability review. In addition, a number of recommendations focused on PBM reform and transparency. Several constituents also recommended strategies beyond the Board's scope of authority that would likely require federal action (e.g., regulation of direct-to-consumer advertising, prohibition of pay-for-delay arrangements, and drug patent reform). This is consistent with feedback received through both surveys and focus group meetings, where constituents suggested that federal action was necessary to resolve the issue of drug affordability, rather than states implementing varied solutions that further complicate the already complex system. The tables below provide a comprehensive listing of constituent recommendations organized by the following themes: UPL methodology/process, approach to determining affordability, transparency, UPL implementation, alternative approaches, and protections. Recommendations cited by three or more constituent groups are highlighted in bold/italic font.

Table 5. Recommendations: UPL Methodology/Process

Constituent Group Recommendations								
Recommendation	**340B CEs**	**Carriers**	**Hospitals**	**Patient Advocacy Groups**	**Pharmaceutical Manufacturers**	**PBMs**	**Retail Pharmacies (Ind./GPO/PSAO)**	**Retail Pharmacies (Grocery/Chain/ Wholesalers)**
UPL Methodology/Process								
Exempt 340B providers from UPL requirements	✓							
Focus UPLs on non-340B drugs (i.e., those ineligible for 340B purchasing such as vaccines, especially high-cost vaccines such as RSV for example)	✓							
Focus on disparities in reimbursement for high-cost infusions (e.g., hospital outpatient departments compared to physician offices) rather than setting a UPL for those products	✓							
Focus UPLs on drug classes, rather than individual drugs, especially those drugs without lower cost alternatives and those representing Oregonians highest percentage of spending		✓	✓	✓			✓	
Develop a funding formula to use savings generated by the UPL program to supplement lost 340B revenues to ensure access to critical services	✓							

Constituent Group Recommendations								
Recommendation	**340B CEs**	**Carriers**	**Hospitals**	**Patient Advocacy Groups**	**Pharmaceutical Manufacturers**	**PBMs**	**Retail Pharmacies (Ind./GPO/PSAO)**	**Retail Pharmacies (Grocery/Chain/ Wholesalers)**
UPL Methodology/Process								
Focus UPLs on generic drugs with relatively high price points or brand name drugs that are lower priced but still unaffordable (e.g., epinephrine, enoxaparin, some third generation cephalosporins, Narcan®, glucose test strips, etc.)	✓							
Model the UPL impact to each constituent group before implementing	✓							
Add patients, clinicians, and pharmaceutical manufacturers to the affordability review and UPL planning processes					✓	✓		
Use Oregon-specific data in developing UPL benchmarks rather than relying on national pricing benchmarks and consider adopting the Medicare Maximum Fair Price	✓				✓			
Work with constituent groups to identify data and/or other relevant information from carriers and PBMs that would support the Board's work, and develop corresponding protections to ensure confidentiality of those data and/or information					✓	✓		
Incorporate lessons learned from other state PDABs into the Board's affordability reviews and UPL planning processes		✓		✓			✓	
Assess market dynamics by conducting a detailed analysis of the drug market to understand pricing models, manufacturing costs, and profit margins of pharmaceutical companies to help set a UPL that doesn't compromise access	✓							
Differentiate UPLs based on availability of therapeutic alternatives to address specific market failures such as monopoly pricings for drugs with no alternative	✓							
Implement tiered UPLs that reflect the varying research and development costs and societal value of different drugs, such as higher limits for innovative treatments for serious diseases and lower limits for generic or less essential medications; allow higher UPLs or exceptions for orphan drugs and treatments for rare conditions where research and development costs are significantly higher	✓							

Table 6. Recommendations: Approach to Determining Affordability

Constituent Group Recommendations								
Recommendation	**340B CEs**	**Carriers**	**Hospitals**	**Patient Advocacy Groups**	**Pharmaceutical Manufacturers**	**PBMs**	**Retail Pharmacies (Ind./GPO/PSAO)**	**Retail Pharmacies (Grocery/Chain/ Wholesalers)**
Approach to Determining Affordability								
Refine the definition of affordability considering factors such as direct and indirect costs incurred by patients (medical and non-medical); the impact of medical cost avoidance; the cost of complementary therapies; and the impact of benefit design on patient out-of-pocket expenses (such as insurance premiums and co-payments)				✓	✓			
Leverage more recent data when selecting drugs for affordability reviews and when evaluating affordability				✓	✓			

Table 7. Recommendations: Transparency

Constituent Group Recommendations								
Recommendation	**340B CEs**	**Carriers**	**Hospitals**	**Patient Advocacy Groups**	**Pharmaceutical Manufacturers**	**PBMs**	**Retail Pharmacies (Ind./GPO/PSAO)**	**Retail Pharmacies (Grocery/Chain/ Wholesalers)**
Transparency								
Ensure that the UPL is enforced across the entire supply chain (i.e., that no one pays more than the UPL), that there is transparency to the process, and that savings pass-through to patients in the form of reduced premiums or reduced drug costs is demonstrated	✓	✓		✓		✓		
Ensure transparency in affordability reviews and how UPLs are established (i.e., how the Board arrives at its conclusions); establish a periodic review process for UPLs to adapt to market changes, innovation, and economic conditions, ensuring they remain relevant and effective	✓	✓		✓		✓		
Require pharmaceutical manufacturers to provide more granular information regarding costs associated with patient assistance and co-pay assistance programs (i.e., non-aggregated data)				✓				
Require pharmaceutical manufacturers to provide cost information that clearly explains their established list prices for drugs and to disclose research and development costs, marketing expenses, and real-world outcomes to justify pricing structures	✓			✓				
Establish a centralized portal for all necessary UPL reporting to simplify the process and reduce the risk of non-compliance due to confusion or complexity, as well as for stakeholders to report issues and provide feedback on the UPL process that can be used to make iterative improvements	✓							
Implement a robust monitoring system to track the effectiveness of UPLs and their impact on drug prices, availability, and healthcare outcomes	✓							

Table 8. Recommendations: UPL Implementation

Constituent Group Recommendations								
Recommendation	**340B CEs**	**Carriers**	**Hospitals**	**Patient Advocacy Groups**	**Pharmaceutical Manufacturers**	**PBMs**	**Retail Pharmacies (Ind./GPO/PSAO)**	**Retail Pharmacies (Grocery/Chain/ Wholesalers)**
UPL Implementation								
Use a phased implementation and consider a pilot program; provide comprehensive guidance and training, maintain regular communication with all constituents, establish working groups from each constituency	✓		✓					
Establish a central purchasing system that hospitals can use to track, order, and manage UPL-affected drugs			✓					
Make grants or other state resources available to support implementation			✓					
Establish a “safe harbor” for purchasers who are unable to purchase medications at, or below, the UPL			✓					

Table 9. Recommendations: Alternative Approaches

Constituent Group Recommendations								
Recommendation	**340B CEs**	**Carriers**	**Hospitals**	**Patient Advocacy Groups**	**Pharmaceutical Manufacturers**	**PBMs**	**Retail Pharmacies (Ind./GPO/PSAO)**	**Retail Pharmacies (Grocery/Chain/ Wholesalers)**
Alternative Approaches								
Require PBMs to have a fiduciary duty to their clients (i.e., legal responsibility to protect the financial interests health plan clients)				✓	✓			
Implement fiduciary duties for health plans, PBMs, wholesalers, GPOs, and PSAOs to pharmacies/providers							✓	
Pursue comprehensive PBM reform (i.e., prohibit clawbacks, spread pricing, mandatory mail order; permit pharmacy choice, including specialty pharmacies, and a shared and common definition of specialty drugs)	✓	✓	✓	✓	✓		✓	
Require that all drug rebates be "passed through" to consumers at the point of sale					✓		✓	
Import drugs from Canada				✓				
Eliminate the use of rebates in the various levels of the supply chain	✓		✓				✓	
Leverage bulk purchasing programs				✓				
Establish a state manufacturing program (e.g., California model)				✓				
Implement a cost basis approach (i.e., eliminate rebates, 340B, and implement an acquisition cost model with fair and equitable mark-up strategies)			✓					
Modify state regulations to allow pharmacist substitution of all biosimilars (currently only allowed for interchangeable biosimilars)			✓					
Apply the Inflation Reduction Act's inflation rebate provisions at the State level			✓					
Promote value-based pricing and payment models that link the cost of drugs to their clinical effectiveness and patient outcomes	✓							

Table 10. Recommendations: Protections

Constituent Group Recommendations								
Recommendation	**340B CEs**	**Carriers**	**Hospitals**	**Patient Advocacy Groups**	**Pharmaceutical Manufacturers**	**PBMs**	**Retail Pharmacies (Ind./GPO/PSAO)**	**Retail Pharmacies (Grocery/Chain/ Wholesalers)**
Protections								
Establish a mechanism to protect patients from benefit design changes that may result from a UPL (i.e., co-pays, utilization management, formularies) and established a corresponding mechanism to ensure compliance				✓		✓		
Consider penalties for adverse actions that affect reimbursement, reduce access, negatively impact benefit design, or for reductions in the supply chain				✓		✓		
Ensure that pharmacies are paid no less than the UPL and separate the dispensing fee from the cost of the drug; dispensing fees should be adequate to cover the enhanced clinical services required for specialty drugs and the cost of drugs and services in pharmacies in general	✓		✓	✓	✓		✓	
Offer tax incentives or fast-track benefits for companies that adhere to UPL guidelines voluntarily	✓							
Establish fines or restrictions on market participation for companies that consistently price drugs above UPLs without justification and penalties for manufacturers and insurance companies that don't abide by the requirements that are put in place	✓		✓					
Strengthen current PBM regulations (i.e., penalize non-compliance)	✓							
Prohibit diversion of manufacturer co-pay assistance programs and require that payments made on behalf of patients count toward their cost-sharing burden				✓	✓			

Table of Concerns

As described throughout this report, constituent groups shared a number of concerns regarding development and implementation of a UPL. These concerns were largely focused on the potential negative impact a UPL might have on provider revenue, patient access, and supply chain operations; however, the prevailing concern, expressed across groups, was that constituents did not have enough information to understand how a drug would be deemed to be unaffordable; how a UPL would or should be established; and how a UPL would be implemented and enforced throughout the supply chain. As a reminder, affordability reviews were not the focus of this outreach. The tables below provide a comprehensive listing of constituent concerns organized by the following themes: financial impact, access and enforcement, and logistics. Concerns cited by three or more constituent groups are highlighted in bold/italic font.

Table 11. Concerns: Financial Impact

Constituent Group Concerns								
Concern	**340B CEs**	**Carriers**	**Hospitals**	**Patient Advocacy Groups**	**Pharmaceutical Manufacturers**	**PBMs**	**Retail Pharmacies (Ind./GPO/PSAO)**	**Retail Pharmacies (Grocery/Chain/ Wholesalers)**
Financial Impact								
UPL will impact revenue and limit the ability to provide cost sharing support and/or provide non-revenue generating services	✓		✓	✓			✓	
UPL will result in reimbursement below costs	✓		✓				✓	
UPL will result in financial losses that could exacerbate the issue of pharmacy deserts							✓	
UPL will result in a loss of rebates that will not be offset by decreased drug costs		✓	✓					
UPL is, in effect, illegal price setting						✓		
UPL will have a direct impact on other financial benchmarks (i.e., Medicaid rebates and 340B ceiling price calculations)					✓	✓		

Table 12. Concerns: Access and Enforcement

Constituent Group Concerns								
Concern	**340B CEs**	**Carriers**	**Hospitals**	**Patient Advocacy Groups**	**Pharmaceutical Manufacturers**	**PBMs**	**Retail Pharmacies (Ind./GPO/PSAO)**	**Retail Pharmacies (Grocery/Chain/ Wholesalers)**
Access and Enforcement								
UPL will reduce patient access to medications due to benefit design changes (e.g., preference for more highly rebated drugs when there are multiple therapeutic options)	✓	✓	✓	✓	✓	✓	✓	
UPL will incentivize patient steering to out of state pharmacies				✓			✓	
UPL will result in increased use of alternative funding programs or encourage manufacturers to withdraw from the state or to stop selling the drug in the state; wholesalers may also choose not to sell in the state if a UPL reduces revenues	✓		✓	✓	✓		✓	
There is not a current mechanism to enforce a UPL throughout the supply chain or to ensure that savings are realized by patients		✓	✓		✓	✓	✓	

Table 13. Concerns: Logistics

Constituent Group Concerns								
Concern	**340B CEs**	**Carriers**	**Hospitals**	**Patient Advocacy Groups**	**Pharmaceutical Manufacturers**	**PBMs**	**Retail Pharmacies (Ind./GPO/PSAO)**	**Retail Pharmacies (Grocery/Chain/ Wholesalers)**
Logistics								
National scope of health care, including contracting and length of contract negotiations		✓	✓	✓			✓	✓
Staffing knowledge to support appropriate product selection (i.e., staff may not have knowledge of product pricing)			✓					
Increased administrative burden	✓	✓	✓		✓		✓	
National nature of healthcare, including healthcare benefits provision, wholesaler and carrier contracting, and distribution and dispensing systems		✓						✓
Complexities of the Drug Supply Chain Security Act								✓
Theoretical nature of a UPL, especially the "manufacturer agrees to sell at UPL" concept								✓

Table of Obstacles

An obstacle is generally considered something that impedes progress or achievement, while a concern is something that causes uncertainty and apprehension. For purposes of this report, we characterized the issues raised by the constituent groups as concerns, the implication being that an opportunity exists to address and overcome them. The issues identified in the Table below, however, will require a concerted and perhaps more intense effort to reach consensus across and within constituent groups. Obstacles cited by three or more constituent groups are highlighted in bold/italic font.

Table 14. Obstacles

Constituent Group Obstacles								
Obstacle	**340B CEs**	**Carriers**	**Hospitals**	**Patient Advocacy Groups**	**Pharmaceutical Manufacturers**	**PBMs**	**Retail Pharmacies (Ind./GPO/PSAO)**	**Retail Pharmacies (Grocery/Chain/ Wholesalers)**
Differing opinions within specific constituent groups as to the impacts of a UPL and the validity of proposed solutions will likely impede the Board's ability to reach a consensus on how to proceed with the UPL process.				✓		✓		
A need to fully understand how the UPL would be developed, implemented, enforced, and updated before constituent group members could commit to supporting a UPL; the concerns related to 340B revenue and adequate pharmacy reimbursement are especially strong	✓	✓	✓	✓	✓	✓	✓	✓

Board Considerations

This report documents constituent recommendations, concerns, and obstacles as they relate to a UPL, and is intended to support the Board as it develops a plan to establish UPLs. It is important to note that, while supportive of the Board's efforts to improve drug affordability, constituents were generally reluctant to voice support for a UPL, given lack of detailed information regarding how it would be developed, applied, and enforced throughout the supply chain. Further, as one participant suggested, "a UPL is only one important part in a comprehensive overall strategy to address affordability." What follows is intended as a summary of key feedback received, along with considerations for the Board to evaluate as it moves forward. These considerations are not exhaustive and, in many cases, would require the Board to work with legal counsel to understand the implications of certain policies and to identify the appropriate legal authority required to implement them (i.e., statutory and/or regulatory).

Continued Engagement

Constituents repeatedly suggested that the Board continue to directly engage individuals and entities to clearly understand the potential impacts of a UPL and to ensure solutions are developed and implemented appropriately. Given the consistency of this feedback, and constituents' desire to bridge the gap between theory and practice, the Board may wish to consider additional outreach including, but not limited to, hosting additional constituent "panel discussions;" developing an advisory council or other formal mechanism for constituents to directly engage in and support the Board's work; as well as direct education and knowledge building opportunities such as learning collaboratives, which involve bringing together teams from different organizations and using experts to educate and coach the teams to develop new solutions, implement best practices, and measure the effects. Though not a focus of this outreach, continued collaboration with constituents may also support the Board's recent decision to assess its approach to conducting affordability reviews. For example, constituents have expressed a willingness to provide supplemental data, subject to confidentiality protections, and to help refine the Board's definition of affordability by providing the perspectives of patients and clinicians. Moreover, ongoing engagement creates an opportunity for the Board to continue to build support for its work and reinforce its purpose.

Patient Protections

Constituents expressed the belief that a UPL would compromise patient access and that any savings generated from a UPL program would not be realized by patients. The most commonly cited concerns were that carriers and/or PBMs would institute benefit changes favoring products without a UPL; that pharmaceutical manufacturers and/or wholesalers would exit the Oregon market; and that other supply chain entities would retain UPL-generated savings as profit. Given UPLs are intended to improve market function and expand access, it remains to be seen whether they would result in these unintended consequences; however, the Board may wish to consider working with legal counsel to assess the risks and develop corresponding mitigation strategies.[11] Regarding potential access issues, the Board could evaluate the feasibility of expanding the UPL concept beyond a single drug to include all therapeutic

[11] Vertex, the manufacturer of Trikafta, recently stated in a letter to the Colorado Prescription Drug Affordability Board that, "[g]iven the national market architecture for drug pricing, as a consequence of the PDAB's rules, manufacturers subject to an (upper payment limit) may have no practical choice but to withdraw from Colorado." Letter from Vertex Pharmaceuticals Incorporated to Colorado Prescription Drug Affordability Board (Oct. 2, 2023), https://drive.google.com/drive/folders/1XE9JRGHPYeov3raRVGCoCokNZiHhFBCI

alternatives, as a strategy to limit benefit changes and expand the impact of the UPL. The Board could also evaluate policies that encourage manufacturers and wholesalers to remain in the Oregon market. In Washington State, for example, any manufacturer withdrawing a UPL-affected drug from sale or distribution in the State must provide advanced notice and is subsequently prohibited from selling that drug in the State for three years.[12] Further, the Board could assess the feasibility of Oregon contracting with a dedicated wholesaler to provide access to UPL-affected drugs. With respect to cost savings, the Board could consider policies that ensure UPL-related savings are directly passed through to patients. For example, Colorado requires that any health plan savings attributable to a UPL-affected drug be used to reduce consumer costs, prioritizing out-of-pocket expenses, and that annual reports be submitted to document compliance.[13] Similarly, West Virginia requires all PBMs to reduce patient cost sharing at the point of sale equal to the amount of all rebates; to pass along any rebate beyond the defined cost sharing to the health plan to reduce premiums; and to attest that they are charging the same price for a prescription drug to a health benefit plan administered by the State.[14]

Provider Protections

Constituents expressed the belief that a UPL would negatively affect pharmacy revenue, resulting in additional pharmacy closures across the State. Independent pharmacies and CEs were particularly vocal on this point, with the latter stating that any revenue loss would directly impede their ability to provide local communities with certain non-reimbursable health care services. As such, Board may wish to consider working with legal counsel to assess whether and to what extent protections could be established that ensure any UPL-generated cost savings are not the result of reductions in payment to providers. For example, pending legislation in Michigan would allow for the creation of a Prescription Drug Affordability Board and, notably, would prohibit any third-party payer from reimbursing an independent pharmacy for a drug in an amount less than a UPL for the prescription drug product.[15] Similarly, the Board could assess the feasibility of aligning statewide drug ingredient reimbursement with Medicaid program requirements, such that pharmacies are reimbursed no less than their acquisition cost plus a reasonable professional dispensing fee.

Enhanced Data

While not the focus of this outreach, constituents expressed the belief that the Board's affordability reviews were hampered by various data limitations including, but not limited to, the recency of data used to determine drugs subject to evaluation, as well as the type of data and level of detail available to ensure accurate reviews. As described above, constituents have expressed a willingness to support the affordability review process. The Board may wish to consider working with constituents to assess current data, identify supplemental data (public or private) that would enhance the Board's reviews, and determine what confidentiality protections would be required for constituents to provide the Board with additional data. Further, the Board may wish to consider working with constituents, the Department of Consumer and Business Services, and legal counsel to determine what, if any, changes

[12] WASH. REV. CODE ANN. § 70.405.070 (2023) https://www.hca.wa.gov/assets/program/pdab-rcw-70.405-pdab.pdf

[13] COLO. REV. STAT. § 10-16-1410. (2022) https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=10629

[14] W. VA CODE § 33-51-9. (2020) https://code.wvlegislature.gov/33-51-9/

[15] Mich. Senate Bill 483 (2024) https://legislature.mi.gov/documents/2023-2024/billengrossed/Senate/htm/2023-SEBS-0483.htm

could be made to statutorily required PBM and carrier reports to assist the Board in its efforts to improve the affordability review process.[16]

Administrative Burden

Constituents expressed the belief that variations in drug pricing structures, drug purchasing arrangements, and delivery systems would make UPL implementation administratively burdensome. For example, pharmacy providers would likely need to modify claims processing systems and train staff regarding new processes for managing and dispensing UPL-affected drugs. Similarly, PBMs and carriers would likely need to update contract terms to accommodate UPL-pricing. In some instances, these entities would likely include changes to benefit design that would need to be assessed by plan sponsors and, eventually, consumers. While not insurmountable, the Board may wish to consider these activities when developing a UPL implementation plan. Specifically, the Board may wish to consider directly engaging pharmacy providers and other impacted entities to better understand the financial and administrative impact of system and staffing changes, and work with legal counsel to assess opportunities to make a UPL immediately applicable to current contracts, so as to mitigate any implementation delays that may occur as a result of annual contracting cycles.

Other Strategies

Constituents suggested that the Board consider alternative and/or complementary solutions to improve drug affordability. Most frequently mentioned were PBM reforms such as policies that ensure UPL-related savings and or rebates/discounts are directly passed through to patients, elimination of spread pricing (i.e., PBM practice of charging carriers a higher amount than is reimbursed to the pharmacy), and elimination of clawbacks (i.e., occurs when a patient's co-pay is higher than the PBM or carriers total cost for a drug, or when brand and generic "effective rates" are reconciled post-payment).[17] Further, constituents recommended that the Board evaluate UPL initiatives in other states to identify and leverage best practices. As most of these solutions have been tested in other states, the Board may wish to consider working with legal counsel to assess the feasibility of implementation in Oregon.

[16] PBMs registered in Oregon are required to provide the aggregated amount of rebates, fees, price protection payments, and any other payments the PBM received from manufacturers related to managing the pharmacy benefits for insurers issuing health benefit plans in the State. OR. REV. STAT. § 735.537 (2023) https://www.oregonlegislature.gov/bills_laws/ors/ors735.html.

[17] U.S. FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: THE POWERFUL MIDDLEMEN INFLATING DRUG COSTS AND SQUEEZING MAIN STREET PHARMACIES (Jul. 2024) https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf

Appendix A: Sample Survey

Under the authority granted by Senate Bill 192 (2023), the Oregon Prescription Drug Affordability Board (PDAB) is soliciting feedback on the use of upper payment limits (UPLs) for drugs sold in Oregon that are subject to affordability reviews. Specifically, the PDAB is evaluating a scenario whereby it would establish UPLs that leverage current discounts in the system (i.e., rebates and other price concessions), and that serve as the maximum amount to be paid by wholesalers and others in Oregon in the prescription drug supply chain, thereby supplanting the Wholesale Acquisition Cost (WAC) as the ceiling amount. When responding to the questions that follow, please consider the impact that use of a UPL might have on your organization and/or your patients or members. At the end of the survey, you will have an opportunity to provide detailed narrative responses and recommendations. This survey will not only provide input as the Board develops a model for establishing UPLs, it will also be used to guide ongoing stakeholder engagement activities.

*Name of person completing survey:

*Name of facility/entity:

*Email:

*Organization Type (Carrier, Hospital or Health System, 340B Covered Entity, Pharmacy, Pharmaceutical Manufacturer, Pharmacy Benefit Manager, Advocacy Group, Wholesaler/Distributor, Group Purchasing Organization (GPO), Pharmacy Services Administrative Organization (PSAO))

When thinking about drug affordability within your organization, how much concern do you have about the impact of the cost of drugs on your organization?

- Very concerned
- Somewhat concerned
- Not concerned
- Not applicable

When thinking about drug affordability within your organization, how much concern do you have about the impact of the cost of drugs on your patient population?

- Very concerned
- Somewhat concerned
- Not concerned
- Not applicable

How do you anticipate that an upper payment limit would impact your organization's drug spending and budgetary considerations?

- Positive impact

- Neutral impact
- Negative impact
- Not applicable

How do you perceive the potential effects of an upper payment limit on patient *access* to necessary medications?

- Create opportunities for a positive impact on patient access
- Neutral impact on patient access
- Create challenges to patient access

What kind of impact do you think an upper payment limit would have on a patient's *ability to afford* their medications?

- Positive impact
- Neutral impact
- Negative impact

What challenges might your organization face in adjusting to the constraints imposed by an upper payment limit (select all that apply)?

- Increased administrative burden
- Disruptions in drug supply chains
- Compliance with regulatory requirements
- Other (please specify)

For example, imagine a high-cost drug in a market with limited competition and few manufacturer price concessions or rebates offered. How much of a discount from wholesale acquisition cost (WAC) would an upper payment limit need to be set at to be meaningful?

- 10 percent less than WAC
- 30 percent less than WAC
- 50 percent less than WAC
- Other (please specify)

Please elaborate on your choice in the previous question.

- Free text

How do you anticipate that an upper payment limit would impact your pharmacy's revenue and financial viability?

- Positive impact
- Neutral impact
- Negative impact

The Oregon PDAB is also interested in hearing about alternative policy approaches and recommendations that you may have. The following questions will provide you with an opportunity to provide more detailed information on approaches, recommendations, or concerns.

How could upper payment limits create meaningful cost savings for all consumers and purchasers?

- Free text

How would your organization utilize savings resulting from an upper payment limit (if applicable)?

- Free text

What could be potential administrative burdens or operational challenges associated with implementing an upper payment limit?

- Free text

What recommendations, if any, do you have regarding the potential administrative burdens or operational challenges associated with implementing an upper payment limit?

- Free text

Are there alternative policy approaches that you believe would be more effective in addressing drug affordability while preserving innovation and investment in research and development?

- Free text

How can policymakers ensure that an upper payment limit policy is implemented in a manner that promotes transparency, fairness, and affordability for both payers and patients?

- Free text

What specific factors or considerations should policymakers take into account when setting an upper payment limit for prescription drugs?

- Free text

Appendix B: Sample Meeting Agenda

Pharmacy Constituent Focus Group
Session 1
May 16, 2024 9:00 AM

- Myers and Stauffer Welcome and Introductions
- Project Overview Presentation
- Constituent Focus Group Facilitated Discussion and Feedback
- Wrap Up and Next Steps

Pharmacy Constituent Focus Group
Session 2
June 12, 2024 10:00 AM

- Myers and Stauffer Welcome and Introductions
- UPL Refresher
- Constituent Focus Group Facilitated Discussion and Feedback
- Wrap Up

Appendix C: Sample UPL Overview

Oregon Upper Payment Limit (UPL) – Proposed Approach

The Prescription Drug Affordability Board is based on the public service/public utility commissions present in all states which set the amount that consumers will pay for vital public services. Upon implementation, the Oregon upper payment limit (UPL) will be applied to all supply chain participants involved in a prescription drug product being dispensed or administered within the state. These participants include wholesalers, hospitals, clinics, physician offices, pharmacies, pharmacy benefit managers, insurance carriers, health plans, and most importantly, patients.

Currently, the national supply chain for brand (patented, single source only) prescription medications is oriented around a legally defined list price set by the manufacturer called the Wholesale Acquisition Cost (WAC). All supply chain participants are eligible to negotiate their contract terms defined in relation to the WAC.

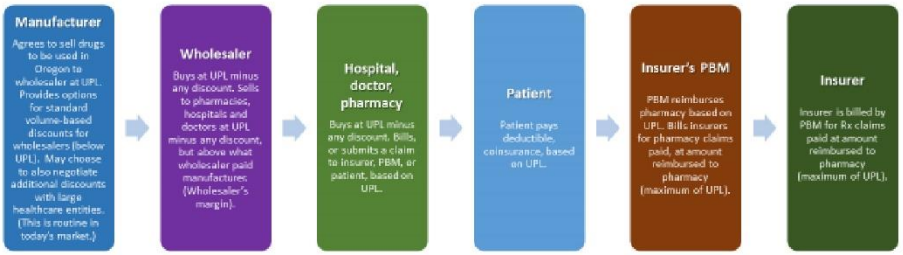
The proposed model for the Oregon UPL would be for the UPL to replace the WAC for all supply chain transactions for prescription drugs dispensed or administered within the state. Once determined, the Oregon UPL could be loaded to the same drug pricing compendia that currently serves as the industry "source of truth" for WAC pricing information. All supply chain participants would be able to amend current business processes and/or pricing algorithms to be based upon the UPL instead of the WAC.

Starting at the first transaction in the supply chain, wholesalers purchasing from manufacturers, the Oregon UPL would be the maximum amount paid by the wholesaler. The wholesaler may get a discount off the UPL, as occurs currently with the WAC. All downstream supply chain participants could purchase at or below the UPL, but not above.

The diagram on the following page demonstrates the Oregon UPL proposed model.

Horvath Health Policy. Innovations in Healthcare Financing. March 2024

Basics of UPL acquisition cost, billing, and payment



Note: UPL replaces WAC, AWP, AAC, EAC etc. UPL is the metric for all financial transactions for ingredient cost. Like existing metrics, there will be 'UPL minus' in the supply chain.

Dispensing or administration fees, independent of ingredient cost, may still be charged by pharmacies or the health care provider administering the drug to the patient.

Horvath Health Policy. Innovations in Healthcare Financing. March 2024

For an observer looking to predict downstream effects of a WAC being reset downward to the UPL (in Oregon), fortunately, there have been multiple recent examples of significant decreases in the WAC value of highly utilized prescription drug products. For example, effective 1/1/2024, the WAC value for NDC 00186037020 (SYMBICORT 160-4.5 MCG INHALER) decreased by 40 percent. The entire prescription drug supply chain needed to adjust to this significant decrease in WAC, and has since done so. All supply chain transactions for this product are now occurring at the much lower WAC, just as they had prior to the price decrease.

The implementation of an Oregon UPL would require other supply chain system changes as business processes and/or reimbursement algorithms would need to be re-based around the UPL value instead of WAC, but with respect to supply chain participants adjusting to decreases in list prices, the recent natural market events provide are a case study and a preview of the future supply chain implications of a UPL.

For 340B Covered Entities, acquisition cost would not change. Product remains available at or below the federal 340B ceiling price through the prime vendor or other source. 340B covered entities or their contract pharmacies will not be able to be reimbursed more than the UPL, consistent with all other Oregon market participants. The UPL will not be lower than 340B acquisition cost, and likely will be much higher. 340B covered entities will continue to make margin on outpatient products with a UPL.

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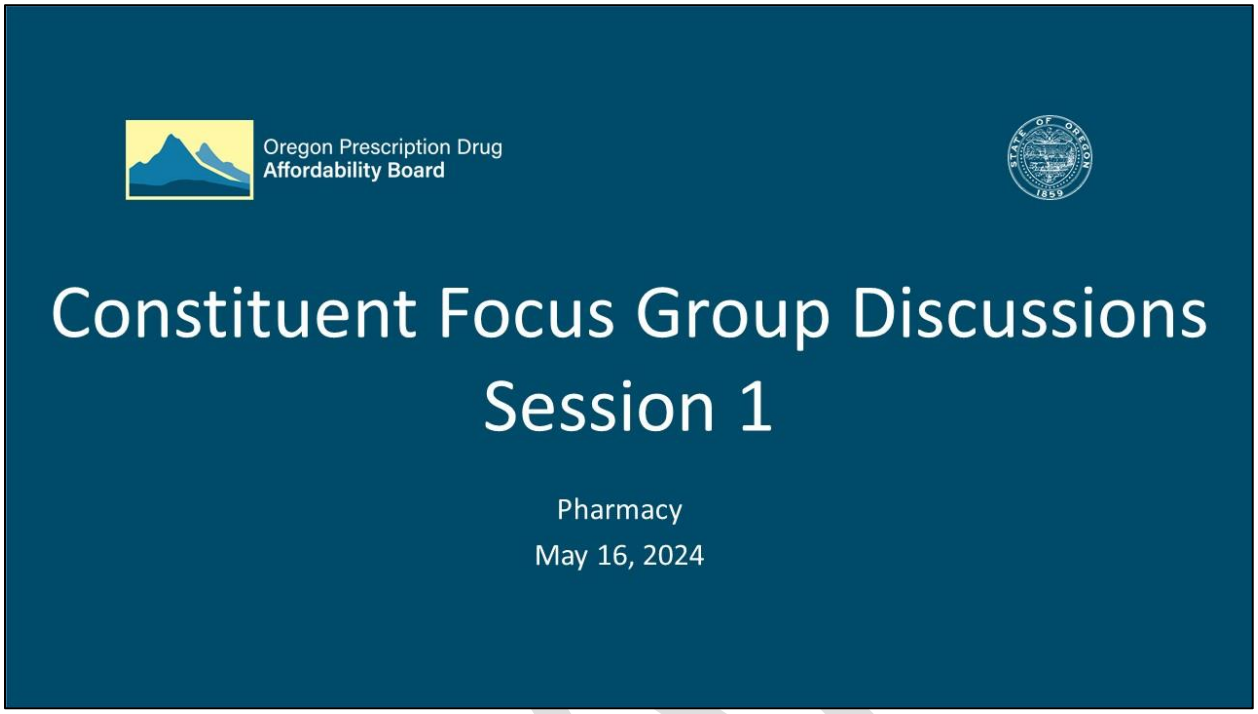
Appendix D: Sample Meeting Presentation



Background: Legislative Authority

Enabling Legislation (SB192)

SECTION 3. (1) The Prescription Drug Affordability Board established in ORS 646A.693 *shall develop a plan for establishing upper payment limits* on drugs sold in this state that are subject to affordability reviews under ORS 646A.694. The *plan shall include:*

(a) A *methodology for establishing upper payment limits*;
(b) An *analysis of the resources needed by the board to implement the plan*;
(c) An *analysis of how upper payment limits would be enforced*; and
(d) An *analysis of how upper payment limits could be implemented* with respect to:
(A) Plans administered by the *Public Employees' Benefit Board*;
(B) Plans administered by the *Oregon Educators Benefit Board*;
(C) Other *state-administered health benefits*;
(D) *Health benefit plans*, as defined in ORS 743B.005; and
(E) *Other forms of insurance that provide pharmaceutical benefits*, to the extent permitted by federal law.

Oregon Prescription Drug Affordability Board

Background: PDAB Process

- Authority:
  - The Prescription Drug Affordability Board (PDAB) will select from the list of eligible prescription drugs, provided by the Department of Consumer and Business Services pursuant to ORS 646A.694, a subset of drugs to prioritize for an affordability review under OAR 925-200-0020.
  - OAR 925-200-0020 Conducting an Affordability Review: The PDAB will conduct an affordability review on the prioritized subset of prescription drugs, selected under OAR 925-200-0010 to identify nine prescription drugs and at least one insulin product that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon.

Oregon Prescription Drug Affordability Board

Background: PDAB Process

- Drugs Under Review & Board Schedule
  - As posted on website: https://dfr.oregon.gov/pdab/Pages/affordability-review.asp

Board Meeting Date	Drugs for Review
January 26, 2024 (Completed)	Tresiba Tresiba FlexTouch Humulin R U-500 KwikPen
May 15, 2024	Ozempic Trulicity
June 26, 2024	Shingrix Ocrevus
July 24, 2024	Entyvio Inflectra
August 21, 2024	Cosentyx Skyrizi
September 18, 2024	Tremfya Vyvanse
October 16, 2024	Genvoya Triumeq

Oregon Prescription Drug Affordability Board

PDAB UPL Landscape

- What other states have UPL authority
  - Colorado, Minnesota, Washington have full authority to set a UPL.
  - Maryland is required to conduct a study on policy options, which may include setting UPLs.
  - Maine's PDAB is responsible for developing spending targets for prescription drugs purchased by public payers.
  - The New Hampshire Board is charged with recommending strategies for public purchasers to meet drug spend targets.
  - Massachusetts and New York are authorized to negotiate Medicaid supplemental rebates for high-cost drugs.
- Status of other state reviews
  - Colorado has determined that they will "initiate rulemaking to establish a UPL for Enbrel.*
  - * See Colorado PDAB DRAFT Meeting Minutes from Friday, February 23, 2024; https://drive.google.com/drive/folders/1mJFy7nfisd-lZqDQGA5fbYUtOopQlaaH, accessed 3/29/2024, 5/8/2024

Oregon Prescription Drug Affordability Board

Oregon UPL Description

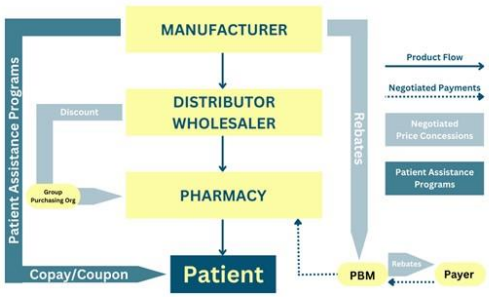
- Oregon UPL
  - Establishes the maximum amount that can be paid for a prescription drug that is dispensed in Oregon.
  - Leverages existing processes of negotiating price concessions that already exist in the supply chain.
  - Does not regulate how manufacturers list or set prices.
  - Concept is similar to using a Federal Upper Limit (FUL), National Average Drug Acquisition Cost (NADAC), or Maximum Allowable Cost (MAC).
  - Concept is intended to avoid impacting the "best price" in Medicaid.

2022 Prescription Drug Affordability Board – Report 2022; https://dfr.oregon.gov/pdab/Documents/reports/PDAB-Report_2022.pdf (Accessed 2/28/2024)

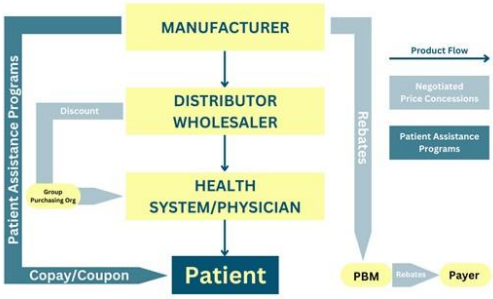
Oregon Prescription Drug Affordability Board

Supply Chain Impacts: Drug and Pricing Flow

Retail



Health-System/Physician-Administered



Oregon Prescription Drug Affordability Board

Potential UPL Principles

- UPLs should improve market function for prescription products that have a UPL by achieving one or more of the following:
  - Improve patient access to the product
  - Improve manufacturer product access to the state market
  - Reduce health plan costs for the product
  - Reduce overall market dysfunction
  - Market competition continues but is reset to the UPL as the starting point

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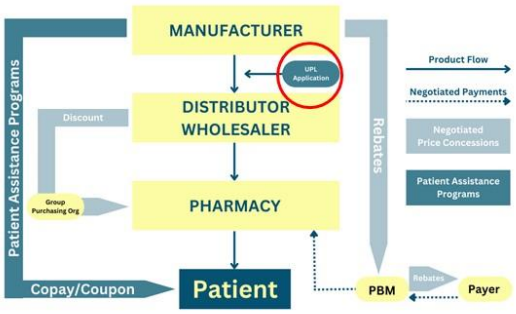
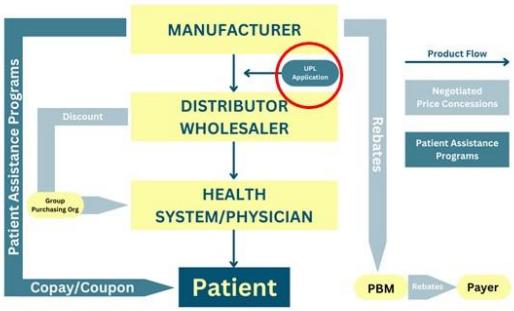
Oregon Prescription Drug Affordability Board

Supply Chain Impacts: Drug and Pricing Flow

Retail

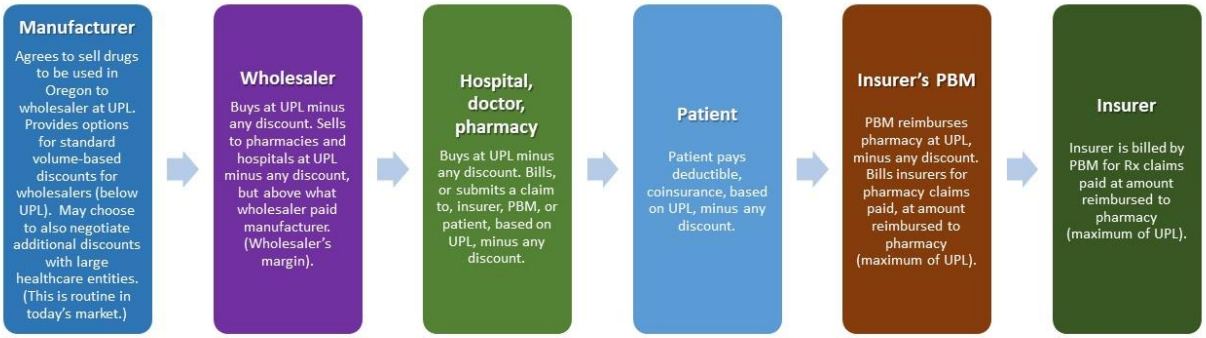


Health-System/Physician-Administered



Oregon Prescription Drug Affordability Board

Basics of UPL acquisition cost, billing, and payment



Note: UPL replaces WAC, AWP, AAC, EAC etc. UPL is the metric for all financial transactions for ingredient cost. Like existing metrics, there will be 'UPL minus' ingredient costs in the supply chain.

Dispensing or administration fees, independent of ingredient cost, may still be charged by pharmacies or the health care provider administering the drug to the patient.

Horvath Health Policy. Innovations in Healthcare Financing. March 2024

Oregon Prescription Drug Affordability Board

Supply Chain Impacts: Recent Industry Events

- In January, 2024, there was a decrease in the WAC cost of several prescription drugs.
- This happened as a result of changes to the Medicaid program that would have reduced the cost of drugs below $0 and required manufacturers to pay rebates that were higher than the drug cost paid by Medicaid.
- Manufacturers responded by decreasing the published Wholesale Acquisition Cost (WAC) for these drugs (for example, Advair Diskus and some insulins).
- This is important, because it can serve as an analogy for how a UPL might similarly impact the supply chain. We will come back to this concept in our discussion questions.

Oregon Prescription Drug Affordability Board

Group Discussion

- Impact of Drug Affordability
- Desired State of Drug Affordability
- UPL Impact
- UPL Methodologies
- Recommendations
- Final Thoughts

- Written feedback related to the UPL focus group discussions or the survey concepts may be provided to OregonPDAB@mslc.com . Please provide this feedback by 6/4/2024.
- You may also participate in the public comment process by writing and submitting a letter to the board or signing up to speak during a board meeting. The participation form may be found here https://dfr.oregon.gov/pdab/Pages/public-comment.aspx

Oregon Prescription Drug Affordability Board

Appendix E: Sample Meeting Script

Slide	Scripting
Slide 1: Cover	• *When the meeting starts, have the Blue "Constituent Focus Group Discussions" slide open and shared. Begin recording when the Facilitator begins speaking.*
Slide 2: Meeting Agenda	• Welcome and Introduction *(Primary Facilitator)* ○ My name is [INSERT NAME], and I am a [INSERT TITLE] with Myers and Stauffer, a national accounting and compliance firm supporting government sponsored health care programs. I'm joined by my colleague [INSERT NAME, INSERT TITLE], who will be assisting me with today's session. ○ We are here today on behalf of the Oregon Prescription Drug Affordability Board (PDAB) to solicit constituent feedback related to the use of upper payment limits (UPLs) to improve drug affordability, and to gather any recommendations you have on improving drug affordability for Oregonians. We will be recording these sessions to ensure that we capture the feedback correctly. If you wish to speak and are uncomfortable with having a specific comment recorded, please let us know and we will temporarily stop the recording. ○ Joining us from the PDAB Board are [INSERT NAME] and from the PDAB Staff [INSERT NAME]. ○ Finally, I would also like to introduce Jane Horvath of Horvath Health Policy, who is also supporting the Board with their work. • Meeting Logistics (*Primary Facilitator)* ○ Before we begin today's session, I'd first like to thank you all for attending. I know your time is incredibly valuable, and we appreciate your willingness to share your perspectives on this important topic. ○ In order to "level-set" on today's topic, we have a brief series of prepared slides that we would like to review before we get into our discussion. These should take about 15 minutes and we ask that you please hold any questions or comments until we've completed the presentation. ○ Once we've completed the slide deck we have a series of questions designed to solicit your input and generate dialogue among the group. During that time we will not be able to answer specific questions related to methodology or affordability evaluations; however, we will be providing a mechanism for you to submit those directly to the PDAB for consideration. ○ When we get to that point in the session, we ask that you introduce yourselves and speak clearly so that we may accurately capture your feedback in our notes. In addition, we ask that you please mute yourself when not speaking.

	○ Please use the function to "raise your hand" to be recognized to speak. ○ Lastly, we recognize that this is a very complex topic, and one that will likely generate considerable feedback among stakeholders. As such, we will be hosting a second meeting to continue our discussion, and to allow everyone an opportunity to share their perspectives.
Slide 3: Background: Legislative Authority	• The Prescription Drug Affordability Board (which we will refer to as the PDAB or the Board) was established within the Department of Consumer and Business Services (DCBS) and is committed to protecting residents of Oregon, state and local governments, commercial and employer health plans, health care providers, pharmacies licensed in Oregon, and other constituent groups within the health care system from the high costs of prescription drugs. The Board was established by the legislature under Senate Bill 844 (2021), later codified into Oregon Revised Statutes section 646A.693. • Again, our goal with these sessions is to get your perspectives on the use of upper payment limits (UPLs) to improve drug affordability and gather any recommendations you have on improving drug affordability for Oregonians. These sessions will inform the Board's work on developing a plan for establishing UPLs as required under Senate Bill 192
Slide 4: Background: PDAB Process	• Through the authority granted by the Oregon legislature, the Board is tasked with establishing a subset of drugs to review for affordability challenges within health care systems or high out-of-pocket costs for patients in Oregon.
Slide 5: Background: PDAB Process	• The Board is currently reviewing the drugs list on this slide and encourages you to review the website periodically for changes to the schedule or drugs currently under review.
Slide 6: PDAB UPL Landscape	• For purposes of providing additional context, several other states have established PDABs, with 3 – Colorado, Minnesota and Washington having full authority to establish UPLs. • Colorado is furthest along in the process, and has initiated the rulemaking process to establish a UPL on Enbrel.
Slide 7: Oregon UPL Description	• In their 2022 report to the Oregon legislature, the Board describes their concept for a UPL in Oregon. • Specifically, this would establish a maximum amount that can be paid for a prescription drug, similar to the Federal Upper Limits, NADAC, or MAC prices that are currently established and used in prescription drug reimbursement today.
Slide 8: Supply chain impacts: Drug and Pricing Flow	• Everyone in attendance is already familiar with the complexities of the pharmaceutical supply chain; however, again for purposes of level setting, this slide is intended to illustrate the process for retail and health system/physician administered drugs with their associated system of payments, rebates, and product flow.
Slide 9: Potential UPL Principles	• This next slide is adopted from work conducted by Jane Horvath, from Horvath Health Policy.

	• In principle, UPLs should improve market function for prescription drugs with a UPL by achieving one or more of the listed outcomes– such as improved access and reduced costs within the system.
Slide 10: Supply chain impacts: Drug and Pricing Flow	• In this diagram, we describe a situation in which the UPL is implemented at the top of supply chain flow
Slide 11: Basics of UPL	• Again, this material was adopted from work conducted by Jane Horvath, and offers a different view of the concept presented on the prior slide. • Specifically, this is intended to illustrate the progression of the UPL through various parts of the pharmaceutical supply chain.
Slide 12: Supply Chain Impacts: Recent Industry Events	• As we wrap up the presentation, we would like to highlight a few recent industry events that may serve as a guide to how a UPL might work in the marketplace. • Most notably, a recent change to the federal Medicaid Drug Rebate Program (MDRP) rules had an impact on the rebate rates that would be paid by manufacturers, in some cases significantly. • In response, manufacturers for certain highly-rebated drugs (in the Medicaid space) implemented reductions in WAC for these drugs. • We would encourage you to keep this concept in mind as we move into the interactive session.
Slide 13: Group Discussions	• Many of you participated in the survey that was provided in advance of these sessions and we appreciate those responses. • We will explore some of those same questions now in our session and appreciate your feedback and comments. • As a reminder, please remain on mute unless you are commenting and state your name and organization for us when making comments. • Written feedback can be provided as indicated on the slide.

Appendix F: Sample Meeting Questions

Focus Group Area	Focus Group Question
Instructions to MSLC Staff	• *Days 1 and 2 Begin with PowerPoint presentations* • *Scribes should note where the session ended on Day 1 for each Focus Group so that the facilitator can begin at the appropriate question.* • *Reminder to pause and restart recordings if there are objections by specific members.*
Impact of drug affordability	• When thinking about drug costs today, what does "affordability" mean to your organization? • To the extent you believe drugs generally, or specific drugs, are "unaffordable" what challenges does that present to your organization? • In responding to the survey, respondents indicated that they were somewhat or very concerned about the impact of drug affordability on their organizations. Could you tell us more about what those impacts are to your organization?
Desired State of Drug Affordability	• What outcomes would be needed for you to consider a drug affordability or upper payment limit program successful? • What do you think an *ideal* drug affordability or UPL program would look like within Oregon? ○ This can be regarding the methodology or PDAB authority

UPL Impact	• Think back to the presentation where we discussed the WAC changes that occurred in January of this year. How would a UPL implemented at the manufacturer to wholesaler level in the supply chain impact your organization?
	• Some respondents indicated that a UPL would create challenges for patient access to medication.
	  ○ What might some of those challenges be?
	  ○ Are you concerned that UPLs could prompt changes in benefit design, utilization management strategies, etc.?
	  ○ How do you think those changes might impact your organization?
	  ○ How do you think those changes might impact your patients/members?
	  ○ Should the PDAB try to address these changes? If so, what should they do?
	• Respondents were concerned that a UPL would be challenging to implement because of operational challenges around members or payers in other states.
	  ○ What are those challenges?
	  ○ Are there things that the Board could do or should consider to eliminate those challenges?

	• Some respondents indicated that a UPL could create opportunities for a positive impact on patient access. What might some of those positive impacts be?
	• Respondents mentioned transparency as being important to the UPL program.
	  ○ What does transparency mean to this group?
	  ○ How should transparency be demonstrated?
	• Specific to your organization, what barriers, challenges, or risks do you see to implementing UPLs?
	  ○ Do you believe changes to formularies as a result of UPLs could prompt changes in provider referral patterns, prescribing patterns, acquisition patterns, etc.?
	• Some respondents indicated that a UPL would have a negative impact on their organization's budget and spending.
	  ○ What would some of those impacts be?
	  ○ What actions would you recommend the PDAB take to mitigate those impacts?

UPL Methodologies	• What specific data should be evaluated when calculating a UPL?
	• Are there challenges with access to certain data?
	• Some respondents thought that medical necessity of drugs should be evaluated before determining if they are UPL eligible.
	  ○ What does that mean to this group?
	  ○ How would the Board do that? What mechanism would they use and how should they evaluate medical necessity?
	• Respondents mentioned that a standard pharmacy price could be implemented – something that would be separate from the UPL for wholesalers.
	  ○ Could you elaborate on this? How would this separate price be used and how would it be different from a UPL?

Recommendations	• Are there other strategies that the PDAB should consider in addition to the UPL? • If other strategies are considered, what would the potential positive impacts be? • What about any negative impacts of these strategies? • Eliminating Direct to Consumer Advertising was mentioned several times in the survey by pharmacy providers. How might that lead to increased affordability for drugs?
Final Thoughts	• As we wrap up this discussion, what else would you like to say about UPLs or drug affordability you have not had a chance to say already? Any concerns, challenges, or expectations we have not discussed?

Appendix G: Meeting Summary Reports

MYERS AND STAUFFER LC
CERTIFIED PUBLIC ACCOUNTANTS

Deliverable 2: Constituent Group Summary
Carriers

Background

The Oregon Prescription Drug Affordability Board (hereinafter referred to as "PDAB," or "the Board") was established in 2021 through Senate Bill 844. The purpose of the Board is to protect residents of Oregon, state and local governments, commercial health plans, health care providers, pharmacies licensed in Oregon, and other stakeholders within the health care system from the high costs of prescription drugs. The Board is responsible for annually identifying and reviewing nine drugs and at least one insulin product that may create affordability challenges for the healthcare systems or high out-of-pocket costs for patients in Oregon.

In June 2023, the Oregon Legislature passed Senate Bill 192, which tasked the Board with developing a plan to establish upper payment limits ("UPL") on drugs sold in the State that are subject to the Board's affordability reviews. The Board must report its plan to the interim committees of the Legislative Assembly related to health in fall 2024. The report must include an analysis of potential savings from, or costs of implementing, the plan with respect to the State, as well as carriers (e.g., public and private health benefit plans), hospitals, pharmacies, and consumers (hereinafter collectively referred to as "constituents" or "constituent groups").

In December 2023, the State of Oregon, acting through its Department of Consumer and Business Services, Division of Financial Regulation, contracted with Myers and Stauffer LC ("Myers and Stauffer") (PO-44000-00028053) to provide prescription drug consulting and outreach services related to SB192. As part of these services, Myers and Stauffer is conducting focus group meetings with constituent groups as identified and approved by the Board including, carriers, consumer organizations, hospitals, retail pharmacies, Medicaid 340B covered entities, pharmaceutical manufacturers, pharmacy benefit managers, and patient advocacy groups.[1]

Approach

Myers and Stauffer routinely conducts internal and external constituent engagement activities designed to support well-informed and collaborative policy development. Given the complexity of the subject matter associated with this particular engagement, the unique experiences of the distinct constituent groups, and the potential for unintended consequences associated with a UPL plan, we conducted a series of structured, professionally facilitated constituent group engagement sessions designed to solicit input on several key themes. A summary of our approach to these sessions is briefly described below.

[1] Note, pharmaceutical manufacturers and related entities, pharmacy benefit managers, and patient advocacy groups were added as a subsequent contract amendment in May 2024.

1

- *Collaborated with the Board to develop a constituent engagement plan.*
- *Collaborated with the Board to develop an electronic, pre-session survey to obtain constituent input regarding UPLs and their potential impacts. Additional information regarding this survey is presented below.*
- *Collaborated with the Board to identify constituent groups and appropriate contacts to receive the survey and be included in the sessions.*
- *Collaborated with Horvath Health Policy to draft an introductory document for constituents to establish a baseline level of understanding prior to the sessions.*
- *Collaborated with the Board to develop constituent-facing documents, communications, and questions for each session.*

Leveraging the approach described above, Myers and Stauffer conducted two engagement sessions for each Board-identified constituent group. Sessions were conducted throughout May, June, and July 2024, each lasting approximately one hour, and were facilitated by a team of Myers and Stauffer facilitators, subject matter experts, scribes, and logistics coordinators. During each session, the Myers and Stauffer team described the Board's rationale for engaging constituents, provided an overview of the UPL process, and asked a series of scripted and unscripted questions designed to solicit constituent perceptions of drug affordability and the potential impact of a UPL, as well as recommendations regarding the development of a UPL methodology and strategies the Board should consider to address drug affordability.

Preliminary Survey Results

Pre-session surveys (mentioned above) were developed to garner constituent understanding and perspective regarding UPL methodology and perceived impacts of implementation. Key characteristics of the survey are highlighted below:

- *The survey included four mandatory questions designed to collect respondent demographic information. Replies to non-mandatory questions included nine quantitative and eight qualitative responses, respectively.*
- *Invalid responses were excluded that met the following requirements:*
  - *Respondents who submitted multiple identical responses; only one response was reviewed in these instances.*
  - *Respondents who did not answer questions beyond the initial four mandatory questions.*

- *A number of responses answered some, but not all, non-mandatory questions. In these instances, only completed questions were reviewed.*
- *Responses to non-mandatory questions which did not contain valid data (e.g., Lorem ipsum or clearly unresponsive text such as "text"). In these instances, only questions with valid data were reviewed.*

Invitations to participate in the surveys and a brief UPL proposed approach document were sent to 53 unique emails approximately three weeks prior to sending meeting invitations. Recipients were asked to forward the survey to others within their organization if/where appropriate, and no limits were placed on the number of responses that could be submitted by each organization. We received six survey responses from six different organizations.

Table 1: Survey Respondents

Organization
Cambia Health Solutions
Centene
Cigna Healthcare
Gainwell Technologies
Timber Products Manufacturers Trust
United Healthcare

Preliminary results were leveraged to inform constituent group meetings and are presented below. Analysis of final survey responses will be included in the constituent group summary report (PO-44000-00028053 Deliverable #3).

- *Five survey responses contained answers to every non-mandatory question. One survey response did not contain answers to every non-mandatory question.*
- *Six of six responses indicated they were very concerned about the impact of the cost of drugs on their organization.*
- *Four of six responses indicated they were very concerned about the impact of the cost of drugs on their members. One response indicated they were somewhat concerned, and one response indicated they were not concerned.*
- *Four of six responses indicated a UPL would have a neutral impact on their organization's drug spending and budgetary considerations. Two responses indicated a positive impact.*

- *Three of six responses indicated a UPL would create challenges to patient access to medications. Two of six responses indicated a neutral impact, and one response indicated a positive impact.*
- *Four of six responses indicated a UPL would have a neutral impact on patients' ability to afford their medications. Two responses indicated a positive impact.*
- *Four of six responses indicated they were unsure if a UPL would affect premiums paid by members. One response indicated a positive impact on premiums, and one response was blank.*

Constituent Group Description

Two carrier constituent group engagement sessions were held on May 16 and May 29, 2024. A total of 53 invitations were distributed (including a list of discussion questions), with 12 individuals attending across both sessions. Attendees largely consisted of health plans serving Oregon. Below is a list of organizations and their attendance.

Table 2: Attendees

Organization	Session 1	Session 2
Cambia Health Solutions	X	
Health Net of Oregon and Trillium Community Health Plan		X
PacificSource Health Plans	X	X
Providence Health Plan	X	X
Regence BCBS of OR	X	X
Samaritan Health Plans		X
UnitedHealthcare	X	

Summary of Discussion

As described above, Myers and Stauffer facilitators asked attendees a series of scripted and unscripted questions to solicit constituent input. Sessions were not intended to provide responses to specific attendee questions and, if asked, facilitators requested that attendees provide their recommendations for how the Board might use its authority to address the issue presented and/or directly submit the question to the Board through its online public comment form or via email at OregonPDAB@mslc.com. What follows is a summary of the carrier constituent group engagement sessions, identifying critical discussions, recommendations, and follow-up items presented by attendees (i.e., PO-44000-00028053 Deliverable #2).

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Deliverable 2: Constituent Group Summary
Carriers

Critical Discussions

- *UPL impact on the entire system, both within and outside Oregon. For example, setting a UPL on a single drug may cause shifts in utilization of other drugs in the same class. The implementation of UPLs in Oregon could cause impacts in other states. Further, carriers need to consider UPL impact not just on costs associated with the specific drugs with a UPL, but the aggregate impact on healthcare spending, rebates and overall actuarial modeling.*
- *Setting a UPL on select drugs and effects on the market basket. Again, setting a UPL on a single drug could shift utilization to similar non-UPL products in the same class. Participants were concerned that a UPL on a single drug could create disparities between manufacturers that could cause negative downstream effects.*
- *Questions regarding PDAB authority, UPL enforcement, and frequency of updates. Participants want to ensure UPL information will be available in compendia and were curious how often it would be updated. Members were curious about UPL enforcement and asked about the consequences of non-adherence. They asked about safeguards to mitigate risks of negative consequences on patients, such as drug shortages.*
- *Administrative burden of UPL implementation within an already highly regulated environment and complex pricing system. Participants had concerns regarding timing, logistics and the complexities of contract updates. They questioned if the cost of these administrative updates could offset any potential UPL savings to members. Participants also noted that in addition to any complexities added by a UPL process, they currently experience increased complexity due to the implementation of Medicare Maximum Fair Prices as a result of the Inflation Reduction Act.*

Recommendations

- *Expansion of the UPL beyond the wholesaler/manufacturer level. Participants explained that at the carrier level, premium calculations are based on utilization trends and risk is pooled across the entire organization. They had concerns that a UPL set at the manufacturer/wholesaler level and affecting individual transactions may not have an appreciable effect on member premiums.*
- *Set UPLs on an entire market basket, rather than individual drugs. As explained above, setting a UPL for a single drug may shift utilization to non-UPL drugs. By setting the UPL for an entire market basket, the UPL may have a more significant*

effect on costs, remove focus from a single manufacturer, and allow UPLs to be set on new drugs.

- *UPL enforcement across the entire supply chain. Participants would like to ensure the UPL is maintained within all transactions. They felt reimbursement should have the same UPL as drug purchasing.*
- *Incorporation of lessons learned from other PDAB states. They recommended use of a work plan that allows for course corrections, evaluations of lessons learned and ongoing process improvement.*

Follow-up Items

- *UPL impact on rebates. Participants were curious how a UPL would affect the current manufacturer rebate system.*
- *Session 2 garnered very little input from attendees. As such, the Board may wish to leverage additional means of engagement for carriers.*

Next Steps

Following completion of all constituent group engagement sessions, Myers and Stauffer will generate a final report for the Agency showing recommendations, concerns, and obstacles identified at each stakeholder session and identified by any Agency provided data. This report will include, but not be limited to, an executive summary outlining the contents of the report that does not exceed two pages, as well as analyses of pre-session survey responses and input collected during facilitated discussions (PO-44000-00028053 Deliverable #3).

MYERS AND STAUFFER LC
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Deliverable 2: Constituent Group Summary
Hospitals

Background

The Oregon Prescription Drug Affordability Board (hereinafter referred to as "PDAB," or "the Board") was established in 2021 through Senate Bill 844. The purpose of the Board is to protect residents of Oregon, state and local governments, commercial health plans, health care providers, pharmacies licensed in Oregon, and other stakeholders within the health care system from the high costs of prescription drugs. The Board is responsible for annually identifying and reviewing nine drugs and at least one insulin product that may create affordability challenges for the healthcare systems or high out-of-pocket costs for patients in Oregon.

In June 2023, the Oregon Legislature passed Senate Bill 192, which tasked the Board with developing a plan to establish upper payment limits ("UPL") on drugs sold in the State that are subject to the Board's affordability reviews. The Board must report its plan to the interim committees of the Legislative Assembly related to health in fall 2024. The report must include an analysis of potential savings from, or costs of implementing, the plan with respect to the State, as well as carriers (e.g., public and private health benefit plans), hospitals, pharmacies, and consumers (hereinafter collectively referred to as "constituents" or "constituent groups").

In December 2023, the State of Oregon, acting through its Department of Consumer and Business Services, Division of Financial Regulation, contracted with Myers and Stauffer LC ("Myers and Stauffer") (PO-44000-00028053) to provide prescription drug consulting and outreach services related to SB192. As part of these services, Myers and Stauffer is conducting focus group meetings with constituent groups as identified and approved by the Board including, carriers, consumer organizations, hospitals, retail pharmacies, Medicaid 340B covered entities, pharmaceutical manufacturers, pharmacy benefit managers, and patient advocacy groups.[1]

Approach

Myers and Stauffer routinely conducts internal and external constituent engagement activities designed to support well-informed and collaborative policy development. Given the complexity of the subject matter associated with this particular engagement, the unique experiences of the distinct constituent groups, and the potential for unintended consequences associated with a UPL plan, we conducted a series of structured, professionally facilitated constituent group engagement sessions designed to solicit input on several key themes. A summary of our approach to these sessions is briefly described below.

[1] Note, pharmaceutical manufacturers and related entities, pharmacy benefit managers, and patient advocacy groups were added as a subsequent contract amendment in May 2024.

1

- *Collaborated with the Board to develop a constituent engagement plan.*
- *Collaborated with the Board to develop an electronic, pre-session survey to obtain constituent input regarding UPLs and their potential impacts. Additional information regarding this survey is presented below.*
- *Collaborated with the Board to identify constituent groups and appropriate contacts to receive the survey and be included in the sessions.*
- *Collaborated with Horvath Health Policy to draft an introductory document for constituents to establish a baseline level of understanding prior to the sessions.*
- *Collaborated with the Board to develop constituent-facing documents, communications, and questions for each session.*

Leveraging the approach described above, Myers and Stauffer conducted two engagement sessions for each Board-identified constituent group. Sessions were conducted throughout May, June, and July 2024, each lasting approximately one hour, and were facilitated by a team of Myers and Stauffer facilitators, subject matter experts, scribes, and logistics coordinators. During each session, the Myers and Stauffer team described the Board's rationale for engaging constituents, provided an overview of the UPL process, and asked a series of scripted and unscripted questions designed to solicit constituent perceptions of drug affordability and the potential impact of a UPL, as well as recommendations regarding the development of a UPL methodology and strategies the Board should consider to address drug affordability.

Preliminary Survey Results

Pre-session surveys (mentioned above) were developed to garner constituent understanding and perspective regarding UPL methodology and perceived impacts of implementation. Key characteristics of the survey are highlighted below:

- *The survey included four mandatory questions designed to collect respondent demographic information. Replies to non-mandatory questions included nine quantitative and eight qualitative responses, respectively.*
- *Invalid responses were excluded that met the following requirements:*
  - *Respondents who submitted multiple identical responses; only one response was reviewed in these instances.*
  - *Respondents who did not answer questions beyond the initial four mandatory questions.*

- *A number of responses answered some, but not all, non-mandatory questions. In these instances, only completed questions were reviewed.*
- *Responses to non-mandatory questions which did not contain valid data (e.g., Lorem ipsum or clearly unresponsive text such as "text"). In these instances, only questions with valid data were reviewed.*

Invitations to participate in the surveys and a brief UPL proposed approach document were sent to 51 unique emails approximately three weeks prior to sending meeting invitations. Recipients were asked to forward the survey to others within their organization if/where appropriate, and no limits were placed on the number of responses that could be submitted by each organization. We received 17 survey responses from 15 different organizations.

Table 1: Survey Respondents

Organization
Adventist Health Portland
Asante, Rogue Regional Medical Center, Three Rivers Medical Center, Ashland Community Hospital
Bay Area Hospital
Confederated Tribes of Grand Ronde Health & Wellness Center
Good Shepherd Health Care System
Kaiser Permanente
Nelco Advisory
PeaceHealth
PeaceHealth at River Bend Hospital
Pendleton Primary Care Clinic
Salem Health
Samaritan Health Services
Santiam Hospital
St Charles Health System
Willamette Valley Medical Center

Preliminary results were leveraged to inform constituent group meetings and are presented below. Analysis of final survey responses will be included in the constituent group summary report (PO-44000-00028053 Deliverable #3).

- *Six survey responses contained answers to every non-mandatory question. Eleven survey responses did not contain answers to every non-mandatory question.*

- *Fourteen of 17 responses indicated they were very concerned about the impact of the cost of drugs on their organization. One response indicated they were somewhat concerned, and two responses were blank.*
- *Fifteen of 17 responses indicated they were very concerned about the impact of the cost of drugs on their patients. Two responses were blank.*
- *Nine of 17 responses indicated a UPL would have a negative impact on their organization's spending and budgetary concerns. Five responses indicated a neutral impact, one indicated a positive impact, and two responses were blank.*
- *Eleven of 17 responses indicated a UPL would create challenges to patient access to medications. Three responses indicated a positive impact, one indicated a neutral impact, and two responses were blank.*
- *Eight of 17 responses indicated a UPL would have a neutral impact on patients' ability to afford their medications. Four responses indicated a positive impact, three responses indicated a negative impact, and two responses were blank.*
- *Eleven of 17 responses indicated a UPL would have a negative impact on their facility's drug procurement and supply chain management. Five responses indicated a neutral impact, and one indicated a positive impact.*
- *Eight of 17 responses indicated a UPL would have no impact on chargemaster (i.e., comprehensive listing of items billable to a patient or a patient's health plan) prices. Seven responses indicated prices would decrease, and two responses indicated prices would increase.*

Constituent Group Description

Two hospital constituent group engagement sessions were held on May 20 and May 30, 2024. A total of 51 invitations were distributed (including a list of discussion questions), with 14 individuals attending across both sessions. Attendees largely consisted of hospital pharmacy leadership. Below is a list of organizations and their attendance.

Table 2: Attendees

Organization	Session 1	Session 2
Adventist Health Columbia Gorge	X	
Bay Area Hospital		X
McKenzie Willamette Medical Center	X	
Nelco Advisory		X
PeaceHealth	X	X

Salem Health	X	X
Southern Coos Hospital	X	X

Summary of Discussion

As described above, Myers and Stauffer facilitators asked attendees a series of scripted and unscripted questions to solicit constituent input. Sessions were not intended to provide responses to specific attendee questions and, if asked, facilitators requested that attendees provide their recommendations for how the Board might use its authority to address the issue presented and/or directly submit the question to the Board through its online public comment form or via email at OregonPDAB@mslc.com. What follows is a summary of the hospital constituent group engagement sessions, identifying critical discussions, recommendations, and follow-up items presented by attendees (i.e., PO-44000-00028053 Deliverable #2).

Critical Discussions

- *Affordability is a concern primarily for outpatient drugs. Participants explained that outpatient drugs are paid according to pricing benchmarks, whereas inpatient drugs are bundled into diagnosis-related group payments.*
- *Complexities of hospital drug purchasing and reimbursement. Members discussed that some hospitals rely on pharmacy technicians to make drug purchases, and they may not be trained or have sufficient information to select the most affordable or highly-reimbursed product. Participants had concerns about adding complexity to an already complicated process. They questioned how a UPL would affect contracts and how group purchasing organizations would respond.*
- *Concerns regarding drug shortages and formulary changes. Respondents asked if wholesalers would be required to sell to a state with a UPL. If not, several indicated that this could negatively affect drug availability. Similarly, they expressed concern that a PBM could remove UPL drugs from their formularies, and that shortages could create patient access issues, especially for marginalized groups.*
- *Administrative burden of UPL implementation. Participants expressed concerns about maintaining chargemasters and billing algorithms specific to UPLs. They discussed existing complex regulatory requirements associated with 340B drugs, which were perceived as burdensome, and the need to adapt to 340B pricing updates occurring every three months.*

- *Effects on 340B programs. The group discussed potential effects that a UPL could have on 340B programs, including reduced margins if payer reimbursements for drugs decreased. One participant was concerned that reduced 340B margins may cause problems for rural critical access hospitals, who already struggle to maintain drug inventory and staffing. Another participant explained that reduced margins on 340B drugs would reduce the ability to provide clinical services led by pharmacists.*

- *UPL function across state lines. Group members questioned how a UPL would work for pharmacies and healthcare systems that cross state lines. A participant was curious how a UPL would affect transactions for pharmacies located both in and outside Oregon utilizing a central fill facility located in Oregon.*

Recommendations

- *National policy and regulations. Participants felt UPLs or other strategies to positively impact drug affordability may be better implemented at a national level. The group discussed the need for national requirements regarding coverage levels and drug formularies to ensure drugs with a UPL are available and covered.*

- *UPL focus. Respondents recommended affordability reviews focused on drugs that are medically impactful and placing UPLs on drugs where there are no less expensive alternatives. Another respondent recommended focusing UPL efforts on drugs that represent the highest percentage of Oregonians' healthcare dollars.*

- *Non-UPL strategies. Participants discussed implementation of national price negotiations and transparency mandates at the federal level. The group discussed the need to focus on concerns associated with the vertical integration of PBMs, pharmacies and health plans. Participants also suggested potential benefits of a single payer system for health care within the state. Participants agreed on the importance of ensuring that a UPL program doesn't put physicians, hospitals, or pharmacies at a disadvantage.*

Follow-up Items

- *No follow-up items were identified by constituents or facilitators.*

Next Steps

Following completion of all constituent group engagement sessions, Myers and Stauffer will generate a final report for the Agency showing recommendations, concerns, and obstacles identified at each stakeholder session and identified by any Agency provided

data. This report will include, but not be limited to, an executive summary outlining the contents of the report that does not exceed two pages, as well as analyses of pre-session survey responses and input collected during facilitated discussions (PO-44000-00028053 Deliverable #3).

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Deliverable 2: Constituent Group Summary
Federally Qualified Health Centers/340B

Background

The Oregon Prescription Drug Affordability Board (hereinafter referred to as "PDAB," or "the Board") was established in 2021 through Senate Bill 844. The purpose of the Board is to protect residents of Oregon, state and local governments, commercial health plans, health care providers, pharmacies licensed in Oregon, and other stakeholders within the health care system from the high costs of prescription drugs. The Board is responsible for annually identifying and reviewing nine drugs and at least one insulin product that may create affordability challenges for the healthcare systems or high out-of-pocket costs for patients in Oregon.

In June 2023, the Oregon Legislature passed Senate Bill 192, which tasked the Board with developing a plan to establish upper payment limits ("UPL") on drugs sold in the State that are subject to the Board's affordability reviews. The Board must report its plan to the interim committees of the Legislative Assembly related to health in fall 2024. The report must include an analysis of potential savings from, or costs of implementing, the plan with respect to the State, as well as carriers (e.g., public and private health benefit plans), hospitals, pharmacies, and consumers (hereinafter collectively referred to as "constituents" or "constituent groups").

In December 2023, the State of Oregon, acting through its Department of Consumer and Business Services, Division of Financial Regulation, contracted with Myers and Stauffer LC ("Myers and Stauffer") (PO-44000-00028053) to provide prescription drug consulting and outreach services related to SB192. As part of these services, Myers and Stauffer is conducting focus group meetings with constituent groups as identified and approved by the Board including, carriers, consumer organizations, hospitals, retail pharmacies, Medicaid 340B covered entities, pharmaceutical manufacturers, pharmacy benefit managers, and patient advocacy groups.[1]

Approach

Myers and Stauffer routinely conducts internal and external constituent engagement activities designed to support well-informed and collaborative policy development. Given the complexity of the subject matter associated with this particular engagement, the unique experiences of the distinct constituent groups, and the potential for unintended consequences associated with a UPL plan, we conducted a series of structured, professionally facilitated constituent group engagement sessions designed to solicit input on several key themes. A summary of our approach to these sessions is briefly described below.

[1] Note, pharmaceutical manufacturers and related entities, pharmacy benefit managers, and patient advocacy groups were added as a subsequent contract amendment in May 2024.

- *Collaborated with the Board to develop a constituent engagement plan.*
- *Collaborated with the Board to develop an electronic, pre-session survey to obtain constituent input regarding UPLs and their potential impacts. Additional information regarding this survey is presented below.*
- *Collaborated with the Board to identify constituent groups and appropriate contacts to receive the survey and be included in the sessions.*
- *Collaborated with Horvath Health Policy to draft an introductory document for constituents to establish a baseline level of understanding prior to the sessions.*
- *Collaborated with the Board to develop constituent-facing documents, communications, and questions for each session.*

Leveraging the approach described above, Myers and Stauffer conducted two engagement sessions for each Board-identified constituent group. Sessions were conducted throughout May, June, and July 2024, each lasting approximately one hour, and were facilitated by a team of Myers and Stauffer facilitators, subject matter experts, scribes, and logistics coordinators. During each session, the Myers and Stauffer team described the Board's rationale for engaging constituents, provided an overview of the UPL process, and asked a series of scripted and unscripted questions designed to solicit constituent perceptions of drug affordability and the potential impact of a UPL, as well as recommendations regarding the development of a UPL methodology and strategies the Board should consider to address drug affordability.

Preliminary Survey Results

Pre-session surveys (mentioned above) were developed to garner constituent understanding and perspective regarding UPL methodology and perceived impacts of implementation. Key characteristics of the survey are highlighted below:

- *The survey included four mandatory questions designed to collect respondent demographic information. Replies to non-mandatory questions included nine quantitative and eight qualitative responses, respectively.*
- *Invalid responses were excluded that met the following requirements:*
  - *Respondents who submitted multiple identical responses; only one response was reviewed in these instances.*
  - *Respondents who did not answer questions beyond the initial four mandatory questions.*

- *A number of responses answered some, but not all, non-mandatory questions. In these instances, only completed questions were reviewed.*
- *Responses to non-mandatory questions which did not contain valid data (e.g., Lorem ipsum or clearly unresponsive text such as "text"). In these instances, only questions with valid data were reviewed.*

Invitations to participate in the surveys and a brief UPL proposed approach document were sent to 34 unique emails approximately four weeks prior to sending meeting invitations. Recipients were asked to forward the survey to others within their organization if/where appropriate, and no limits were placed on the number of responses that could be submitted by each organization. We received 20 survey responses from 19 different organizations.

Table 1: Survey Respondents

Organization
Cascadia Health
Central City Concern
CHC of Benton and Linn Counties
Klamath Health Partnership
La Clinica del Valle
La Pine Community Health Center
Mosaic Community Health
Multnomah County Health Center
NARA Northwest
Neighborhood Health Center
One Community Health
Oregon State University College of Pharmacy/ Community Health Centers of Benton County
Outside In Pharmacy
Providence
Siskiyou Community Health Center
Three Rivers Pharmacy
Wallace
Winding Waters Clinic
Yakima Valley Farm Workers Clinic

Preliminary results were leveraged to inform constituent group meetings and are presented below. Analysis of final survey responses will be included in the constituent group summary report (PO-44000-00028053 Deliverable #3).

- *Seven survey responses contained answers to every non-mandatory question. Thirteen survey responses did not contain answers to every non-mandatory question.*
- *Eighteen of 20 responses indicated they were very concerned about the impact of the cost of drugs on their organization. Two responses indicated they were somewhat concerned.*
- *Sixteen of 20 responses indicated they were very concerned about the impact of the cost of drugs on their patients. Three responses indicated they were somewhat concerned, and one response indicated they were not concerned.*
- *Sixteen of 20 responses indicated a UPL would have a negative impact on their organization's drug spending and budgetary considerations. Two responses indicated a neutral impact, and two responses indicated a positive impact.*
- *Twelve of 20 responses indicated a UPL would create challenges to patient access to medications. Six responses indicated a neutral impact, and two responses indicated a positive impact.*
- *Ten of 20 responses indicated a UPL would have a negative impact on patients' ability to afford their medications. Two responses indicated a neutral impact, and one response indicated a positive impact.*
- *Eighteen of 20 responses indicated a UPL would have a negative impact on their 340B program. Two responses indicated a neutral impact.*

Constituent Group Description

Two FQHC/340B constituent group engagement sessions were held on May 22 and May 30, 2024. A total of 34 invitations were distributed (including a list of discussion questions), with 26 individuals attending across both sessions. Attendees largely consisted of community health centers and health departments. Below is a list of organizations and their attendance.

Table 2: Attendees

Organization	Session 1	Session 2
Aviva Health		X
Cascade AIDS Project & Prism Health	X	
Cascadia Health	X	
Clackamas Health Centers	X	X
FQHC 340B Compliance		X
Health Services Pharmacy/	X	

Benton County Health Department		
Klamath Health Partnership	X	X
La Clinica	X	X
Mosaic Community Health	X	X
Multnomah County	X	X
Native American Rehabilitation Association of the Northwest	X	X
Neighborhood Health Center		X
Northwest Human Services	X	X
One Community Health	X	X
Oregon Primary Care Association	X	X
Virginia Garcia Memorial Health Center	X	X
Yakima Valley Farm Workers Clinic	X	X

Summary of Discussion

As described above, Myers and Stauffer facilitators asked attendees a series of scripted and unscripted questions to solicit constituent input. Sessions were not intended to provide responses to specific attendee questions and, if asked, facilitators requested that attendees provide their recommendations for how the Board might use its authority to address the issue presented and/or directly submit the question to the Board through its online public comment form or via email at OregonPDAB@mslc.com. What follows is a summary of the FQHC constituent group engagement sessions, identifying critical discussions, recommendations, and follow-up items presented by attendees (i.e., PO-44000-00028053 Deliverable #2).

Critical Discussions

- *UPL questions and potential lost income. Participants expressed concerns that there is still ambiguity regarding how and at what level a UPL would be set. The group worried that a UPL could significantly reduce their organizations' income from the 340B program which would result in reduced funds for other FQHC services. Revenue derived from the 340B program is reinvested into other health and social services, including clinical pharmacy programs, diabetes management, behavioral health, dental services, outreach services, and a variety of other programs. Group members were concerned that loss of funding for these programs could have negative effects on their ability to care for patients.*

- *Potential impact of UPLs. Participants were concerned that implementation of a UPL may cause changes to which drugs are preferred within a therapeutic class and result in formulary changes (either internally or by payers) and that these changes could shift utilization into non-UPL drugs.*

- *Current program restrictions. Members expressed concerns that their facilities are already experiencing losses of 340B revenue due to manufacturer restriction of 340B inventory to contract pharmacies, and increased PBM fees.*
- *Copay concerns. The group explained that their patient population is very sensitive to even low pharmacy co-payments, and that a reduction in 340B revenues could alter the extent to which facilities can minimize or remove pharmacy co-payments.*

Recommendations

- *UPL exemption for 340B facilities. Respondents strongly recommended that drugs provided through 340B providers be exempt from a state UPL program.*
- *Focus on non-340B drugs. The group felt that the PDAB should focus on drugs that are ineligible for the 340B drug purchasing program, such as vaccines, especially expensive vaccines like RSV.*
- *Focus on high-cost infusions. Participants recommended that the PDAB focus on high-cost infusions and infusion reimbursement practices, rather than setting a UPL.*
- *Focus on PBMs. Participants recommended focusing on PBM reform and drug pricing transparency rather than setting a UPL.*
- *UPL modeling. Participants encouraged modeling the impacts of UPLs prior to implementing the program.*

Follow-up Items

- *List of alternative drugs. One participant offered to draft a list of non-340B drugs for the Board to consider for UPLs.*

Next Steps

Following completion of all constituent group engagement sessions, Myers and Stauffer will generate a final report for the Agency showing recommendations, concerns, and obstacles identified at each stakeholder session and identified by any Agency provided data. This report will include, but not be limited to, an executive summary outlining the contents of the report that does not exceed two pages, as well as analyses of pre-session survey responses and input collected during facilitated discussions (PO-44000-00028053 Deliverable #3).

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Deliverable 2: Constituent Group Summary
Pharmacy

Background

The Oregon Prescription Drug Affordability Board (hereinafter referred to as "PDAB," or "the Board") was established in 2021 through Senate Bill 844. The purpose of the Board is to protect residents of Oregon, state and local governments, commercial health plans, health care providers, pharmacies licensed in Oregon, and other stakeholders within the health care system from the high costs of prescription drugs. The Board is responsible for annually identifying and reviewing nine drugs and at least one insulin product that may create affordability challenges for the healthcare systems or high out-of-pocket costs for patients in Oregon.

In June 2023, the Oregon Legislature passed Senate Bill 192, which tasked the Board with developing a plan to establish upper payment limits ("UPL") on drugs sold in the State that are subject to the Board's affordability reviews. The Board must report its plan to the interim committees of the Legislative Assembly related to health in fall 2024. The report must include an analysis of potential savings from, or costs of implementing, the plan with respect to the State, as well as carriers (e.g., public and private health benefit plans), hospitals, pharmacies, and consumers (hereinafter collectively referred to as "constituents" or "constituent groups").

In December 2023, the State of Oregon, acting through its Department of Consumer and Business Services, Division of Financial Regulation, contracted with Myers and Stauffer LC ("Myers and Stauffer") (PO-44000-00028053) to provide prescription drug consulting and outreach services related to SB192. As part of these services, Myers and Stauffer is conducting focus group meetings with constituent groups as identified and approved by the Board including, carriers, consumer organizations, hospitals, retail pharmacies, Medicaid 340B covered entities, pharmaceutical manufacturers, pharmacy benefit managers, and patient advocacy groups.[1]

Approach

Myers and Stauffer routinely conducts internal and external constituent engagement activities designed to support well-informed and collaborative policy development. Given the complexity of the subject matter associated with this particular engagement, the unique experiences of the distinct constituent groups, and the potential for unintended consequences associated with a UPL plan, we conducted a series of structured, professionally facilitated constituent group engagement sessions designed to solicit input on several key themes. A summary of our approach to these sessions is briefly described below.

[1] Note, pharmaceutical manufacturers and related entities, pharmacy benefit managers, and patient advocacy groups were added as a subsequent contract amendment in May 2024.

- *Collaborated with the Board to develop a constituent engagement plan.*
- *Collaborated with the Board to develop an electronic, pre-session survey to obtain constituent input regarding UPLs and their potential impacts. Additional information regarding this survey is presented below.*
- *Collaborated with the Board to identify constituent groups and appropriate contacts to receive the survey and be included in the sessions.*
- *Collaborated with Horvath Health Policy to draft an introductory document for constituents to establish a baseline level of understanding prior to the sessions.*
- *Collaborated with the Board to develop constituent-facing documents, communications, and questions for each session.*

Leveraging the approach described above, Myers and Stauffer conducted two engagement sessions for each Board-identified constituent group, with the pharmacy group further split into two subgroups. Sessions were conducted throughout May, June and July 2024, each lasting approximately one hour, and were facilitated by a team of Myers and Stauffer facilitators, subject matter experts, scribes, and logistics coordinators. During each session, the Myers and Stauffer team described the Board's rationale for engaging constituents, provided an overview of the UPL process, and asked a series of scripted and unscripted questions designed to solicit constituent perceptions of drug affordability and the potential impact of a UPL, as well as recommendations regarding the development of a UPL methodology and strategies the Board should consider to address drug affordability.

Preliminary Survey Results

Pre-session surveys (mentioned above) were developed to garner constituent understanding and perspective regarding UPL methodology and perceived impacts of implementation. Key characteristics of the survey are highlighted below:

- *The survey included four mandatory questions designed to collect respondent demographic information. Replies to non-mandatory questions included nine quantitative and eight qualitative responses, respectively.*
- *Invalid responses were excluded that met the following requirements:*
  - *Respondents who submitted multiple identical responses; only one response was reviewed in these instances.*
  - *Respondents who did not answer questions beyond the initial four mandatory questions.*

- *A number of responses answered some, but not all, non-mandatory questions. In these instances, only completed questions were reviewed.*
- *Responses to non-mandatory questions which did not contain valid data (e.g., Lorem ipsum or clearly unresponsive text such as "text"). In these instances, only questions with valid data were reviewed.*

Invitations to participate in the surveys and a brief UPL proposed approach document were sent to 396 unique emails approximately three weeks prior to sending meeting invitations. This initial survey group included grocery and non-grocery/independent pharmacies. At the direction of the Board, wholesalers, distributors, pharmacy services administrative organizations (PSAOs) and group purchasing organizations (GPOs) were also included in this constituent group, resulting in an additional 16 recipients. These additional recipients were asked to forward the survey to others within their respective organizations if/where appropriate, and no limits were placed on the number of responses that could be submitted by each organization. In total, we received 40 survey responses from 37 different organizations.

Table 1: Survey Respondents

Organization
Achterhof Healthcare Pharmacy, LLC dba Managed Healthcare Pharmacy
AlignRx, LLC
Ardon Health, LLC
Asante Pharmacy
BHS Pharmacy
Bowman's Hillsdale Pharmacy
Broadway Apothecary
Broadway Pharmacy
Brooklyn Pharmacy
Clinic Pharmacy
Drug Mart Pharmacy
Emerging Health, LLC
Gateway Medical Pharmacy
Harrisburg Pharmacy
Hi-School Pharmacy
Irby Pharmacy
Malheur Drug, Inc.
McCoys Pharmacy
Nehalem Bay Health Center and Pharmacy
Nelco Advisory
OHSU Pharmacies

Olson Pharmacy Services
Philomath Pharmacy
Pill Box Drugs Inc.
Prescryptive Pharmacy
Red Cross Drug Store
Rice's Pharmacy
River Road Health Mart
Sky Lakes Medical Center Retail Pharmacy
Square Care Medical & Pharmacy
Westside Pharmacy

Preliminary results were leveraged to inform constituent group meetings and are presented below. Analysis of final survey responses will be included in the constituent group summary report (PO-44000-00028053 Deliverable #3).

- *Twenty-seven survey responses contained answers to every non-mandatory question. Thirteen survey responses did not contain answers to every non-mandatory question.*
- *Thirty-four of 40 responses indicated they were very concerned about the impact of the cost of drugs on their organization. Six responses indicated they were somewhat concerned.*
- *Thirty of 40 responses indicated they were very concerned about the impact of the cost of drugs on their patients. Ten responses indicated they were somewhat concerned.*
- *Twenty of 40 responses indicated a UPL would have a negative impact on their organization's spending and budgetary considerations. Fifteen responses indicated a neutral impact, and five indicated a positive impact.*
- *Seventeen of 40 responses indicated a UPL would create challenges to patient access. Twelve responses indicated it would create opportunities for a positive impact, and 11 felt it would have a neutral impact.*
- *Twenty-one of 40 responses indicated a UPL would have a neutral impact on patients' ability to afford their medications. Twelve responses indicated a positive impact, and seven responses indicated a negative impact.*
- *Twenty of 40 responses indicated a UPL would have a negative impact on their pharmacy's revenue and financial viability. Fifteen responses indicated a neutral impact, and five responses were blank.*

Constituent Group Description

Two independent pharmacy/PSAO/GPO constituent group engagement sessions were held on May 16 and June 12, 2024. Invitations were distributed by PDAB staff (including a list of discussion questions), with 10 unique individuals attending across both sessions. Table 2 includes a list of organizations and their attendance.

Table 2: Independent Pharmacy/PSAO/GPO Attendees

Organization	Meeting 1	Meeting 2
AlignRx LLC		X
American Pharmacists Association	X	
BHS Pharmacy	X	
Independent Pharmacy Cooperative		X
National Community Pharmacists Association	X	
Nelco Advisory	X	
Oregon State Pharmacy Association	X	X
OSU College of Pharmacy	X	X
Rogue Community Health	X	

Two non-independent pharmacy/wholesaler/distributor constituent group engagement sessions were held on May 29 and June 5, 2024. A total of 43 invitations were distributed (including a list of discussion questions), with six unique individuals attending across both sessions. Table 3 includes a list of organizations and their attendance.

Table 3: Non-Independent Pharmacy/Wholesaler/Distributor Attendees

Organization	Meeting 1	Meeting 2
Albertsons Companies Inc.	X	
Cencora	X	
Costco Wholesale Corporation		X
CVS Health		X
Healthcare Distribution Alliance	X	

Summary of Discussion

As described above, Myers and Stauffer facilitators asked attendees a series of scripted and unscripted questions to solicit constituent input. Sessions were not intended to provide responses to specific attendee questions and, if asked, facilitators requested that attendees provide their recommendations for how the Board might use its authority

to address the issue presented and/or directly submit the question to the Board through its online public comment form or via email at OregonPDAB@mslc.com.
The following are summaries of the independent pharmacies/PSAO/GPO and non-independent pharmacy/wholesaler constituent group engagement sessions, identifying critical discussions, recommendations, and follow-up items presented by attendees (i.e., PO-44000-00028053 Deliverable #2). It should be noted that only one attendee at the non-independent pharmacy/wholesaler/distributor focus group provided input at the first meeting. There was no input provided by attendees of that group's second facilitated session despite multiple attempts from facilitators and the Board chair (at both meetings) to encourage participation.

Critical Discussions from Independent Pharmacy/PSAO/GPO Group

- *Pharmacy constituents expressed concerns that a UPL would cause pharmacies to be reimbursed below their drug acquisition cost, which is often the case with PBM reimbursement. Constituents also noted that current PBM contracts do not have provisions for a UPL and could require an extended time to amend (6-12 months).*
- *Pharmacy constituents expressed concerns that should a UPL result in financial losses for pharmacies, it could lead to pharmacy closures or decisions to not dispense specific medications with an applied UPL, either of which could result in challenges to patient access to medication.*
- *Constituents expressed concerns around the impact to 340B-owned pharmacies; as described in other sessions, any UPL that lowers list prices could result in decreased 340B savings and, subsequently, reduction or elimination of non-revenue generating services funded through these savings (e.g., food pantries, community health workers, dental and behavioral health programs).*
- *Pharmacy constituents expressed concerns that applying a UPL to a single drug product within a drug class could cause PBMs to alter benefit designs in a manner that results in preferred status for drugs not subject to a UPL and/or presents better rebate opportunities. In addition, pharmacy constituents expressed concerns that PBMs would steer patients to out-of-state mail order pharmacies, including PBM-owned pharmacies, to avoid the UPL requirement.*
- *Pharmacy constituents expressed concerns that PBMs and/or Medicaid plans often require the use of Brand products (due to rebates) over the use of generic or biosimilar alternatives.*
- *Pharmacy constituents expressed interest in the concept of PBM negotiated rebates being passed through to the patient at point of sale, thereby decreasing*

patient out-of-pocket spending.

- *Pharmacy constituents expressed concerns regarding enforcement of a UPL, specifically whether PBMs would be held accountable for implementing and applying a UPL to the Oregon market.*
- *Constituents expressed appreciation for the legislature and Board's efforts to gather input and analyzing the feedback from constituents; however, they also expressed concern with how a UPL would address costs throughout the supply chain and whether/to what extent patients would experience savings.*

Recommendations from Independent Pharmacy/PSAO/GPO Group

- *Pharmacy constituents recommended that if an Actual Acquisition Cost (AAC) benchmark were used in the UPL process, it should be representative of data from Oregon pharmacies (i.e., a state-specific AAC, rather than the National Average Drug Acquisition Cost benchmark).*
- *Pharmacy constituents requested that pharmacies be given explicit protections when implementing a UPL to ensure that PBMs include dispensing costs as part of overall reimbursement. Additionally, one constituent specifically recommended that the legislature consider these costs as a factor in the UPL and avoid "divorcing" the professional dispensing fee from the UPL.*
- *Pharmacy constituents recommended that the UPL be applied to drug classes as a whole, to avoid negative impacts to patient benefits and cost-sharing through benefit design changes.*

Follow-up Items from Independent Pharmacy/PSAO/GPO Group

- *No follow-up items were identified by constituents or facilitators.*

Critical Discussions from Non-Independent Pharmacy/Wholesaler/Distributor Group

- *There is a concern that wholesale contracts are managed at the national level; however, the speaker did not elaborate on the implications of this process.*
- *There was a mention of the complexities around the 340B program and the Drug Supply Chain Security Act; there was no discussion of details related to these complexities.*

Recommendations from Non-Independent Pharmacy/Wholesaler/Distributor Group

- *None*

Follow-up Items from Non-Independent Pharmacy/Wholesaler/Distributor Group

- *None from attendees. However, there was minimal input from attendees and the Board may wish to identify an additional mechanism for engagement with this focus group members.*

Next Steps

Following completion of all constituent group engagement sessions, Myers and Stauffer will generate a final report for Agency showing recommendations, concerns, and obstacles identified at each stakeholder session and identified by any Agency provided data. This report will include, but not be limited to, an executive summary outlining the contents of the report that does not exceed two pages, as well as analyses of pre-session survey responses and input collected during facilitated discussions (PO-44000-00028053 Deliverable #3).

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Deliverable 2: Constituent Group Summary
Pharmaceutical Manufacturers

Background

The Oregon Prescription Drug Affordability Board (hereinafter referred to as "PDAB," or "the Board") was established in 2021 through Senate Bill 844. The purpose of the Board is to protect residents of Oregon, state and local governments, commercial health plans, health care providers, pharmacies licensed in Oregon, and other stakeholders within the health care system from the high costs of prescription drugs. The Board is responsible for annually identifying and reviewing nine drugs and at least one insulin product that may create affordability challenges for the health care systems or high out-of-pocket costs for patients in Oregon.

In June 2023, the Oregon Legislature passed Senate Bill 192, which tasked the Board with developing a plan to establish upper payment limits ("UPL") on drugs sold in the State that are subject to the Board's affordability reviews. The Board must report its plan to the interim committees of the Legislative Assembly related to health in fall 2024. The report must include an analysis of potential savings from, or costs of implementing, the plan with respect to the State, as well as carriers (e.g., public and private health benefit plans), hospitals, pharmacies, and consumers (hereinafter collectively referred to as "constituents" or "constituent groups").

In December 2023, the State of Oregon, acting through its Department of Consumer and Business Services, Division of Financial Regulation, contracted with Myers and Stauffer LC ("Myers and Stauffer") (PO-44000-00028053) to provide prescription drug consulting and outreach services related to SB192. As part of these services, Myers and Stauffer is conducting focus group meetings with constituent groups as identified and approved by the Board including, carriers, consumer organizations, hospitals, retail pharmacies, Medicaid 340B covered entities, pharmaceutical manufacturers, pharmacy benefit managers, and patient advocacy groups.[1]

Approach

Myers and Stauffer routinely conducts internal and external constituent engagement activities designed to support well-informed and collaborative policy development. Given the complexity of the subject matter associated with this particular engagement, the unique experiences of the distinct constituent groups, and the potential for unintended consequences associated with a UPL plan, we conducted a series of structured, professionally facilitated constituent group engagement sessions designed to solicit input on several key themes. A summary of our approach to these sessions is briefly described below.

[1] Note, pharmaceutical manufacturers and related entities, pharmacy benefit managers, and patient advocacy groups were added as a subsequent contract amendment in May 2024.

1

- *Collaborated with the Board to develop a constituent engagement plan.*
- *Collaborated with the Board to develop an electronic, pre-session survey to obtain constituent input regarding UPLs and their potential impacts. Additional information regarding this survey is presented below.*
- *Collaborated with the Board to identify constituent groups and appropriate contacts to receive the survey and be included in the sessions.*
- *Collaborated with Horvath Health Policy to draft an introductory document for constituents to establish a baseline level of understanding prior to the sessions.*
- *Collaborated with the Board to develop constituent-facing documents, communications, and questions for each session.*

Leveraging the approach described above, Myers and Stauffer conducted two engagement sessions for each Board-identified constituent group. Sessions were conducted throughout May, June, and July 2024, each lasting approximately one hour, and were facilitated by a team of Myers and Stauffer facilitators, subject matter experts, scribes, and logistics coordinators. During each session, the Myers and Stauffer team described the Board's rationale for engaging constituents, provided an overview of the UPL process, and asked a series of scripted and unscripted questions designed to solicit constituent perceptions of drug affordability and the potential impact of a UPL, as well as recommendations regarding the development of a UPL methodology and strategies the Board should consider to address drug affordability.

Preliminary Survey Results

Pre-session surveys (mentioned above) were developed to garner constituent understanding and perspective regarding UPL methodology and perceived impacts of implementation. Key characteristics of the survey are highlighted below:

- *The survey included four mandatory questions designed to collect respondent demographic information. Replies to non-mandatory questions included nine quantitative and eight qualitative responses, respectively.*
- *Invalid responses were excluded that met the following requirements:*
  - *Respondents who submitted multiple identical responses; only one response was reviewed in these instances.*
  - *Respondents who did not answer questions beyond the initial four mandatory questions.*

- *A number of responses answered some, but not all, non-mandatory questions. In these instances, only completed questions were reviewed.*
- *Responses to non-mandatory questions which did not contain valid data (e.g., Lorem ipsum or clearly unresponsive text such as "text"). In these instances, only questions with valid data were reviewed.*

Invitations to participate in the surveys and a brief UPL proposed approach document were sent to 56 unique emails approximately one week prior to sending meeting invitations. Recipients were asked to forward the survey to others within their organization if/where appropriate, and no limits were placed on the number of responses that could be submitted by each organization. We received seven survey responses from six different organizations.

Table 1: Survey Respondents

Organization
Biotechnology Innovation Organization (BIO)
Bristol Myers Squibb
Genentech Inc.
Gilead Sciences, Inc.
Johnson & Johnson Health Care System Inc.
Novartis

Preliminary results were leveraged to inform constituent group meetings and are presented below. Analysis of final survey responses will be included in the constituent group summary report (PO-44000-00028053 Deliverable #3).

- *Three survey responses contained answers to every non-mandatory question. Four survey responses did not contain answers to every non-mandatory question.*
- *Two of seven responses indicated they were very concerned about the impact of the cost of drugs on their patients. One response indicated they were somewhat concerned, and four responses were blank.*
- *Two of seven responses indicated a UPL would have a negative impact on their organization's revenue and budgetary considerations. Five responses were blank.*
- *Five of seven responses indicated a UPL would create challenges to patient access to medication. Two responses were blank.*

- *Two of seven responses indicated a UPL would have a negative impact on patients' ability to afford their medications. Two responses indicated a neutral impact, one response indicated a positive impact, and two responses were blank.*

Constituent Group Description

Two pharmaceutical manufacturer constituent group engagement sessions were held on July 1 and July 10, 2024. A total of 56 invitations were distributed (including a list of discussion questions), with 25 individuals attending across both sessions. Attendees consisted of pharmaceutical manufacturers and manufacturing trade groups. Below is a list of organizations and their attendance.

Table 2: Attendees

Organization	Session 1	Session 2
AstraZeneca	X	X
Biotechnology Innovation Organization (BIO)	X	X
Bristol Myers Squibb	X	
Genentech	X	X
Gilead Sciences	X	X
JHack Consulting		X
Johnson & Johnson	X	X
Merck	X	X
Oregon Bioscience Association	X	X
PhRMA	X	X
Takeda Pharmaceuticals	X	X

Summary of Discussion

As described above, Myers and Stauffer facilitators asked attendees a series of scripted and unscripted questions to solicit constituent input. Sessions were not intended to provide responses to specific attendee questions and, if asked, facilitators requested that attendees provide their recommendations for how the Board might use its authority to address the issue presented and/or directly submit the question to the Board through its online public comment form or via email at OregonPDAB@mslc.com. What follows is a summary of the pharmaceutical manufacturers constituent group engagement sessions, identifying critical discussions, recommendations, and follow-up items presented by attendees (i.e., PO-44000-00028053 Deliverable #2).

Critical Discussions

- *The health care payment system is highly complex. Patient out of pocket costs are dependent on benefit design and vary greatly. Participants felt that insurers and pharmacy benefit managers (PBMs) are not passing cost savings to patients. Federal health care reform may be necessary to address these issues.*

- *Manufacturers currently provide mechanisms to improve affordability for patients. The group provided details regarding patient assistance programs, cost sharing assistance, 340B and Ryan White programs, clinical trial benefits, and rebates and discounts to insurers and PBMs. While rebates are highly variable and drug-specific, respondents estimated that rebates account for cost savings of 50% on branded products and as much as 80% on highly competitive drugs.*
- *PDAB focus. The group felt a UPL is a shortsighted view in addressing the root cause of drug affordability issues. They expressed concerns with unintended consequences of a UPL, including increased costs to patients or loss of patient access to drugs.*
- *Definition of "affordability." The group questioned to whom the question of affordability was focused, as well as the cost of the drug.*
- *UPL interaction with other benchmarks. Attendees requested that more information be shared about how the Board would ensure that UPLs would not impact Medicaid rebates, federal match, and 340B ceiling price calculations.*

Recommendations

- *Rebate pass-through legislation. Participants cited legislation in West Virginia, Arkansas, and Indiana requiring that PBMs share rebate savings with patients. The group explained that implementation would be relatively easy and would likely not result in increased premiums.*
- *Utilization management. Respondents recommended that the Board examine the use of utilization management tools and how regulations could ensure sustained reductions in out of pocket costs to patients.*
- *PBM reform. The group recommended establishing a fiduciary responsibility requirement for PBMs and disconnecting PBM compensation from list price of drugs.*
- *Focus of affordability reviews. Participants recommended that affordability reviews focus on direct costs to patients. They expressed concerns regarding the age of data used for affordability reviews as well as patent expirations and biosimilar availability for some drugs selected for review. They encouraged consistency and review of robust data when performing affordability reviews. The group stressed the importance of considering the medical costs avoided by patients who have access to necessary medications in addition to indirect costs including rescue medications, transportation to treatment appointments, and the impact of benefit design on patient out of pocket costs.*

- *Enhance Board membership. The group recommended that the Board include physician specialists and patients to help understand the clinical effects of the drugs, as well as the impact of setting a UPL.*

Follow-up Items

- *Mechanism for submission of confidential data. The group discussed a lack of options for submitting confidential data to the Board, and expressed willingness to share additional data if confidentiality is guaranteed.*

Next Steps

Following completion of all constituent group engagement sessions, Myers and Stauffer will generate a final report for Agency showing recommendations, concerns, and obstacles identified at each stakeholder session and identified by any Agency provided data. This report will include, but not be limited to, an executive summary outlining the contents of the report that does not exceed two pages, as well as analyses of pre-session survey responses and input collected during facilitated discussions (PO-44000-00028053 Deliverable #3).

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Deliverable 2: Constituent Group Summary
Advocacy Groups

Background

The Oregon Prescription Drug Affordability Board (hereinafter referred to as "PDAB," or "the Board") was established in 2021 through Senate Bill 844. The purpose of the Board is to protect residents of Oregon, state and local governments, commercial health plans, health care providers, pharmacies licensed in Oregon, and other stakeholders within the health care system from the high costs of prescription drugs. The Board is responsible for annually identifying and reviewing nine drugs and at least one insulin product that may create affordability challenges for the healthcare systems or high out-of-pocket costs for patients in Oregon.

In June 2023, the Oregon Legislature passed Senate Bill 192, which tasked the Board with developing a plan to establish upper payment limits ("UPL") on drugs sold in the State that are subject to the Board's affordability reviews. The Board must report its plan to the interim committees of the Legislative Assembly related to health in fall 2024. The report must include an analysis of potential savings from, or costs of implementing, the plan with respect to the State, as well as carriers (e.g., public and private health benefit plans), hospitals, pharmacies, and consumers (hereinafter collectively referred to as "constituents" or "constituent groups").

In December 2023, the State of Oregon, acting through its Department of Consumer and Business Services, Division of Financial Regulation, contracted with Myers and Stauffer LC ("Myers and Stauffer") (PO-44000-00028053) to provide prescription drug consulting and outreach services related to SB192. As part of these services, Myers and Stauffer is conducting focus group meetings with constituent groups as identified and approved by the Board including, carriers, consumer organizations, hospitals, retail pharmacies, Medicaid 340B covered entities, pharmaceutical manufacturers, pharmacy benefit managers, and patient advocacy groups.[1]

Approach

Myers and Stauffer routinely conducts internal and external constituent engagement activities designed to support well-informed and collaborative policy development. Given the complexity of the subject matter associated with this particular engagement, the unique experiences of the distinct constituent groups, and the potential for unintended consequences associated with a UPL plan, we conducted a series of structured, professionally facilitated constituent group engagement sessions designed to solicit input on several key themes. A summary of our approach to these sessions is briefly described below.

[1] Note, pharmaceutical manufacturers and related entities, pharmacy benefit managers, and patient advocacy groups were added as a subsequent contract amendment in May 2024.

1

- *Collaborated with the Board to develop a constituent engagement plan.*
- *Collaborated with the Board to develop an electronic, pre-session survey to obtain constituent input regarding UPLs and their potential impacts. Additional information regarding this survey is presented below.*
- *Collaborated with the Board to identify constituent groups and appropriate contacts to receive the survey and be included in the sessions.*
- *Collaborated with Horvath Health Policy to draft an introductory document for constituents to establish a baseline level of understanding prior to the sessions.*
- *Collaborated with the Board to develop constituent-facing documents, communications, and questions for each session.*

Leveraging the approach described above, Myers and Stauffer conducted two engagement sessions for each Board-identified constituent group. Sessions were conducted throughout May, June, and July 2024, each lasting approximately one hour, and were facilitated by a team of Myers and Stauffer facilitators, subject matter experts, scribes, and logistics coordinators. During each session, the Myers and Stauffer team described the Board's rationale for engaging constituents, provided an overview of the UPL process, and asked a series of scripted and unscripted questions designed to solicit constituent perceptions of drug affordability and the potential impact of a UPL, as well as recommendations regarding the development of a UPL methodology and strategies the Board should consider to address drug affordability.

Preliminary Survey Results

Pre-session surveys (mentioned above) were developed to garner constituent understanding and perspective regarding UPL methodology and perceived impacts of implementation. Key characteristics of the survey are highlighted below:

- *The survey included four mandatory questions designed to collect respondent demographic information. Replies to non-mandatory questions included nine quantitative and eight qualitative responses, respectively.*
- *Invalid responses were excluded that met the following requirements:*
  - *Respondents who submitted multiple identical responses; only one response was reviewed in these instances.*
  - *Respondents who did not answer questions beyond the initial four mandatory questions.*

- *A number of responses answered some, but not all, non-mandatory questions. In these instances, only completed questions were reviewed.*
- *Responses to non-mandatory questions which did not contain valid data (e.g., Lorem ipsum or clearly unresponsive text such as "text"). In these instances, only questions with valid data were reviewed.*

Invitations to participate in the surveys and a brief UPL proposed approach document were sent to 60 unique emails of 44 advocacy groups approximately one week prior to sending meeting invitations. Recipients were asked to forward the survey to others within their organization if/where appropriate, and no limits were placed on the number of responses that could be submitted by each organization. We received 11 survey responses from 10 different organizations.

Table 1: Survey Respondents

Organization
AARP Oregon
AiArthritis (International Foundation for Autoimmune & Autoinflammatory Arthritis)
American Federation of Teachers - Oregon
Caring Ambassadors Program
EACH Coalition
ICAN, International Cancer Advocacy Network
National Bleeding Disorders Foundation
National Psoriasis Foundation
Oregon Coalition for Affordable Prescriptions
Pacific Northwest Bleeding Disorders

Preliminary results were leveraged to inform constituent group meetings and are presented below. Analysis of final survey responses will be included in the constituent group summary report (PO-44000-00028053 Deliverable #3).

- *Three survey responses contained answers to every non-mandatory question. Eight survey responses did not contain answers to every non-mandatory question.*
- *Five of 11 responses indicated they were very concerned about the impact of the cost of drugs on their organization. Two responses indicated they were somewhat concerned, two responses indicated they were not concerned, and two responses were blank.*

- *Nine of 11 responses indicated they were very concerned about the impact of the cost of drugs on their patients. One response indicated they were somewhat concerned, and one response was blank.*
- *Five of 11 responses indicated a UPL would have a neutral impact on their organization's spending and budgetary concerns. One response indicated a negative impact, one indicated a positive impact, and four responses were blank.*
- *Seven of 11 responses indicated a UPL would create challenges to patient access to medications. Three responses indicated a positive impact, and one indicated a neutral impact.*
- *Five of 11 responses indicated a UPL would have a negative impact on patients' ability to afford their medications. Three responses indicated a neutral impact, and three responses indicated a positive impact.*

Constituent Group Description

Two advocacy group engagement sessions were held on July 1 and July 11, 2024. A total of 60 invitations were distributed (including a list of discussion questions), with 10 individuals attending across both sessions. Attendees largely consisted of groups representing various patient populations, population demographics, and industries. Below is a list of organizations and their attendance.

Table 2: Attendees

Organization	Session 1	Session 2
AARP	X	
AiArthritis (International Foundation for Autoimmune & Autoinflammatory Arthritis)	X	X
American Federation of Teachers - Oregon		X
Caring Ambassadors Program	X	X
ICAN, International Cancer Advocacy Network	X	
National Bleeding Disorders Foundation	X	
Oregon Bioscience Association		X
Oregon Coalition for Affordable Prescriptions (OCAP)	X	X
OSPIRG	X	X
Pacific Northwest Bleeding Disorders		X

Summary of Discussion

As described above, Myers and Stauffer facilitators asked attendees a series of scripted and unscripted questions to solicit constituent input. Sessions were not intended to provide responses to specific attendee questions and, if asked, facilitators requested that attendees provide their recommendations for how the Board might use its authority

to address the issue presented and/or directly submit the question to the Board through its online public comment form or via email at OregonPDAB@mslc.com. What follows is a summary of the advocacy group constituent engagement sessions, identifying critical discussions, recommendations, and follow-up items presented by attendees (i.e., PO-44000-00028053 Deliverable #2).

Critical Discussions

- *Focus on patient costs. The group suggested that the Board focus on affordability at the patient level, including both drug copays and insurance premiums.*
- *PBM reform. Participants emphasized a desire for PBM reform and the necessity of transparency throughout the system. Specific goals of PBM reform included the ability for patients to choose their own pharmacy, prohibiting pharmacy "clawbacks" (retroactive recovery of paid claims by PBMs), and delinking PBM fees from the list price of drugs.*
- *Definition of specialty drugs. Participants suggested requiring PBMs and payers to use a common, shared definition of specialty drugs, such as the one currently defined in Oregon statute.[2] Drugs are often designated as specialty based on the PBM's determination, which often results in limited patient access through retail pharmacies and higher costs (copays) to patients and may also be out of alignment with the Oregon statutes.*
- *Specialty carve-outs. The group expressed concern regarding specialty drugs being carved out of traditional employer benefits and placed in alternative funding programs (i.e., a specific type of specialty drug carve-out being used by some employer-sponsored self-funded health plans) and how the UPL would impact or accelerate use of those programs.*
- *Drug access concerns with UPL. Participants discussed that implementation of a UPL could result in loss of patient access to necessary medications. Patients would be negatively affected if manufacturers opt to no longer sell a drug in Oregon.*
- *Data for UPL calculations. The group had numerous questions about the UPL process, including how affordability would be determined and the metrics used to assess costs and outcomes since Quality Adjusted Life Years are prohibited as a metric. Participants encouraged the use of fair and unbiased patient data specifically from the Oregon population.*

[2] https://www.oregonlegislature.gov/bills_laws/lawsstatutes/2019orlaw0526.pdf

- *Interstate concerns. One participant questioned UPL logistics for a purchaser in a buying group with other states. Another noted the difficulty of implementing a UPL for multi-state employers.*

- *Differing opinions. It was noted that there were differences of opinion regarding patient impact and implementation of a UPL between the participants in this focus group. Because the participants represented different types of advocacy organizations, there was not universal agreement that the UPL would have a positive or negative impact on patients or that manufacturer programs resulted in a savings for most patients, especially insured patients.*

Recommendations

- *Insurer or PBM reporting on savings. Participants highlighted the importance of tracking potential savings resulting from UPL implementation. Specifically, participants wanted to ensure savings are passed to patients in the form of reduced premiums or other patient out-of-pocket costs. The Board must consider the unintended impact on formularies and benefit design in order to avoid negatively impacting patients.*

- *Affordability definition and UPL process transparency. The group recommended that the Board consider refining and expanding the definition of affordability, including how it is measured and the groups to which it applies (patients, employers, carriers, etc.). The UPL process requires transparency so that everyone understands how prices are derived and how the UPL will be implemented.*

- *Manufacturer price justification. The group suggested that manufacturers be required to present cost information to explain the list price of drugs.*

- *Consider PBM reform that includes:*
  - *Patient ability to choose their pharmacy;*
  - *Elimination of mandatory mail order;*
  - *Prohibition of "clawbacks" from providers;*
  - *Mandatory pass-through of savings/rebates to health plans and patients;*
  - *Delinking PBM reimbursement from the list price; and*
  - *Utilization of a common, shared specialty drug definition.*

- *Other approaches for addressing drug affordability. Respondents discussed the use of other cost saving measures, noting that addressing affordability will require multiple approaches. Proposed approaches include:*
  - *Importation of drugs from Canada (not fully supported by all participants);*
  - *Use of bulk purchasing programs;*

- *Federal patent reform;*
- *In-state manufacturing of drugs; and*
- *Utilization of the Medicare maximum fair price.*

Follow-up Items

- *Survey. Representatives from Caring Ambassadors and AiArthritis indicated they developed and conducted an independent UPL survey of their stakeholders. They offered to share the results after publishing.*

Next Steps

Following completion of all constituent group engagement sessions, Myers and Stauffer will generate a final report for Agency showing recommendations, concerns, and obstacles identified at each stakeholder session and identified by any Agency provided data. This report will include, but not be limited to, an executive summary outlining the contents of the report that does not exceed two pages, as well as analyses of pre-session survey responses and input collected during facilitated discussions (PO-44000-00028053 Deliverable #3).

MYERS AND STAUFFER LC
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Deliverable 2: Constituent Group Summary
Pharmacy Benefit Managers

Background

The Oregon Prescription Drug Affordability Board (hereinafter referred to as "PDAB," or "the Board") was established in 2021 through Senate Bill 844. The purpose of the Board is to protect residents of Oregon, state and local governments, commercial health plans, health care providers, pharmacies licensed in Oregon, and other stakeholders within the health care system from the high costs of prescription drugs. The Board is responsible for annually identifying and reviewing nine drugs and at least one insulin product that may create affordability challenges for the healthcare systems or high out-of-pocket costs for patients in Oregon.

In June 2023, the Oregon Legislature passed Senate Bill 192, which tasked the Board with developing a plan to establish upper payment limits ("UPL") on drugs sold in the State that are subject to the Board's affordability reviews. The Board must report its plan to the interim committees of the Legislative Assembly related to health in fall 2024. The report must include an analysis of potential savings from, or costs of implementing, the plan with respect to the State, as well as carriers (e.g., public and private health benefit plans), hospitals, pharmacies, and consumers (hereinafter collectively referred to as "constituents" or "constituent groups").

In December 2023, the State of Oregon, acting through its Department of Consumer and Business Services, Division of Financial Regulation, contracted with Myers and Stauffer LC ("Myers and Stauffer") (PO-44000-00028053) to provide prescription drug consulting and outreach services related to SB192. As part of these services, Myers and Stauffer is conducting focus group meetings with constituent groups as identified and approved by the Board including, carriers, consumer organizations, hospitals, retail pharmacies, Medicaid 340B covered entities, pharmaceutical manufacturers, pharmacy benefit managers (PBMs), and patient advocacy groups.[1]

Approach

Myers and Stauffer routinely conducts internal and external constituent engagement activities designed to support well-informed and collaborative policy development. Given the complexity of the subject matter associated with this particular engagement, the unique experiences of the distinct constituent groups, and the potential for unintended consequences associated with a UPL plan, we conducted a series of structured, professionally facilitated constituent group engagement sessions designed to solicit input on several key themes. A summary of our approach to these sessions is briefly described below.

[1] Note, pharmaceutical manufacturers and related entities, pharmacy benefit managers, and patient advocacy groups were added as a subsequent contract amendment in May 2024.

- *Collaborated with the Board to develop a constituent engagement plan.*
- *Collaborated with the Board to develop an electronic, pre-session survey to obtain constituent input regarding UPLs and their potential impacts. Additional information regarding this survey is presented below.*
- *Collaborated with the Board to identify constituent groups and appropriate contacts to receive the survey and be included in the sessions.*
- *Collaborated with Horvath Health Policy to draft an introductory document for constituents to establish a baseline level of understanding prior to the sessions.*
- *Collaborated with the Board to develop constituent-facing documents, communications, and questions for each session.*

Leveraging the approach described above, Myers and Stauffer conducted two engagement sessions for each Board-identified constituent group. Sessions were conducted throughout May, June, and July 2024, each lasting approximately one hour, and were facilitated by a team of Myers and Stauffer facilitators, subject matter experts, scribes, and logistics coordinators. During each session, the Myers and Stauffer team described the Board's rationale for engaging constituents, provided an overview of the UPL process, and asked a series of scripted and unscripted questions designed to solicit constituent perceptions of drug affordability and the potential impact of a UPL, as well as recommendations regarding the development of a UPL methodology and strategies the Board should consider to address drug affordability.

Preliminary Survey Results

Pre-session surveys (mentioned above) were developed to garner constituent understanding and perspective regarding UPL methodology and perceived impacts of implementation. Key characteristics of the survey are highlighted below:

- *The survey included four mandatory questions designed to collect respondent demographic information. Replies to non-mandatory questions included nine quantitative and eight qualitative responses, respectively.*
- *Invalid responses were excluded that met the following requirements:*
  - *Respondents who submitted multiple identical responses; only one response was reviewed in these instances.*
  - *Respondents who did not answer questions beyond the initial four mandatory questions.*
  - *A number of responses answered some, but not all, non-mandatory questions. In these instances, only completed questions were reviewed.*

- *Responses to non-mandatory questions which did not contain valid data (e.g., Lorem ipsum or clearly unresponsive text such as "text"). In these instances, only questions with valid data were reviewed.*

Invitations to participate in the surveys and a brief UPL proposed approach document were sent to 159 unique emails approximately two weeks prior to sending meeting invitations. Recipients were asked to forward the survey to others within their organization if/where appropriate, and no limits were placed on the number of responses that could be submitted by each organization. We received five survey responses from five different organizations.

Table 1: Survey Respondents

Organization
Costco Health Solutions
Pharma Force Group LLC
Prescryptive Health
ProAct, Inc.
TRHC TPA, LLC

Preliminary results were leveraged to inform constituent group meetings and are presented below. Analysis of final survey responses will be included in the constituent group summary report (PO-44000-00028053 Deliverable #3).

- *Three survey responses contained answers to every non-mandatory question. Two survey responses did not contain answers to every non-mandatory question.*
- *Four of five responses indicated they were very concerned about the impact of the cost of drugs on their organization. One response indicated they were somewhat concerned.*
- *Three of five responses indicated they were very concerned about the impact of the cost of drugs on their members. One response indicated they were somewhat concerned, and one response indicated they were not concerned.*
- *Three of five responses indicated a UPL would have a neutral impact on their organization's spending and budgetary considerations. Two responses indicated it would have a negative impact.*
- *Two of five responses indicated a UPL would create challenges to patient access to medications. Two responses indicated a neutral impact, and one response indicated a positive impact.*

- *Three of five responses indicated a UPL would have a neutral impact on patients' ability to afford their medications. One response indicated a negative impact, and one response indicated a positive impact.*
- *Three of five responses indicated a UPL would have a neutral impact on their company's revenue and financial viability. Two responses indicated a negative impact.*

Constituent Group Description

Two PBM constituent group engagement sessions were held on July 2 and July 16, 2024. A total of 159 invitations were distributed (including a list of discussion questions). While six individuals registered for the first session, none attended. Four individuals attended the second session. Attendees were diverse, consisting of traditional PBMs, a public benefit corporation PBM operating under a "transparent model" and a PBM trade association. Below is a list of organizations and their attendance.

Table 2: Attendees

Organization	Session 1	Session 2
AffirmedRx		X
FairosRx		X
PCMA		X
Prime Therapeutics		X

Summary of Discussion

As described above, Myers and Stauffer facilitators asked attendees a series of scripted and unscripted questions to solicit constituent input. Sessions were not intended to provide responses to specific attendee questions and, if asked, facilitators requested that attendees provide their recommendations for how the Board might use its authority to address the issue presented and/or directly submit the question to the Board through its online public comment form or via email at OregonPDAB@mslc.com. What follows is a summary of the PBM constituent group engagement sessions, identifying critical discussions, recommendations, and follow-up items presented by attendees (i.e., PO-44000-00028053 Deliverable #2).

Critical Discussions

- *PBMs improve drug affordability. Participants explained that PBMs take a comprehensive approach to drug affordability, including formulary management, utilization management, and encouraging use of generics and biosimilars.*

- *PBMs offer options to carriers, who ultimately determine the model that they will use to offer benefits to patients. Participants described the different pricing options available to insurers, including rebate pass-through, spread pricing, and fee-based models.*
- *UPL as price control. The group expressed concerns that a UPL may be considered price setting, which is illegal. UPLs may also be a disincentive to manufacturers to produce drugs.*
- *Respondents expressed concern about the theoretical nature of the UPL, especially the manufacturer "agrees to sell … at UPL" concept presented in the "Basics of UPL acquisition cost, billing, and payment" slide, and how this could be implemented.*
- *Supply chain impacts. There were concerns about the impact on the supply chain if they are obligated to provide the drugs/services to members if they cannot purchase the product at the UPL cost.*

Recommendations

- *Rebate pass-through at point-of-sale. Respondents discussed this model as an option available to carriers. The group explained that this model offers rebate benefits to a small number of brand-name drug utilizers, whereas when rebates are sent back to the PBM, savings are shared and benefit all participants. The group also discussed complexities of the rebate program and how rebates are paid approximately three months after the claim is processed. There were differences of opinion between the respondents as to how difficult or easy this is to implement, with one respondent indicating that the retrospective nature makes a point of sale pass-through difficult.*
- *Manufacturer engagement. Respondents suggested that manufacturers needed to be brought into the conversation to discuss implementation in a manner that mitigates unintended consequences.*
- *Respondents indicated a need for oversight, accountability and transparency to the process, while protecting proprietary rate information that allows the free market to get the best prices.*

Follow-up Items

- *More information on the West Virginia model. The representative from Prime Therapeutics offered to follow up with a colleague who provides services in West Virginia, where rebates are passed through at the point-of-sale.*

- *The survey and the focus group sessions garnered very limited participation from this constituent group. As such, the Board may wish to leverage additional means of engagement for PBMs.*

Next Steps

Following completion of all constituent group engagement sessions, Myers and Stauffer will generate a final report for Agency showing recommendations, concerns, and obstacles identified at each stakeholder session and identified by any Agency provided data. This report will include, but not be limited to, an executive summary outlining the contents of the report that does not exceed two pages, as well as analyses of pre-session survey responses and input collected during facilitated discussions (PO-44000-00028053 Deliverable #3).

Oregon Prescription Drug
Affordability Board

Prescription Drug Affordability Board

Affordability review

Agenda

- Review of past decisions
- Criteria added to the 2022 information
- Impacts of the previous affordability review
- Affordability review process

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 out-of-pocket costs

Identified preliminary list in August:
- Reviewed list types (MC/GI/ME/MP)
- Most Costly identified as key data point
- 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

Additional 2022 affordability review information

- Prescription drugs Shingrix, Genvoya, and Triumeq were not included in the carrier data call
- Additional columns of information were added to the drug list during the review process:
  - Total annual spend per enrollee
  - Average YoY price change
  - Brand or generic
  - Whether drug had therapeutic equivalent or biosimilar
  - First FDA approved date
  - Whether drug was on the IRA CMS negotiation list
  - Beginning and end of year WAC
  - WAC price change percentage over the year
  - Drug approved through expeditated pathway
  - Patent expiration date within 18 months
  - Exclusivity expiration date within 18 months

Impacts from 2022 affordability review information

- November board meeting drug categorization changes
  - From “orphan only” to “no”: **Suboxone**, **Shingrix**
  - From “orphan only” to “both orphan and non-orphan”: **Biktarvy, Mavyret**
  - From “non-listed” to “yes for Rx with therapeutic equivalent or biosimilar: **Stelara**
  - From “no” to “yes” for exclusivity expiration date within 18 months: **Ultomiris**
  - From “yes” to “no” for exclusivity expiration date within 18 months: **Eylea**
- November board decisions for Rx removal
  - Manufacturer drug information filed with the Drug Price Transparency team would not be reviewed for the first review
  - Carrier top drug information first removal was “orphan only” & “orphan & non-orphan” designations
  - Second removal was drugs on the IRA CMS list
- December board meeting
  - Some Rx were not properly identified or classified, resulting in removal from the list: **Suboxone, Symbicort, Albuterol, Soliqua, Xultophy, Lyumjev, & Humulin R**

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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

Phase 2: Select prescription drugs for affordability review

- Rule 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

- Rule 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

OAR 925-200-0010

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.

Any carrier Rx on mfr. new drug report or price increase report

- DPT collects information from manufacturers under ORS 646A.689. Data submitted under sections (6) 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 review.

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 determine the historical and current WAC price.
- For drugs with multiple national drug codes (NDC), a measure of central tendency will be used for a price comparison.

FDA

- PDAB staff will look up expedited approvals of fast track, priority review, accelerated approval, and breakthrough therapy designation.
- PDAB staff will use Medi-Span to look up brand-name drugs and biological products, and whether there are any approved and marketed generic drugs or biosimilar drugs.

Are therapeutic alternatives available?

- PDAB staff will review Rx under review and research if there are therapeutic alternatives and if cost and availability can be determined.

Does the Rx have a patent expiration or exclusivity expiration within 18 months

- PDAB staff will review Rx under review and research if there are patent or data exclusivity expirations within 18 months of affordability review.

Phase 2: Select prescription drugs for affordability review

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

OAR 925-200-0010

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

(a) Overall spend;
(b) Per-patient spend; and
(c) Patient out-of-pocket cost

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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