

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; Lauri Hoagland.

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: <i>limited to 3 minutes.</i> Written comments are reviewed by the board prior to meeting.	Chair Bailey	10 minutes
Vote	Adjournment	Chair Bailey	2 minutes

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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 <u>PDAB public comment form</u> no later than 24 hours before the PDAB meeting. **Written:** to provide written comments to the board, please submit the <u>PDAB public comment form</u> with attachments no later than 72 hours before the PDAB meeting. The board reviews all written comments. All written comments are posted on the website.

Open and closed sessions

All board meetings except executive sessions are open to the public. Pursuant to ORS 192.660, executive sessions are closed to everyone but news media and staff. No action will be taken in the executive session.



Oregon Prescription Drug Affordability Board (PDAB) Regular Meeting Wednesday, 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

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 <u>00:00:56</u>.

Approval of board minutes: Chair Bailey asked for a motion and second to approve the board minutes as shown on <u>Pages 3-4</u> of the agenda materials, with any amendments. Dan Kennedy made a motion to approve the minutes and Robert Judge provided a second. View at video minute <u>00:03:10</u>.

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 O0:07:43.



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 <u>02:24:40</u>.

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

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



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

Multi-state Collaborations Health Process and Systems Engineering

Data Analysis and Public Evidence Dissemination

Single-state Evidence Assistance

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).	Context for SB844 §2(1)(f) and §2(1)(g)
	Optional: Summary of pipeline therapies in phase 3 testing, with any information on estimated costs.	
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





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





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 PDAB1

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 PDAB³

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.

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; 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 PDAB⁴

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 PDAB⁶

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.

Concept/Source	Description	Methodology Considerations	Implementation Considerations
Reference Pricing to Therapeutic	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. It applies to commercial and state purchasers, and to ERISA plans that optin. 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). Establish UPL based on the price of drugs that can be used in place of the selected	UPL could be set at an amount other than lowest amount, depending on	 Amendment to add UPL to pharmacy reimbursement method. Pharmacy claims generally do not include diagnosis codes, which would be
Alternatives	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-	than lowest amount, depending on the drug and market dynamics of that drug (e.g., biosimilars).	problematic because Medicaid and Medicare legally do not cover off-label use; however, there is currently no way t 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/anact-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	Establish a UPL that uses the product	Suitable for a drug that has been on	
Indexing	launch price and indexes that price to the yearly or consolidated average CPI.	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		
Payer Return on Investment (ROI)	patient access. 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. 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
 - o 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?
 - O 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
 - o 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.



Maximum Fair Price (MFP) Modeling Analysis

On Aug. 14, 2024, The Center for Medicare & Medicaid Services (CMS) provided an update on its progress in the Medicare Drug Pricing Negotiation Program. This program stems from the enactment of the Inflation Reduction Act of 2022 which affords CMS the "ability to directly negotiate the prices of certain high expenditure, single source drugs without generic or biosimilar competition." The CMS negotiated price for a given drug is known as the Maximum Fair Price (MFP).

As CMS continues its program, Oregon's Prescription Drug Affordability Board (PDAB) may be able to draw parallels and model similar effects if an upper payment limit (UPL) is used in the state. PDAB staff completed an analysis to examine the potential estimated savings in the state using the recent CMS negotiated drug prices.

It is important to note this analysis is not a one-to-one market comparison. The Oregon data is limited to commercial insurance carrier reporting to the Drug Price Transparency program. This only includes specific plan types (large, small, individual) while excluding groups such as Medicare, Medicaid, self-insured, PEBB, and OEBB. It is only intended to model the potential effects of a maximum drug price.

The analysis shows Oregon's carriers annual expenditure based on the number of prescriptions and number of enrollees for a drug based on the wholesale acquisition cost (WAC). These sections are highlighted in blue. The annual expenditures were then recalculated using Medicare's MFP (highlighted in orange). These potential cost savings calculations are shown in purple and include the percentage savings that could be afforded by a maximum price. Each drug represented in the model demonstrates significant cost savings.

Information	Color code
Wholesale acquisition cost (WAC)	Blue
Medicare Maximum Fair Price (MFP)	Orange
Potential cost savings	Purple

¹¹ "Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026." Centers for Medicare & Medicaid Services. Aug. 14, 2024. https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026. Accessed Sept. 11, 2024.

PDAB vs. MFP Rx Pricing Analysis

*Proprietary name(s)	Non-proprietary name	**Number of carriers reported out of 12	List Price (WAC) for EOY 2023	Number of enrollees prescribed Rx in 2023	Number of prescriptions in 2023	Total (net of rebate) annual spend in 2023	Total annual spend per enrollee in 2023	Average cost per prescription in 2023	Medicare MFP negotiated price for 30- day supply	Potential OR estimated total annual spend per enrollee using Medicare MFP	Potential OR total annual spend using Medicare MFP based on number of prescriptions	Potential OR estimated savings using Medicare MFP (based on total spend)	Potential OR percent savings using Medicare MFP
Eliquis	Apixaban	12	\$561	3,822	17,034	\$9,848,225	\$2,577	\$578	\$231	\$1,030	\$3,934,854	\$5,913,371	60%
Enbrel / Enbrel SureClick	Etanercept	9	\$7,049	607	4,648	\$22,380,528	\$36,871	\$4,815	\$2,355	\$18,033	\$10,946,040	\$11,434,488	51%
Entresto	Sacubitril-Valsartan	8	\$668	1,097	4,374	\$3,742,550	\$3,412	\$856	\$295	\$1,176	\$1,290,330	\$2,452,220	66%
Farxiga	Dapagliflozin Propanediol	6	\$565	821	3,838	\$1,531,108	\$1,865	\$399	\$179	\$834	\$685,083	\$846,025	55%
Imbruvica	Ibrutinib	1	\$17,018	3	11	\$241,556	\$80,519	\$21,960	\$9,319	\$34,170	\$102,509	\$139,047	58%
Januvia	Sitagliptin Phorphate	3	\$547	28	103	\$95,879	\$3,424	\$931	\$113	\$416	\$11,639	\$84,240	88%
Jardiance	Empagliflozin	12	\$593	5,892	23,825	\$10,569,483	\$1,794	\$444	\$197	\$797	\$4,693,525	\$5,875,958	56%
Stelara	Ustekinumab	10	\$26,517	648	2,995	\$31,156,649	\$48,081	\$10,403	\$4,695	\$21,700	\$14,061,525	\$17,095,124	55%
Xarelto	Rivaroxaban	12	\$542	2,160	7,746	\$4,908,208	\$2,272	\$634	\$197	\$706	\$1,525,962	\$3,382,246	69%
Fiasp	Insulin Aspart	2	\$289	15	50	\$55,000	\$3,667	\$1,100	\$119	\$397	\$5,950	\$49,050	89%
Novolog	Insulin Aspart	3	\$289	563	2,163	\$2,122,013	\$3,769	\$981	\$119	\$457	\$257,397	\$1,864,616	88%
Novolog Flexpen	Insulin Aspart	4	\$559	65	164	\$44,456	\$684	\$271	\$119	\$300	\$19,516	\$24,940	56%
					TOTAL Spend =	\$86,695,655				POTENT	AL Total Savings =	\$49,161,325	

This data set is limited to Drug Price Transparency insurance carrier reporting that only includes Large, Small, and Individual plan groups. This excludes groups such as Medicare, Medicaid, self-insured, PEBB, OEBB, etc.

^{*}The proprietary name information is represented by the most frequently used NDC reported in 2023 by Oregon's commercial health insurance carriers.

^{**}The number of carriers that reported the drug under ORS 743.025 for their 2023 top 25 most costly or greatest increase.



PDAB Upper Payment Limit (UPL) Analysis

Oregon Educators Benefit Board (OEBB) and the Public Employees' Benefit Board (PEBB)

Medicaid FFS and CCO

September 2024

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Executive summary

Myers and Stauffer LC, at the request of Prescription Drug and Affordability Board (PDAB) staff, created three upper payment limit (UPL) scenarios for eight prescription drugs to consider for modeling and analysis. These drugs were pulled from the 2023 PDAB Prescription Drug Top Drug Subset List: Cosentyx, Entyvio, Inflectra, Keytruda, Ocrevus, Ozempic, Tremfya, and Trulicity. Additional information on wholesale acquisition cost (WAC) and UPL pricing scenarios for the drugs are at the end of this document.

The Oregon Health Authority (OHA), through its PEBB/OEBB and Medicaid/Oregon Health Plan teams, reviewed and provided preliminary pricing for these scenarios for discussion purposes.

PEBB/OEBB analysis¹

- Under the scenario where it is assumed there are no rebates due to an implemented UPL, the most likely outcomes range from a combined increase of \$12.1M in plan spend (where the modest price reduction is less than existing rebates) to a cost savings of \$18.7M (price reduction exceeds existing rebates).
 - For PEBB, the more likely outcomes result in a range of a cost increase of \$8.9M (1 percent) to an overall savings of \$10.7M (-1.1 percent)
 - For OEBB, the more likely outcomes result in a range a cost increase of \$3.1M (0.4 percent) to an overall savings of \$8M (-1.1 percent)
- For other scenarios that include the assumption that 25 percent to 50 percent of rebates are retained, the following potential costs/savings were identified:
 - PEBB: \$3.6M cost increase to \$20M cost savings, based on the UPL selected
 - o OEBB: \$0.2M savings to \$13.9M savings, based on the UPL selected
- In UPL and rebate scenarios for PEBB/OEBB, the loss of rebates often offsets the reduction in ingredient costs. In general, if implementation of UPLs results in all rebates being removed, only the more aggressive UPL scenarios result in plan savings.

Medicaid/Oregon Health Plan

- For both Fee for Service (FFS) and Coordinated Care Organizations (CCO), the modeling assumed no changes to existing rebates. Both assumptions mean that actually attainable savings will be lower.
- Additionally, due to state and federal budget mechanics, OHA advised that reductions in cost from implementing a UPL would more likely be reinvested in other OHP services rather than directly reducing state costs.
 - For the UPL scenarios, the potential net savings range from \$1.1M to \$2.3M for FFS, and \$25M to \$56M for CCO.²

¹ Mercer Health & Benefits LLC analysis, Aug. 26, 2024. Analysis does not include Kaiser Permanente medical claims.

² Oregon Health Authority, Office of Actuarial and Financial Analytics, Sept. 6, 2024.

OEBB/PEBB upper payment limit analysis

Overview

On behalf of OHA, Mercer analyzed prescription and medical drug costs, utilization, and enrollment data for PEBB and OEBB for the period of April 1, 2023, to March 31, 2024. They calculated the impact of the proposed UPL scenarios for eight selected drugs.

Methodology

To conduct the analysis, Mercer applied various assumptions regarding inflation and utilization to PEBB and OEBB's monthly prescription and medical drug cost, utilization and enrollment data for the period, April 1, 2023 to March 31, 2024, to trend the data to 2025. The UPL scenarios used in the analysis were provided by PDAB. Mercer did not develop these scenarios.

It is expected that the reduction in in the point of sale drug prices due to UPLs will result in lowered or eliminated rebate payments. Because this is a novel proposal, the rebates retained with UPLs in place are uncertain. To account for this uncertainty, the three different UPL scenarios were modeled with no rebates (0 percent) as well as 25 percent and 50 percent of the current rebate retained, with the most conservative estimate being that rebates for the affected drugs are eliminated upon implementation. The analysis never allows the rebate to exceed the ingredient cost for a drug/scenario combination.

Observations

Under the scenario where it is assumed there are no rebates due to an implemented UPL, the most likely outcomes range from a combined increase of \$12.1M in plan spend (where the modest price reduction is less than existing rebates) to a cost savings of \$18.7M (price reduction exceeds existing rebates).

- For PEBB, the more likely outcomes result in a range of a cost increase of \$8.9M (1 percent) to an overall savings of \$10.7M (-1.1 percent)
- For OEBB, the more likely outcomes result in a range a cost increase of \$3.1M (0.4 percent) to an overall savings of \$8M (-1.1 percent)

The UPL scenario prices for drugs commonly used in the medical benefit represent less of a discount from WAC than the UPL scenarios provided for drugs typically dispensed through the pharmacy benefit. As a result, there is more opportunity for savings in the pharmacy benefit than the medical benefit.

Models

In developing prescription drug cost projections, Mercer employed proprietary models. Mercer's tools are developed by a team of experienced professionals, which typically includes actuaries, and have been customized for the purposes of this engagement.

OEBB/PEBB upper payment limit analysis (continued)

Data and assumptions

Mercer used and relied upon information submitted by Merative (for Moda Health Plan, Kaiser, and Providence Health Plan), PEBB and OEBB without further audit. Mercer also used and relied upon participant data and claims cost information supplied by the Merative and PEBB and OEBB. Mercer reviewed the data for internal consistency and reasonableness, but not accuracy. The plan sponsor is solely responsible for the validity and completeness of this information. Assumptions were developed based on input from various sources including Mercer's own analysis, input from PEBB/OEBB, as well as other third-party resources.

Additional details

- Enrollment is based on average 2024 enrollment of 141,065 and 136,536 members for PEBB and OEBB respectively. It is not adjusted for any future changes in enrollment, plan design, or formulary compliance. Claims cost and utilization from the experience data have been trended forward to the projection period based on Mercer's standard annualized trend, utilization, and generic dispensing rate assumptions as well as estimated changes in the drug pipeline. These trends account for estimated changes in the drug pipeline.
- For Ozempic, Mercer observed recent utilization trends to estimate a reasonable ongoing trend given the drug's recent and continued popularity
- A dispensing fee of \$8 per script is assumed for drugs dispensed via pharmacy in the UPL scenarios.
- To estimate future gross costs, Mercer projected WAC using trends from their analysis and then defined the UPL scenarios as the percentage reduction of that WAC. That is, if UPL scenario 1 represents a 10 percent decrease in WAC today, Mercer defines scenario 1 as a 10 percent decrease in expected WAC in 2025.
- 2025 rebate estimates have been applied to the projected claims and current dispensing fees have been removed to arrive at the net allowed cost.
- Rebates for each of the drugs are estimated using the mid-point of the benchmark range for each drug.
 The benchmarks are based on IPD Analytics, LLC, as provided by experts and industry trade relations
 consultants for favorable rebate/formulary positions being offered. The estimated benchmark rebate
 ranges for individual drugs are as low as 0-5 percent to as high as 50 to 55 percent.
- For all medical analysis, it is assumed member cost share as a percentage of allowed cost is a fixed ratio. That is, it is the same in 2023 and 2025.

OEBB/PEBB upper payment limit analysis (continued)

- For prescription drug analysis Mercer varied member cost share assumptions.
 - For PEBB, future member cost share is set equal to current member cost share per unit. This is because all plans have a copay structure for prescription drug claims.
 - o For OEBB, future member cost share is a weighted average with 80 percent weight on the same assumption as above, and a 20 percent assumption mirroring the medical claims. This is because roughly 20 percent of OEBB members have a prescription drug plan based around coinsurance rather than copay. For those members, their cost will decrease with the cost of the drug.
- Projections assume no plan design changes.
- Rebates are shown in the year they are earned; however, a portion will be paid in the subsequent year
 due to the lag in rebate collections from manufacturers and payment to PEBB and OEBB.
- The 2025 projected total pharmacy and medical allowed is based on an annual growth assumption of 6 percent for pharmacy and 2.8 percent for medical.
- For the net total 2025 cost, Mercer assumed that the medical and pharmacy rebates are in the same proportion for OEBB and PEBB for all plan groups.

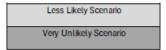
Disclaimer

This analysis provides modeling for the potential impacts of PDAB implementing a prescription drug maximum allowable rate fee schedule (i.e., upper payment limit). The purpose of this report is to facilitate discussions for understanding of the range of financial impacts. This analysis has been prepared by Mercer for Oregon PEBB and OEBB, and is intended to be used by the PDAB to help inform their report on the impacts of a UPL. It should be read in its entirety and has been prepared under the direction of Sara Drake. To the best of Mercer's knowledge, there are no conflicts of interest in performing this work.

All estimates are based upon the information and data available at a point in time and are subject to unforeseen and random events, and actual experience will vary from estimates. Mercer expressly disclaims responsibility, liability, or both for any reliance on this communication by third parties or the consequences of any unauthorized use or disclosure other than as mutually contemplated when Mercer was first retained to perform this work. Mercer is not responsible for the consequences of any unauthorized use.

Financial Results – OEBB (Pharmacy and Medical)

Employer	OEBB
Members	136,536
Channel	Rx + Medical
Drug	Total



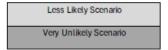
				0% of current rebate percentage				25% of current rebate percentage				50% of current rebate percentage			
	Tren	ded Status Quo		Scenario1	Scenario2	Scenario3		Scenario1	Scenario2	Scenario3		Scenario1	Scenario2	Scenario3	
Ingredient Cost	\$	35,661,000	\$	24,865,000 \$	19,312,000 \$	13,125,000	\$	24,865,000\$	19,312,000 \$	13,125,000	\$	24,865,000 \$	19,312,000 \$	13,125,000	
Dispensing Fees	\$	89,000	\$	89,000 \$	89,000 \$	89,000	\$	89,000 \$	89,000 \$	89,000	\$	89,000 \$	89,000 \$	89,000	
Rebates	\$	13,734,000	. \$				\$	3,434,000 \$	3,434,000 \$	3,434,000	\$	6,867,000 \$	6,867,000 \$	5,993,000	
Net Allowed Cost	\$	22,016,000	\$	24,954,000 \$	19,401,000 \$	13,214,000	\$	21,520,000\$	15,967,000 \$	9,780,000	\$	18,087,000 \$	12,534,000 \$	7,221,000	
Change in Net Allowed Cost			\$	2,938,000 \$	(2,615,000) \$	(8,802,000)	\$	(496,000) \$	(6,049,000) \$	(12,236,000)	\$	(3,929,000) \$	(9,482,000) \$	(14,795,000)	
% Change in Net Allowed Cost				13.3%	-11.9%	-40.0%		-2.3%	-27.5%	-55.6%		-17.8%	-43.1%	-67.2%	
Rebate/Ingred		39%		0%	0%	0%		14%	18%	26%		28%	36%	46%	
Member Cost-share	\$	4,906,000	\$	4,691,000 \$	4,434,000 \$	4,092,000	\$	4,691,000 \$	4,434,000 \$	4,092,000	\$	4,691,000 \$	4,434,000 \$	4,092,000	
Change in Member Cost-Share			\$	(215,000) \$	(472,000) \$	(814,000)	\$	(215,000) \$	(472,000) \$	(814,000)	\$	(215,000) \$	(472,000) \$	(814,000)	
% Change in Member Cost-Share				-4.4%	-9.6%	-16.6%		-4.4%	-9.6%	-16.6%		-4.4%	-9.6%	-16.6%	
Net Plan Allowed Cost	\$	17,110,000	\$	20,263,000 \$	14,967,000 \$	9,122,000	\$	16,829,000\$	11,533,000 \$	5,688,000	\$	13,396,000 \$	8,100,000 \$	3,129,000	
Change in Net Allowed Plan Cost			\$	3,153,000 \$	(2,143,000) \$	(7,988,000)	\$	(281,000) \$	(5,577,000) \$	(11,422,000)	\$	(3,714,000) \$	(9,010,000) \$	(13,981,000)	
% Change in NetAllowed Plan Cost				18.4%	-12.5%	-46.7%		-1.6%	-32.6%	-66.8%		-21.7%	-52.7%	-81.7%	
Change as a % of 2025 Projected Total I	Change as a % of 2025 Projected Total Net Rx + Medical														
Allowed				0.4%	-0.3%	-1.1%		0.0%	-0.8%	-1.6%	l	-0.5%	-1.2%	-1.9%	

- Analysis does not include medical claims from Kaiser as the units reported were inconsistent with the data reported by the other plan groups. This amounts to \$2.4 M which is 25% of the total un-trended allowed medical costs for these drugs.
- . There are 19,200 units reported for Ocrevus with \$0 gross allowed amount. These claims are excluded from the medical cost analysis.

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Financial Results – PEBB (Pharmacy and Medical)

Employer	PEBB
Members	141,065
Channel	Rx + Medical
Drug	Total



			0% of current rebate percentage				25% of current rebate percentage				50% of current rebate percentage			
	Tre	nded Status Quo	 Scenario1	Scenario2	Scenario3	_	Scenario1	Scenario2	Scenario3		Scenario1	Scenario2	Scenario3	
Ingredient Cost	\$	51,906,000	\$ 39,089,000 \$	29,772,000 \$	19,068,000	\$	39,089,000\$	29,772,000 \$	19,068,000	\$	39,089,000 \$	29,772,000 \$	19,068,000	
Dispensing Fees	\$	133,000	\$ 133,000 \$	133,000 \$	133,000	\$	133,000 \$	133,000 \$	133,000	\$	133,000 \$	133,000 \$	133,000	
Rebates	\$	21,663,000	\$ 			\$	5,416,000 \$	5,416,000 \$	5,416,000	\$	10,831,000 \$	10,831,000 \$	9,428,000	
Net Allowed Cost	\$	30,376,000	\$ 39,222,000 \$	29,905,000 \$	19,201,000	\$	33,806,000 \$	24,489,000 \$	13,785,000	\$	28,391,000 \$	19,074,000 \$	9,773,000	
Change in Net Allowed Cost			\$ 8,846,000 \$	(471,000) \$	(11,175,000)	\$	3,430,000 \$	(5,887,000) \$	(16,591,000)	\$	(1,985,000) \$	(11,302,000) \$	(20,603,000)	
% Change in Net Allowed Cost			29.1%	-1.6%	-36.8%		11.3%	-19.4%	-54.6%		-6.5%	-37.2%	-67.8%	
Rebate/Ingred		42%	0%	0%	0%		14%	18%	28%		28%	36%	49%	
Member Cost-share	\$	2,129,000	\$ 1,991,000 \$	1,909,000 \$	1,681,000	\$	1,991,000 \$	1,909,000 \$	1,681,000	\$	1,991,000 \$	1,909,000 \$	1,681,000	
Change in Member Cost-Share			\$ (138,000) \$	(220,000) \$	(448,000)	\$	(138,000) \$	(220,000) \$	(448,000)	\$	(138,000) \$	(220,000) \$	(448,000)	
% Change in Member Cost-Share			-6.5%	-10.3%	-21.0%		-6.5%	-10.3%	-21.0%		-6.5%	-10.3%	-21.0%	
Net Plan Allowed Cost	\$	28,247,000	\$ 37,231,000 \$	27,996,000 \$	17,520,000	\$	31,815,000\$	22,580,000 \$	12,104,000	\$	26,400,000 \$	17,165,000 \$	8,092,000	
Change in Net Allowed Plan Cost			\$ 8,984,000 \$	(251,000) \$	(10,727,000)	\$	3,568,000 \$	(5,667,000) \$	(16,143,000)	\$	(1,847,000) \$	(11,082,000) \$	(20,155,000)	
% Change in Net Allowed Plan Cost			31.8%	-0.9%	-38.0%		12.6%	-20.1%	-57.1%		-6.5%	-39.2%	-71.4%	
Change as a % of 2025 Projected Total No	Change as a % of 2025 Projected Total Net Rx + Medical													
Allowed			1.0%	0.0%	-1.1%		0.4%	-0.6%	-1.7%		-0.2%	-1.2%	-2.1%	

- Analysis does not include medical claims from Kaiser as the units reported were inconsistent with the data reported by the other plan groups. This amounts to \$2.2 M which is 15% of the total un-trended allowed medical costs for these drugs.
- There are 1,800 units reported for Ocrevus with \$0 gross allowed amount. These claims are excluded from the medical cost analysis.

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Medicaid Oregon Health Plan (FFS and CCO) upper payment limit analysis

Overview

Purpose

Perform an evaluation to estimate the financial impact to OHP of applying an UPL to eight identified drugs.

Methodology

OHA's Office of Health Analytics pulled CCO encounter and FFS claims data for the year ending June 2024 from OHA's Decision Support and Surveillance Utilization Review System (DSSURS)/Medicaid Management Information System (MMIS) database.³ The Office of Actuarial and Financial Analytics (OAFA) built models for each payer and claim type, comparing actual payment levels against an estimate of payments limited by a UPL. Savings were estimated on a gross (total payments) and net (OHP payments) basis. Changes to rebates were not considered in the calculation. First-dollar savings were expected to apply to OHP. See individual models for detailed calculations.

Data complications

Data analysis was complicated by several factors, including the following:

- Paid amounts across OHP and non-OHP payers did not consistently total up to allowed amounts.
- Paid amounts by non-OHP payer type varied by claim format.
- CCO encounter claims may not contain complete payment information. Some CCO claims showed \$0 paid amounts, including Medicare.
- Professional and outpatient claims showed little correlation to reported WAC.
- Indian Health Care Providers (IHCP) were not clearly identified in the data, but appear to account for a portion of the claims.

Considerations

Ultimate costs for future years' capitation rates will presumably be recalculated using updated Medicaid data. Changes in caseload, inflation, and available federal medical assistance percentage (FMAP) will materially impact these estimates.

Reductions in cost will more likely be reinvested in OHP rather than reduce state costs:

- Mechanics of CCO rate setting (see below)
- Due to federal match, \$1 saved for OHP is often only \$0.25 to \$0.30 saved for Oregon Oregon may achieve a better return through reinvestment than "savings."

³ "Medicaid Management Information System." Oregon Health Authority, January 2024. https://www.oregon.gov/oha/HPA/ANALYTICS/Documents/Dataprofile MMIS.pdf. Accessed Sept. 16, 2024.

Budgetary Impacts

In terms of budgetary impact, the FFS costs are presumed savings, but would be offset by any reduction in pharmacy rebates. Due to timing and data constraints, OAFA did not attempt to model any rebate impacts. In assessing budgetary impact, OHA would also want to look more closely at members' category of aid to determine what proportion of the total will be state funds – 25 to 30 percent would be the likely proportion of state funds. In addition, there appear to be some IHCP claims (based on payment amounts) that should potentially be excluded from analysis. Put together, these factors suggest the \$2.26M in net FFS savings under the tightest UPL scenario might result in state budget savings of less than half a million dollars.

For CCOs, the financial impact is likely to be "absorbed" in capitation rate setting. Each year OHA tries to set capitation rates approximately 3.4 percent higher than the prior year. To the extent there are benefits or costs expansions that are not separately funded by the legislature (which happens regularly), OHA prices those into capitation rates but still fits the overall rates within the 3.4 percent budgetary increase. This process essentially subjects all other services or policy levers to a lower level of increase within the capitation rates.

In the case of the UPL application, the opposite could become true: any material expected savings to CCOs would be reflected in capitation rate development, but in absence of any direction to the contrary OHA would still target a 3.4 percent overall increase, which would leave more room for inflationary or policy increases in other areas of rate setting. However, if OHA were expecting a decrease in pharmacy rebates, the 3.4 percent target might be adjusted to offset the loss of pharmacy revenue. Therefore, unless the Legislature asks OHA to bank the savings (of which perhaps 25 to 30 percent would be the state's to retain), a UPL likely would not save the state money but rather lead to reinvestment of the proceeds into other CCO expenditures.

For context, the CCO system is expected to incur around \$6.2b in service costs during CY25. A savings of \$56M represents around 0.9 percent of costs, which is a significant impact in the context of rate setting. Again, offsetting for rebates foregone would reduce that potential savings/reinvestment.

Limitations

OHA's pharmacy team further advised of several potential limitations and caveats.

- UPL may impact availability of supplemental rebates or amount collected in supplemental rebates. One
 common stipulation with supplemental rebate offers is that preferred products must be on equal
 footing or not disadvantaged to competitors.
- If manufacturers sell for UPL in Oregon, it could impact federal Medicaid rebates and manufacturer best price for the entire nation.
- If manufacturers sell for UPL in Oregon, it could impact 340B prices for the entire nation. The 340B program provides medications at a substantially lower cost to certain safety net clinics and hospitals.
- An UPL could reduce funding for 340B entities. Currently, outside of the fee-for-service OHP program, 340B entities are usually reimbursed at the usual market rate, though their cost is much lower. With an UPL in place, the entities could charge no more than the UPL.
- If manufacturer does not sell for the UPL, it may create access issues for patients if pharmacies and wholesalers are unwilling to stock products that they have to buy/sell at a loss.

Medicaid Oregon Health Plan (FFS and CCO) upper payment limit analysis (continued)

- If pharmacies chose to buy/sell at a loss, it could impact profit margins and number of pharmacies that are open or who take insurance. There is some risk in shifting costs to patients if pharmacies/hospitals are unwilling to bill insurance because of the reimbursement rate.
- Unclear how an UPL will affect other benefit plan coverage (Third Party Liability or Medicare for Part B drugs). May create disparities in drug coverage for Oregonians vs. other states.
- Unclear how an UPL would impact health equity and which patient populations would be most impacted.
- For FFS, outpatient hospitals are typically reimbursed a percentage of their billed amount for drugs they administer. OHA would need to revise reimbursement methodology to ensure outpatient hospitals are paid at least their acquisition cost.
- Proposed methodology to reprice drug claims does not consider any cost or savings as a result of shift to other clinically equivalent products.

OHP estimate of UPL savings for select drugs – DRAFT

Summary of model findings

Gross (system) cost and savings

		FF	:S		ссо					
	Current Cost	UPL1 Savings	UPL2 Savings	UPL3 Savings	Current	UPL1 Savings	UPL2 Savings	UPL3 Savings		
Rx Claims	2,840,457	789,912	1,359,269	1,951,746	66,831,365	22,194,935	34,028,030	46,019,026		
		28%	48%	69%		33%	51%	69%		
Prof Claims	2,327,711	114,518	257,279	507,143		1,880,890	3,499,352	6,453,717		
		5%	11%	22%		8%	15%	28%		
OP Claims	4,473,531	432,896	698,962	1,230,034		2,704,144	3,993,323	6,388,155		
		10%	16%	27%		11%	17%	27%		
Total	9,641,698	1,337,326	2,315,510	3,688,923		26,779,969	41,520,705	58,860,899		

Net (OHP) cost and savings

		FF	:S		ссо					
	Current	UPL1 Savings	UPL2 Savings	UPL3 Savings	Current	UPL1 Savings	UPL2 Savings	UPL3 Savings		
Rx Claims	1,754,748	583,476	897,733	1,209,062	65,419,138	21,681,300	33,303,332	45,081,832		
		33%	51%	69%		33%	51%	69%		
Prof Claims	587,821	61,160	178,771	287,767		1,698,639	3,138,748	5,736,342		
		10%	30%	49%		9%	16%	30%		
OP Claims	1,318,533	428,293	598,121	767,021		2,434,082	3,505,697	5,388,025		
		32%	45%	58%		13%	19%	29%		
Total	3,661,103	1,072,928	1,674,625	2,263,850		25,814,022	39,947,777	56,206,200		

Source: Oregon Health Authority, September 2024

Myers and Stauffer hypothetical UPL scenarios – Pharmacy

Drug	NDC	Label Name	Route	Manufacturer	Current WAC**	UPL Scenario 1	% off WAC	UPL Scenario 2	% off WAC	UPL Scenario 3	% off WAC
Entyvio	64764010821*	ENTYVIO 108	SUBCUTANEOUS	TAKEDA	\$4,588	\$4,129	10%	\$3,670	20%	\$3,211	30%
	00002143380	TRULICITY 0.75	SUBCUTANEOUS	ELI LILLY & CO.	\$488	\$293	40%	\$244	50%	\$195	60%
Turiliaita	00002143480	TRULICITY 1.5	SUBCUTANEOUS	ELI LILLY & CO.	\$488	\$293	40%	\$244	50%	\$195	60%
Trulicity	00002223680	TRULICITY 3	SUBCUTANEOUS	ELI LILLY & CO.	\$488	\$293	40%	\$244	50%	\$195	60%
	00002318280	TRULICITY 4.5	SUBCUTANEOUS	ELI LILLY & CO.	\$488	\$293	40%	\$244	50%	\$195	60%
	00078063941	COSENTYX	SUBCUTANEOUS	NOVARTIS	\$3,704	\$2,222	40%	\$1,481	60%	\$740	80%
	00078063968	COSENTYX	SUBCUTANEOUS	NOVARTIS	\$7,408	\$4,445	40%	\$2,963	60%	\$1,481	80%
Cocontray	00078063997	COSENTYX 150	SUBCUTANEOUS	NOVARTIS	\$7,408	\$4,445	40%	\$2,963	60%	\$1,481	80%
Cosentyx	00078063998	COSENTYX 300	SUBCUTANEOUS	NOVARTIS	\$3,704	\$2,222	40%	\$1,481	60%	\$740	80%
	00078105697*	COSENTYX 75	SUBCUTANEOUS	NOVARTIS	\$7,408	\$4,445	40%	\$2,963	60%	\$1,481	80%
	00078107068	COSENTYX	SUBCUTANEOUS	NOVARTIS	\$3,704	\$2,222	40%	\$1,481	60%	\$740	80%
Ocrevus	50242015001	OCREVUS 300	INTRAVENOUS	GENENTECH, INC.	\$1,971	\$1,774	10%	\$1,577	20%	\$1,380	30%
Tue mefere	57894064001	TREMFYA 100	SUBCUTANEOUS	JANSSEN BIOTECH	\$13,872	\$11,791	15%	\$7,283	47%	\$2,774	80%
Tremfya	57894064011	TREMFYA 100	SUBCUTANEOUS	JANSSEN BIOTECH	\$13,872	\$11,791	15%	\$7,283	47%	\$2,774	80%
	00169413013	OZEMPIC 1	SUBCUTANEOUS	NOVO NORDISK	\$322	\$193	40%	\$129	60%	\$64	80%
Ozempic	00169418113	OZEMPIC 0.25-	SUBCUTANEOUS	NOVO NORDISK	\$322	\$193	40%	\$129	60%	\$64	80%
	00169477212	OZEMPIC 2	SUBCUTANEOUS	NOVO NORDISK	\$322	\$193	40%	\$129	60%	\$64	80%

Myers and Stauffer hypothetical UPL scenarios – Medical

Drug	Procedure Code	Code Type	NDC	Label Name	Manufacturer	Billing Unit	Current WAC**	UPL Scenario 1	% off WAC		% off WAC	UPL Scenario 3	% off WAC
Entyvio	J3380	Permanent	64764030020	ENTYVIO 300 MG VIAL	TAKEDA PHARMACE	Per MG	\$28.89	\$26.00	10%	\$23.11	20%	\$20.22	30%
Keytruda	J9271	Permanent	00006302602	KEYTRUDA 100 MG/4 ML VIAL	MERCK SHARP & D	Per MG	\$56.69	\$51.02	10%	\$45.35	20%	\$39.68	30%
Inflectra	Q5103	Permanent	00069080901	INFLECTRA 100 MG VIAL	PFIZER US PHARM	Per 10 MG	\$94.63	\$85.17	10%	\$52.05	45%	\$18.93	80%
Ocrevus	J2350	Permanent	50242015001	OCREVUS 300 MG/10 ML VIAL	GENENTECH, INC.	Per MG	\$65.71	\$59.14	10%	\$52.57	20%	\$46.00	30%

^{*} PEBB and OEBB data do not show any utilization for the marked NDCs

^{**} WAC as of June 2024



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 statedetermined 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 costeffective 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 costeffective 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