Oregon Prescription Drug Affordability Board

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Agenda

This is a regular meeting. *Date*: **Oct. 2, 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 08/21/2024 minutes**	Chair Bailey	2 minutes
Informational	Executive director's program update	Ralph Magrish	5 minutes
Informational	**Presentation by OHSU Center for Evidence-Based Policy**	OHSU	20 minutes
Information and Discussion	**Medicare MFP modeling presentation & Senate Bill 192 upper payment limit discussion**	PDAB Staff, Myers and Stauffer LC	85 minutes
Discussion	**Policy recommendations for the Legislature**	Chair Bailey	20 minutes
Informational	Announcements	Chair Bailey	2 minutes
Informational	General public comment: *limited to 3 minutes. Written comments are reviewed by the board prior to meeting.*	Chair Bailey	10 minutes
Vote	Adjournment	Chair Bailey	2 minutes

Next meeting

Oct. 16, 2024, at 9:30 a.m.

Accessibility

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

How to provide testimony to the board

The Prescription Drug Affordability Board invites people to provide testimony. **Oral:** To speak to the board during the public comment portion of the agenda, please submit the 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, August 21, 2024
Draft Minutes

Web link to the meeting video: https://youtu.be/GuBnwg3_B-U
Web link to the meeting materials: https://dfr.oregon.gov/pdab/Documents/20240821-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, John Murray
Absent: None

Declaration of conflict of interest: Dan Hartung, Robert Judge, and John Murray disclosed potential conflicts of interest. View at video minute **00:00:56**.

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 **00:03:10**.

MOTION to approve the July 24, 2024, minutes
Board Vote:
Yes: Dan Hartung, Robert Judge, Dan Kennedy, Chris Laman, Vice Chair Amy Burns, Chair Shelley Bailey
No: None
Abstain: John Murray
Motion passed 6-0

Executive director's program update: Ralph Magrish provided a program update. View the video at minute **00:04:24**.

SB 192 Upper payment limit deliverable presentation: The board heard a presentation by board consultant Myers and Stauffer LC summarizing feedback from constituent meetings with representatives from hospitals, pharmacies, insurance companies, manufacturers, pharmacy benefit managers, advocacy groups, patients and consumers. Myers and Stauffer also presented a draft constituent group engagement report to the board. View the presentation on **Pages 8-22** of the agenda materials. View the Constituent Group Engagement Report on **Pages 23-120** of the agenda materials. View at video minute **00:07:43**.

Affordability review process: Cortnee Whitlock, senior policy advisor, presented a summary of the affordability review process, which the board voted in June to pause for 2024 and start over in 2025. View the presentation on **Pages 121-134** of the agenda materials. View at video minute **01:20:17**.

Executive Director's Program Update Continued: Ralph Magrish continued the program update, which was interrupted earlier in the meeting by technical difficulties. View at video minute **02:21:50**.

Public comment: Chair Bailey said the board received **two public comment letters**, which are posted to the PDAB website. One person, Scott Bertani, Health HIV, signed up to speak during the public comment portion of the agenda. View at video minute **02:24:40**.

Announcements: Chair Bailey said the next board meeting would be Sept. 18, 2024. View at video minute **02:28:44**.

Adjournment: Chair Bailey adjourned the meeting at 12:04 pm with all board members in agreement. View at view minute **02:29:12**.

Oregon PDAB Support Options

September 18, 2024

Beth Shaw, MSC, Research Director

Susan Stuard, MBA, Director of Technical Assistance

CENTER FOR EVIDENCE-BASED POLICY

Today's Discussion

- Introductions
- Options for Support
- Next steps

Introductions

Center for Evidence-based Policy

Addressing policy challenges with evidence and collaboration

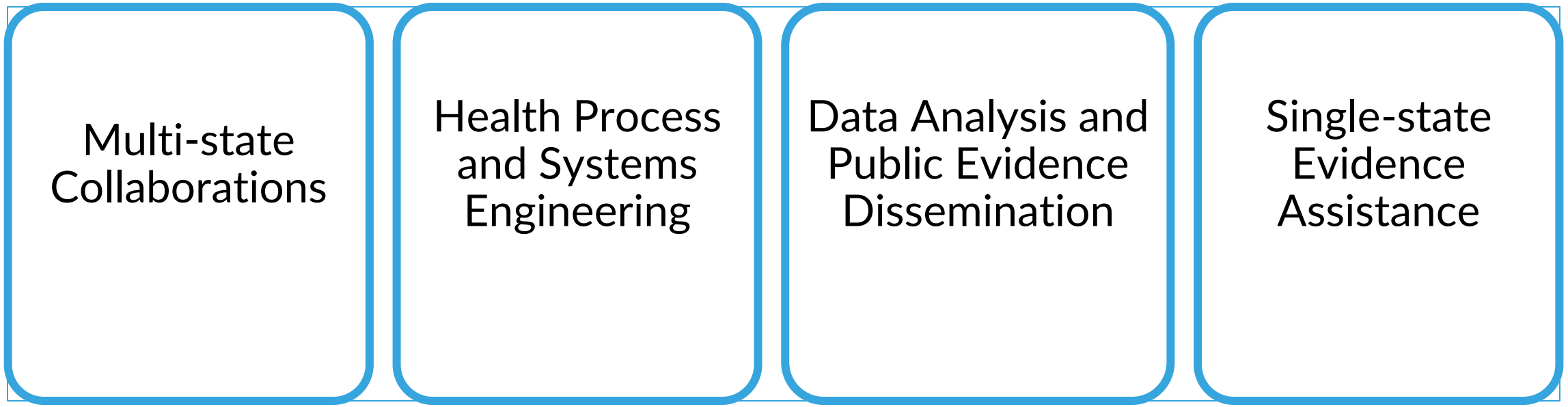
- Established in 2003 at Oregon Health & Science University
- Our work is driven by states, typically Medicaid
- We are not funded by industry or associations
- We have 2 grants (Arnold Ventures and The Commonwealth Fund)

Center for Evidence-based Policy

Addressing policy challenges with evidence and collaboration

- Worked with 37 states over the past 2 years
- We are nonpartisan and we do not lobby
- We apply data and evidence to public policy challenges
- We typically do not publish

Center for Evidence-based Policy



Options to Support Oregon PDAB

Options

Process and Systems Engineering

Decision-Making Support

Stakeholder Engagement

Strategic Planning

Evidence Assistance

Context Reviews

Basic or Enhanced

Process and Systems Engineering Options

- Decision-making algorithms
- System mapping, including cost-driver decision points
- Strategic planning
- Deliberation methods
- Stakeholder engagement
- Interface of stakeholder perspective with decision protocols
- Board member training
- Clinical and process consultation

Process and System Engineering

- The Center has supported systems development work for public boards and processes in several states, including stakeholder input and incorporation of evidence into decision-making
  - New York State Medicaid Evidence Based Benefit Review Advisory Committee
  - Texas Health and Human Services Commission coverage determination process
  - Washington Health Care Authority's Health Technology Assessment program
  - Louisiana Medicaid coverage determination process
  - Oregon Health Evidence Review Commission
  - Colorado Dept. of Health Care Policy & Financing All Payer Global Budget Workgroup

Evidence: Drug Context Review Outline

- Basic and enhanced options
  - Executive Summary
  - Background
  - Benefits and Harms
  - Health Equity
  - Therapeutic Alternatives
  - Disease Summary
  - Place in Care
  - Patient and Caregiver Perspectives
  - Summary

	Drug Context Review	Relevance to SB 844
Background	Short overview of the drugs of interest and the indication(s) for use.	
Benefits and Harms	Summary of data used for approval for each drug of interest (based on information from the FDA and online sources, such as IPD Analytics). Summary of selected effectiveness sources (to be agreed, but could include Cochrane reviews, and health technology assessments from major organizations, such as ICER and CADTH). *Optional*: Summary of relevant published studies identified from database searches and references list of the selected effectiveness sources above (Note. Not a full systematic review but reporting key study characteristics of studies. No risk of bias or assessment of the certainty of the evidence would be conducted.)	
Health Equity	Rapid review of health equity issues related to the use of the drugs of interest (which may include cost as a factor).	Context for SB844 §2(1)(a) and §2(1)(j)
Therapeutic Alternatives	Overview of FDA-approved alternatives other than the selected drugs of interest (based on information from the FDA and online sources, such as IPD Analytics). *Optional*: Summary of pipeline therapies in phase 3 testing, with any information on estimated costs.	Context for SB844 §2(1)(f) and §2(1)(g)
Disease Summary	Short overview of the condition(s) of interest, including US prevalence, mortality, and morbidity	Context for SB844 §2(1)(b)
Patient and Caregiver Perspectives	Rapid review of patient and caregiver perspectives on use of the drugs of interest (for example, ease of use by route of administration). Likely to be qualitative reports of patient and caregiver preferences and experience, or key reports from advocacy groups. May cover general issues related to medication use (e.g., preference for fewer doses, oral vs. injectable etc.).	Context for SB844 §2(1)(i)
Place in Care	Summary of selected clinical practice guidelines (selected based on date of publication, methodological rigor, and relevance to US practice).	Context for SB844 §2(1)(f)
Summary	Brief summary of the information contained in the report.	

Methods Discussion: Drug Context Review

- Threshold of evidence to support decision-making
  - Rapid review approach
  - Key sources of information only (i.e., not a comprehensive assessment of the benefits and harms of the drug)
  - No formal critical appraisal of published studies
  - No formal assessment of the certainty of the evidence

- Incorporation of evidence into Board process
  - Could be informed by process and systems engineering activity

Discussion & Next Steps


CENTER FOR
EVIDENCE-BASED POLICY

Placeholder for MFP Savings Analysis

As of 2024, ten states have operational Prescription Drug Affordability Boards (PDABs). Four of these states are authorized to set Upper Payment Limits (UPLs) on drugs subject to affordability reviews. While none of these four states have set a UPL, the summaries below describe factors these states may consider, or have proposed to consider (i.e., Maryland), when doing so. No state's law limits what factors to consider (other than certain cost effectiveness analysis) or limits the approach to setting a UPL.

Colorado PDAB[1]

Per statute, methodology must include consideration of cost of administering or dispensing the drug; cost of distributing in State; status of drug on FDA shortage list; other relevant costs related to the drug; and impact to older adults and persons with disabilities.

Must not include research or methods that employ dollars per quality adjusted life year (QALY).

Must authorize a pharmacy to charge reasonable fees, to be paid by the health plan for dispensing or delivering a UPL drug and the dispensing fee is not part of the UPL. Per regulation, costs to be considered include wholesale acquisition cost (WAC), average sales price (ASP), National Average Drug Acquisition Cost (NADAC), out-of-pocket spending, carrier paid amounts, public program fee schedules, net-cost estimates, Medicare MFP, and cost information voluntary provided by supply chain entities.

If a drug is on the FDA shortage list, the Board may consider availability and estimated shortage duration; shortage reason; therapeutic classification; and other related information.

With respect to assessing the impact on older adults (i.e., individuals over 65), the Board will consider utilization of the drug, cost of the drug, insurance coverage type for individuals utilizing the drug, and qualitative or quantitative analyses and information submitted by stakeholders with lived experience or expertise of the drug's impact to older adults.

Similarly, when assessing the impact to persons with disabilities, the Board may consider the therapeutic classification of the drug, including its therapeutic purpose and any conditions or diseases the drug may treat, as well as utilization of the drug, cost of the drug, insurance coverage type for individuals utilizing the drug, and qualitative or quantitative analyses and information submitted by stakeholders with lived experience or expertise of the drug's impact to older persons with disabilities. Employee Retirement Income Security Act (ERISA) plans have the option to participate.[2]

Maryland PDAB[3]

Per statute, the UPL will apply to only state and local government payers and purchasers. The methodology must include consideration of the cost of administering and delivering the drug to consumers; other relevant administrative costs related to the drug; and status of drug on FDA shortage list.

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[1] COLO. REV. STAT. § 10-16-1407 (2024); 3 COLO. CODE REGS. § 702-9-4.1 (2024).

[2] Note, Colorado and Washington law require all participating health plans to report on savings and other issues. States generally do not require new administrative functions or benefit coverage of self-funded ERISA plans, hence the opt-in.

[3] MD. CODE, HEALTH-GEN. § 21-2C-13 (2024); MARYLAND PRESCRIPTION DRUG AFFORDABILITY BOARD, PLAN OF ACTION FOR IMPLEMENTING THE PROCESS FOR SETTING UPPER PAYMENT LIMITS (2024), *available at* https://pdab.maryland.gov/Documents/comments/Draft%20Outline%20UPL%20Action%20Plan.2024.08.09.1700.pdf. Note, Maryland is the only UPL state that is not prohibited from using QALYs, which became a concern generally after the State passed its legislation.

Per the Board's *draft action plan to implement a process for setting UPLs*, methodologies for calculating a UPL may include cost effective analysis (i.e., QALY); therapeutic class reference; launch price based (i.e., setting UPL based on launch price adjusted for inflation); same molecule reference (i.e., set UPL based on prices of other products with the same active ingredients with the same indication of use); international reference; budget impact-based; or a blend of multiple methodologies.

The draft action plan also notes additional factors to be considered when setting a UPL including any information gathered during the cost review study process or the policy review process; utilization in government-sponsored health plans; the amount of direct government purchases; net prices for government-sponsored health plans; total out-of-pocket costs for government-sponsored health plans; current coverage status of the drug in government-sponsored health plans; the number of prescriptions paid through the State Medicaid program; the number of patients for the drug helped through the State Medicaid program; the total amount paid for the drug through the State Medicaid program; any budget impact analysis; comparisons of health system costs to research and develop cost; life cycle revenue analysis; and any information that can be derived from the manipulation, aggregation, calculation, and comparison of any available information. The Board has not specified how the State and local government UPL will be operationalized; however, options might include dedicated wholesaler, mail order, rebates, or some combination thereof.

Minnesota PDAB[4]
Per statute, methodology must include consideration of extraordinary supply costs, if applicable; the range of prices at which the drug is sold in the United States according to one or more pricing files (e.g., Medispan or FirstDatabank, or as otherwise determined by the board) and the range at which pharmacies are reimbursed in Canada; and any other relevant pricing and administrative cost information for the drug.[5]

Board may not consider cost-effectiveness analyses that include the cost-per QALY or similar measure to identify subpopulations for which a treatment would be less cost-effective due to severity of illness, age, or pre-existing disability. For any treatment that extends life, if the board uses cost-effectiveness results, it must use results that weigh the value of all additional lifetime gained equally for all patients no matter their severity of illness, age, or pre-existing disability.

When setting a UPL for a drug subject to the Medicare MFP, the Board must set the UPL at the Medicare maximum fair price.

Washington PDAB[6]
Per statute, methodology must include consideration of the cost of administering and delivering the drug to consumers; status of drug on FDA shortage list; and other relevant administrative costs related to the production and delivery of the drug.

Must not include QALY consider a patient's age or severity of illness or disability to identify subpopulations for which a prescription drug would be less cost-effective. For any drug that extends life,

[4] 2023 MINN. LAWS, CHAPTER 57, ARTICLE 2, SECTION 30.

[5] Publicly available Canadian prescription price/cost data comes from provincial public prescription coverage for people without drug coverage. The provinces post their drug by drug pharmacy reimbursement rates.

[6] WASH. REV. CODE § 70.405.050 (2024).

the board's analysis of cost-effectiveness may not employ a measure or metric which assigns a reduced value to the life extension provided by a treatment based on a preexisting disability or chronic health condition of the individuals whom the treatment would benefit.

UPL must apply to all purchases by any entity and reimbursement for a claim by any carrier/health plan when dispensed or administered in the state by any means.

UPL must be reassessed annually based on current economic factors, and carrier may disregard UPL and provide coverage if it is determined the drug should be covered based on medical necessity.

As evidenced by the information above, there are several approaches states may leverage when setting a UPL. In the table that follows, we present brief descriptions of five high-level approaches (general concepts) to setting a UPL, as well as associated methodology and implementation considerations. Regarding the latter, these are not comprehensive, rather they are intended as a framework to drive discussion about what an Oregon-specific UPL approach might look like.

Table 1. UPL Approaches (General Concepts)

UPL Approaches (General Concepts)[7]			
Concept/Source	**Description**	**Methodology Considerations**	**Implementation Considerations**
Net Cost	Establish UPL at or near the existing average net price of the drug after any rebates or discounts negotiated between the drug manufacturer and PBM. UPL then becomes the benchmark from which patient out-of-pocket costs are calculated by payers. This is particularly useful for highly rebated drugs which are generally placed on high formulary cost share tier. Consider leveraging publicly available average sales price (ASP) data for provider administered drugs to ensure that patient out-of-pocket costs are based on reimbursement rates that reflect net price.	• UPL may benefit more payers, purchasers, and consumers if it is below the average of net costs; however, depends on the type of drug, the spread of price concessions among payers, the degree of discounting, and use of national or in-state data.	• Rebate v. supply chain • Supply chain entity applicability/market segmentation
Reference Pricing to Existing Benchmarks	Establish UPL based on prices already negotiated or set by other entities. Reduces the administrative burden of conducting independent UPL analyses, provided that the external prices are useful comparators. Most common external references include the price of drugs negotiated by other countries, Medicare maximum fair price (MFP), and/or price negotiated by the	• Whether the referenced price is included in a manufacturer's calculation of Medicaid Best Price (e.g., Veterans Affairs Federal Supply Schedule, international) • Legal counsel may need to determine if the price already needs to be in the state to avoid a dormant commerce clause challenge, which would not necessarily be successful.	• It will be administratively complex to exclude Medicaid from a UPL, unless the market is otherwise segmented for UPL/non-UPL. If the UPL travels through the supply chain, rather than rebates, Medicaid would save directly on lower claims payment costs. A rebate UPL would require a supplemental rebate agreement. A supply chain UPL would require a Medicaid State Plan

[7] Program On Regulation, Therapeutics, And Law (PORTAL), Determining Upper Payment Limits: Considerations for State Prescription Drug Affordability Boards (PDABs) (2024), *available at* https://eadn-wc03-8290287.nxedge.io/wp-content/uploads/2024/04/Upper-Payment-Limit-White-Paper.pdf.

UPL Approaches (General Concepts)[7]			
Concept/Source	**Description**	**Methodology Considerations**	**Implementation Considerations**
	Department of Veterans Affairs. NASHP has published a model bill leveraging MFP as the ceiling for all purchases of a referenced drug and reimbursements for a claim for a referenced drug when the drug is dispensed, delivered, or administered to a person in the state.[8] It applies to commercial and state purchasers, and to ERISA plans that opt-in. Because Medicaid is a federal/state partnership subject to unique and complex policies, the model act excludes state Medicaid programs. Medicaid programs are already able to access deeply discounted prices for prescription drugs under the Medicaid Drug Rebate Program (MDRP).		Amendment to add UPL to pharmacy reimbursement method.
Reference Pricing to Therapeutic Alternatives	Establish UPL based on the price of drugs that can be used in place of the selected drug. For drugs with multiple approved indications, the therapeutic alternatives may differ for each indication. In these instances, it may be necessary to only include alternatives that are approved for all of the same indications as the selected drug; or to set separate prices based on reference groups for each of the drug's indications. Where multiple alternatives exist, health plans and PBMs often select one or two "preferred" drugs within a class, which often have lower out-of-pocket costs for patients than non-	• UPL could be set at an amount other than lowest amount, depending on the drug and market dynamics of that drug (e.g., biosimilars).	• Pharmacy claims generally do not include diagnosis codes, which would be problematic because Medicaid and Medicare legally do not cover off-label use; however, there is currently no way to enforce.

[8] NATIONAL ACADEMY FOR STATE HEALTH POLICY, AN ACT TO REDUCE PRESCRIPTION DRUG COSTS USING REFERENCE-BASED PRICING (2022), *available at* https://nashp.org/an-act-to-reduce-prescription-drug-costs-using-reference-based-pricing/.

UPL Approaches (General Concepts)[7]			
Concept/Source	**Description**	**Methodology Considerations**	**Implementation Considerations**
	preferred alternatives. Consider setting same UPL for all therapeutic alternatives, based on the lowest-priced drug of the group.		
Launch Price Indexing	Establish a UPL that uses the product launch price and indexes that price to the yearly or consolidated average CPI.	• Suitable for a drug that has been on the market for years or has taken very large price increases more recently, which is increasingly unlikely due to changes in Federal law.	
Percentage off of WAC	Establish a UPL that is a fixed percentage off of WAC. For brand drugs, the federal minimum Medicaid rebate is 23% of the AMP, which is confidential but, given the formula, is likely to be close to WAC. If a board is uncertain about the level of discounting in the market for first-in-class or other type of sole source products, but the drug is causing clear affordability challenges (e.g., clearly resultant premium increases, very high patient cost sharing, minimal manufacturer patient assistance), this approach may be sufficient to induce payers to improve patient access.		
Payer Return on Investment (ROI)	For a drug that has been subject to valid pharmacoeconomic research on value/cost savings, establish an initial UPL with a minimal lower cost and assess health plan savings over a given period (e.g., 5 years). Limiting the period in which medical benefits and savings start to accrue is important, as multimillion dollar drugs that produce savings over a lifetime may not be affordable to the healthcare system for many years.		• Approach could be suitable for breakthrough therapies that underwent small and short clinical trials, so that real world effectiveness and medical spend savings have not been demonstrated.

UPL Approaches (General Concepts)[7]			
Concept/Source	**Description**	**Methodology Considerations**	**Implementation Considerations**
Budget Impact-Based	Establish a UPL such that spending on the drug does not exceed a certain percentage of a given budget or have a disproportionate impact on a given budget. Could be accomplished by limiting the drug's contribution to increases in health insurance premiums (i.e., premium growth thresholds) or by leveraging a modified budget impact analysis to establish cost savings targets (i.e., assessment of costs only, rather than costs and health outcomes, as is done in cost-effectiveness analyses).	• This may be suited to high cost drugs with large, indicated populations (e.g., Hepatitis C products had rapid, countable impact on payer costs; GLP-1 products and new Alzheimer treatments have had an almost immediate expected premium increase/affordability challenge).	• New York and Massachusetts currently apply prescription drug growth caps to Medicaid, and pursue more state-level Medicaid rebates for drugs driving the growth. • Maine and New Hampshire apply spending caps to government-sponsored health plans; however, enforcement and mitigation tools are very limited.
340B Program-Specific	Establish a reimbursement adjustment for some or all 340B entities. The cost of drugs for 340B entities is approximately equal to the net cost after Medicaid rebate for the drug, although unlike Medicaid, it may not go below a penny. The 340B supply chain will continue to be discrete with much lower costs than even a UPL for a variety of programmatic reasons.[9] Regardless, profit on UPL drugs will be less than in the absence of a UPL.	• Status Quo • Oregon UPL + X% for CEs/Disproportionate Share Hospitals • Oregon UPL + Y% for Federally Qualified Health Centers/Rural Health Clinics/Other Safety-Net Providers • Carve-out	

[9] For brand drugs, the Medicaid rebate and corresponding discounts available through the 340B program are based on 23% of the Average Manufacturer Price (AMP), which is roughly equivalent to federal WAC or, if greater, AMP minus the Best Price in the market to almost any entity *and* an inflation penalty rebate. A Consumer Price Index (CPI) penalty is added if/when the AMP of the drug in a given quarter exceeds CPI growth. In general, it is the CPI penalty that produces very low costs and very high rebates, and affects drugs that have been on the market many years. Best Price does *not* include the CPI penalty. Best Price may be much higher than the total 340B cost (i.e., federal rebate + CPI penalty). Under current law, a Board should avoid creating a UPL that creates a new Best Price, as it would likely automatically be extended to every state Medicaid program.

Supply Chain UPL: UPL product travels from manufacturer to wholesaler (or specialty pharmacy) and through the rest of the supply chain to the point of service at no more than UPL. It is the process used today for most drugs using WAC pricing

Rebate UPL: UPL product travels through the supply chain at market price/WAC basis. Manufacturer rebates health plan, pharmacy/provider or possibly individual for the difference between acquisition cost and UPL.

- Medicare Maximum Fair Price (MFP) default system requires manufacturer to rebate pharmacy/provider the difference between acquisition cost at market price and lower MFP billed to health plan and patient. Implemented via federal vendor facilitating between manufacturer and individual pharmacies/providers.

General Issues:

- How UPL is implemented may depend on whether UPL is used in only a small part of total State market (limited reach UPL) or statewide, whether the product is high volume or not, and other product-specific market conditions.
- Is a mix of supply chain UPL and rebate UPL for different products workable for pharmacies/providers and manufacturers?
- Manufacturer concurrence with method will be critical for each product, and perhaps decisive for MFP UPL products.
- The opinion of in-State providers will be vital to successful implementation.

Statewide Market, Supply Chain UPL Implementation:

- UPL replaces WAC in purchases, payments, reimbursements
- Payment systems need to use only the product UPL amount if statewide
- Process can allow multiple competitive wholesalers or one dedicated wholesaler (manufacturer may have a preference for purposes of preventing/monitoring out of state diversion)
- People without insurance can access the UPL at point of service
- In-State diversion is not a large concern since everyone is eligible for the UPL
- Manufacturer participation is clear. Product comes into the state at or below the UPL or manufacturer decides to forgo entire state market

Statewide Market, Rebate UPL Implementation:

- Rebate UPLs may be more resource intensive than supply chain UPL for manufacturers and providers or health plans depending on how they are structured
  - Statewide application to low utilization/small population products may be appropriate.
- Use of rebate UPLs statewide may depend on whether the rebate would be given to providers, plans, or individuals
  - If rebates go to plans or providers, access for uninsured is a question.
- Would rebates to pharmacies/providers be based on average acquisition cost or invoice demonstrating actual acquisition cost?

- Who runs the rebate operation? Each manufacturer? A state sponsored system? Can state use the Medicare rebate process, particularly for any MFP UPL?
  - What are the costs to implement rebates?
- Manufacturer compliance with process not immediately clear and may be variable within the State
- Diversion out of state is not a large concern in rebate model if rebate goes to health plans

Limited Reach Market, Supply Chain UPL Implementation

- Supply chain UPL may be more operationally challenging if UPL is not statewide
- Supply chain UPL may require provider double stocking of product at two reimbursement rates or a new administrative system
- Supply chain UPL used less than statewide creates opportunities for diversion (unless mail order or a dedicated wholesaler is used to work with manufacturer on preventing diversion)
- Pharmacies/providers may or may not know how much of the UPL and non-UPL product to stock.
- Payers with different books of in-State business may need to load two reimbursement amounts if they serve multiple market segments

Limited Reach Market, Rebate UPL Implementation

- Less complexity than supply chain UPL but potentially more costly to healthcare system
- Use of rebate UPL may depend on whether the rebate would be given to providers, plans, or individuals
  - Decision may depend on drug product and indicated population size
  - People without insurance may not have access to the rebate if it goes to health plans.
- Preventing/monitoring for diversion may be easier using rebate UPL if rebates go to health plans relative to other rebate options or supply chain approach.

Note: Mail order may also be an option for limited reach market UPLs or very low volume products statewide, depending on the drug product and other market considerations.

Background: Estimated UPL Impact

- Many of the products selected for affordability review are highly rebateable
- Patient copayments are generally based on the total product cost; therefore, a reduction could lower out of pocket expenses
- Myers and Stauffer leveraged a net price strategy to help state agencies estimate the impact of a UPL (i.e., link UPL to net price after rebates/discounts)

Background: Estimated UPL Impact

- Reviewed insurance carrier list price concessions for specific prescriptions medications
- Three price concession percentages were selected based on the data received or historical experience
- Percentages were applied to the current WAC of each medication, resulting in three theoretical UPLs
- Theoretical UPLs were provided to PDAB staff for modeling

Oregon Prescription Drug Affordability Board

Proposed policy recommendations

Potential Senate Bill 844 clean-up

- Propose a language change from “nine drugs a year” for affordability reviews to “up to nine” drugs a year.
    - The board recommends revising language in SB 844 to remove the requirement to review nine drugs and change the language to “review up to nine prescriptions drugs.” This change will ensure that the board focuses on reviewing drugs that are known to cause affordability challenges, based solely on cost or criteria, rather than trying to identify drugs that may or may not cause challenges to the health system or out-of-pocket costs to meet legislative thresholds. The initial review process revealed challenges in identifying specific drugs, as some may not actually cause affordability issues.

- Remove requirement that Department of Consumer and Business Services (DCBS) provide Prescription Drug Affordability Board (PDAB) with a list of prescription drugs each calendar quarter.
    - The information provided to PDAB by DCBS under ORS 646A.689 (2) and (6) and ORS 743.025, and insulin products that are submitted annually by prescription drug manufacturers and health insurance carriers. Manufacturers are required to report 60 days prior to a price increase for brand-name and generic prescription drugs in accordance with ORS 646A.683 (2), but the information is based on the current year and may not apply to the reporting requirement in Senate Bill 844 to review drugs from the previous calendar year. Removing the quarterly reporting language will ensure a more accurate review of prescription drugs by the board.

- Removal of the generic drug report annual requirement, with a new provision that relevant content would be incorporated into the affordability review report. The information could include generics or biosimilar availability, pricing, and marketplace commentary when relevant to drugs under review
    - The board recommends removing the requirement to submit an annual generic drug report to the Legislature. Instead, include language indicating that market changes will be covered in the annual affordability review report. The generic drug market does not have significant year-over-year changes and the current report does not provide significant market identifiers that impact prescription medication prices and costs. Any significant impact of the market system will be captured in the annual report requirements in Senate Bill 844 Section 5.

Additional recommendations

- **Patient assistance program (PAP) reporting to the Drug Price Transparency (DPT) program**
    - Expand PAP requirements to include manufacturer coupons and any other payment that reduces a patient's out-of-pocket cost to fill a prescription. The board also recommends manufacturers be required to report on all patient assistant programs they maintain or fund.

- **Pharmacy benefit managers (PBM) and insurer reporting on copay accumulators and maximizers**
    - Implement mandatory reporting on copay accumulator and maximizers programs to ensure equitable access to essential medications and prioritize transparency. With enhanced reporting, the board will aim to monitor the impact of copay accumulators on patient costs and access to medications.

- **Uniform reimbursement rate for critical access pharmacies (CAPs). This applies to all PBMs CAPs contract with**
    - Uniform reimbursement rate: All claims for prescription drugs and services provided by critical access pharmacies (CAPs), whether under Fee-For-Service (FFS) Medicaid, coordinated care organizations (CCOs), commercial insurance, or any prescriptions adjudicated through exchange payors, shall be reimbursed at the exact same rate as the CAP FFS Medicaid rate. This ensures payment parity for all payors when reimbursing CAPs.

    - Non-discriminatory reimbursement: CCOs, commercial payors, and PBMs would be prohibited from reducing payments or imposing discriminatory terms on CAPs. All payors must adhere to the CAP FFS Medicaid rate when reimbursing CAPs for identical services or medications.

- **Consolidated Appropriations Act (CAA) disclosures about reimbursements and fees to employer plans from brokers**
    - Any broker or entity facilitating the purchase of health insurance or prescription drug benefits for purchasing entities must provide an annual disclosure of all direct and indirect compensation received, as required by the CAA. This disclosure must include any commissions, fees, or other forms of compensation related to the transaction.

    - Brokers must proactively offer these CAA-compliant disclosure schedules in writing to the relevant purchasing entities (OEBB, PEBB, FFS, Medicaid, ArrayRx, etc.) during contract negotiations or renewals and no later than 30 days prior to the renewal of any contract or service agreement.

- **Minimum dispensing fees across all payers**
    - Minimum reimbursement for all prescriptions: All payors, including CCOs, commercial health plans, exchange-based health insurance plans, and PBMs operating within the state, shall reimburse pharmacies at a rate that is no less than the average actual acquisition cost (AAAC) of the drug plus the state-determined dispensing fee. This reimbursement structure shall apply to all prescriptions dispensed by pharmacies in Oregon.
        - The AAAC of a drug shall be determined based on the Oregon Medicaid AAAC pricing or the equivalent national pricing index adopted by the Oregon Health Authority (OHA).
        - The dispensing fee shall be equal to or greater than the dispensing fee used in Oregon's Fee-for-Service Medicaid program, which is currently $10.65. The dispensing fee may be updated periodically based on updated surveys or economic conditions.
    - Prohibition of below-cost reimbursement: PBM or payors shall not reimburse a pharmacy at or below the pharmacy's acquisition cost for any prescription drug.

- **OHP FFS and CCOs purchasing through a statewide purchasing group**
    - Statewide purchase groups are programs that leverage the collective buying power of state agencies to secure better prices and terms for goods and services. These programs are designed to make procurement more efficient and cost-effective for state and local government entities.

- **Statewide Preferred Drug List (PDL) for Oregon Health Plan (OHP) FFS**
    - OHP FFS has a uniform PDL for some classes. However, to use the most cost-effective medications and to reduce administrative burdens for providers, it is recommended to extend the current PDL for all classes of prescription drugs.

Definition of terms

Name	Abbreviation
Average actual acquisition cost	AAAC
Consolidated Appropriations Act	CAA
Coordinated care organizations	CCOs
Critical access pharmacies	CAP
Department of Consumer and Business Services	DCBS
Drug Price Transparency	DPT
Fee-For-Service	FFS
Oregon Health Authority	OHA
Oregon Health Plan	OHP
Patient assistance program	PAP
Pharmacy benefit managers	PBM
Preferred drug list	PDL
Prescription Drug Affordability Board	PDAB