Oregon Prescription Drug
Affordability Board

Oregon's Drug Pricing Transparency Program and Prescription Drug Affordability Board Program Overview and Updates

Ralph Magrish, Executive Director PDAB
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Senate Interim Committee on Health Care

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Oregon's Prescription Drug Price Transparency Program

Presenter: Ralph Magrish

Drug Price Transparency Program

Program basics:

- Operates under ORS 646A.680 to 646A.692 and administrative rules OAR 836-200-0500 to 836-200-0560

- Reporting manufacturers are required to register, file certain reports, and pay an annual billing to cover program costs

- Reporting manufacturers are those who meet all of the following:
  - Registered with the Oregon Board of Pharmacy
  - Manufacture prescription drugs for sale in Oregon
  - Set the drug's price (wholesale acquisition cost – WAC)

Drug Price Transparency Reporting

Program is directed by statute to receive:

- New drug reports: More than $670
- Annual price increase reports: $100 or more and 10 percent net yearly increase
- 60-day price increase notice: 10 percent or $10,000 increase for brand, 25 percent and $300 increase for generic
- Insurers report: Top 25 most costly and most prescribed drugs, and the impact of drug costs on premium rates
- Consumers report: Personal price increase in Rx they have purchased

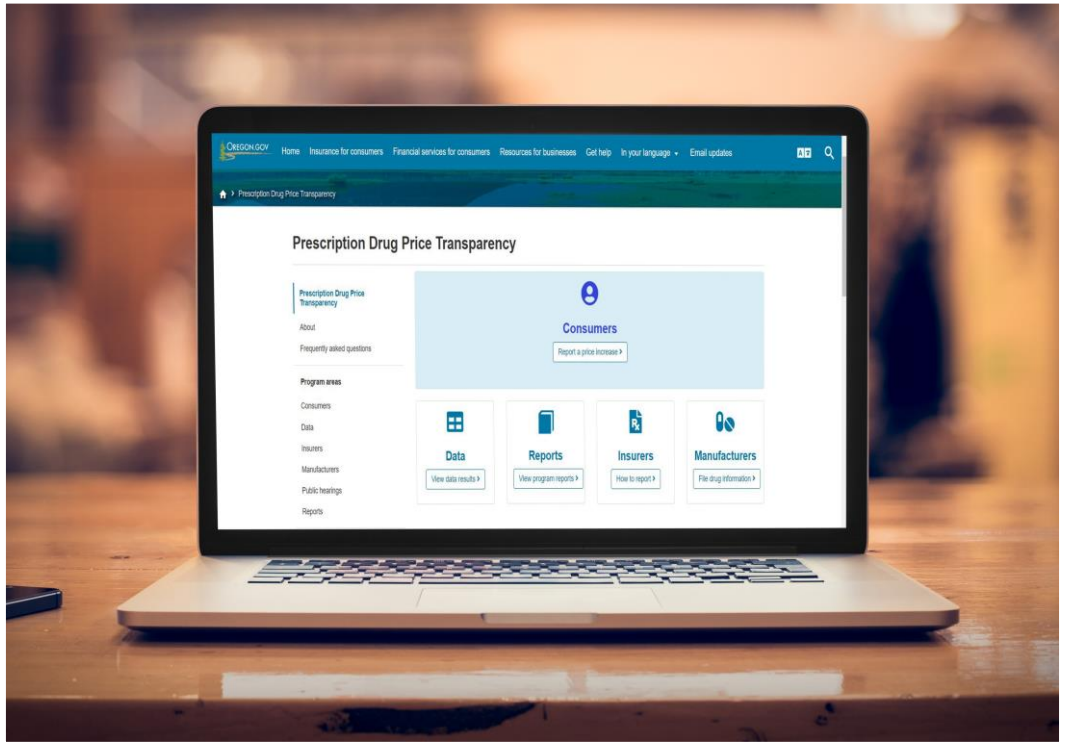
Drug Price Transparency Program

Consumer reporting:

- Price increase reporting
- Stories and questions
- Outreach

Transparency website:

- Reported data from manufacturers (non-trade secret)
- Information from insurers
- Consumer reports submitted



Drug Price Transparency Program overview

The program is directed to:

Host public hearings on drug prices

- Save the date – Dec. 1, 2022
- Review of Annual Report findings and panel discussions
- Slated topics include Insulin pricing and the pharmaceutical supply chain & pharmacy benefit manager rebates

Submit legislative reports

Information collected by the program and recommendations for legislative changes to contain the cost or reduce the effect of prescription drug prices

Reporting challenges

- DPT does not disclose trade secrets. The law provides for conditionally exempting from disclosure information submitted that is determined to be trade secret.
- What do we see?
  - Increasing frequency and volume of some manufacturers' submissions being categorically labeled trade secret **when claimed information is publicly available**.
  - Uptake in third-party entities that prepare filings for state transparency programs.
- What are we doing about it?
  - Partnering with compliance and enforcement unit and the Department of Justice to address manufacturer noncompliance and blanket labeling of submissions as trade secrets.
  - Working with manufacturers to provide meaningful information and technical assistance to help promote voluntary compliance and accurate data submissions.

Program compliance and trade secret reviews

DPT compliance

- Identifying manufacturer noncompliance and sending letters of noncompliance
- Goal is compliance: Noncompliance letters allow 30 days to become compliant before file is referred to Enforcement Unit and manufacturers potentially accrue civil penalties
- Primary areas of potential noncompliance:
  - Failure to respond to the request for additional information
  - Failure to provide accurate and complete information in the required data elements

DPT trade secret

- Beginning to send trade secret determinations involving claims of trade secret for required reporting data elements
- Trade secret determinations include generic and brand-name drugs
- Lengthy and complex process to address determinations both in agreement and in opposition to manufacturer's trade secret claims

New carrier reporting enhancements - 2022

- Total dollars paid for drugs by insured and by insurer after rebates and other price concessions
- Dollars paid for drugs by insured and insurer after rebates, etc., on a per member, per month basis
- Dollars paid for drugs by insurer after rebates, etc., as a percent of premium collected
- Total dollars received by insurer in rebates and other price concessions
- All broken out by market and insurer

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Oregon's Prescription Drug Affordability Board (PDAB)

Presenters : Ralph Magrish & Akil Patterson
Prescription Drug Affordability Board

PDAB introduction

Purpose

- Created under SB 844 (2021) to protect Oregonians, state and local governments, commercial health plans, health care providers, pharmacies, and others in the health care system from the high costs of prescription drugs

Composition

- Five members and three alternates appointed by the governor and confirmed by the Senate
- Required background in clinical medicine or healthcare economics

PDAB responsibilities

Rulemaking input

- Affordability review criteria
- Manufacturer fee structure

Annual reporting requirements

- Generic marketplace report to legislature
- Report to legislature and Cost Growth Target Program (OHA) on:
  - Price trends
  - Drug affordability reviews conducted
  - Recommendations for changes to make drugs more affordable

PDAB functions

- Drug affordability reviews – Identify nine drugs and at least one insulin product that may create affordability challenges for health care systems or high out-of-pocket costs for patients based on criteria adopted by the board
- Study the entire prescription drug distribution and payment system in Oregon and around the world designed to lower the list price of prescription drugs
- Make recommendations to the legislature for statutory changes

Drug affordability reviews – criteria development

Criteria

- Cost as an access issue creating health inequities in communities of color
- Number of residents in Oregon prescribed the drug
- Price sold in Oregon
- Average monetary concessions to insurance plans
- Estimated total price concessions, discounts or rebates manufacturers give pharmacy benefit managers (PBMs)
- Estimated price of therapeutic alternatives

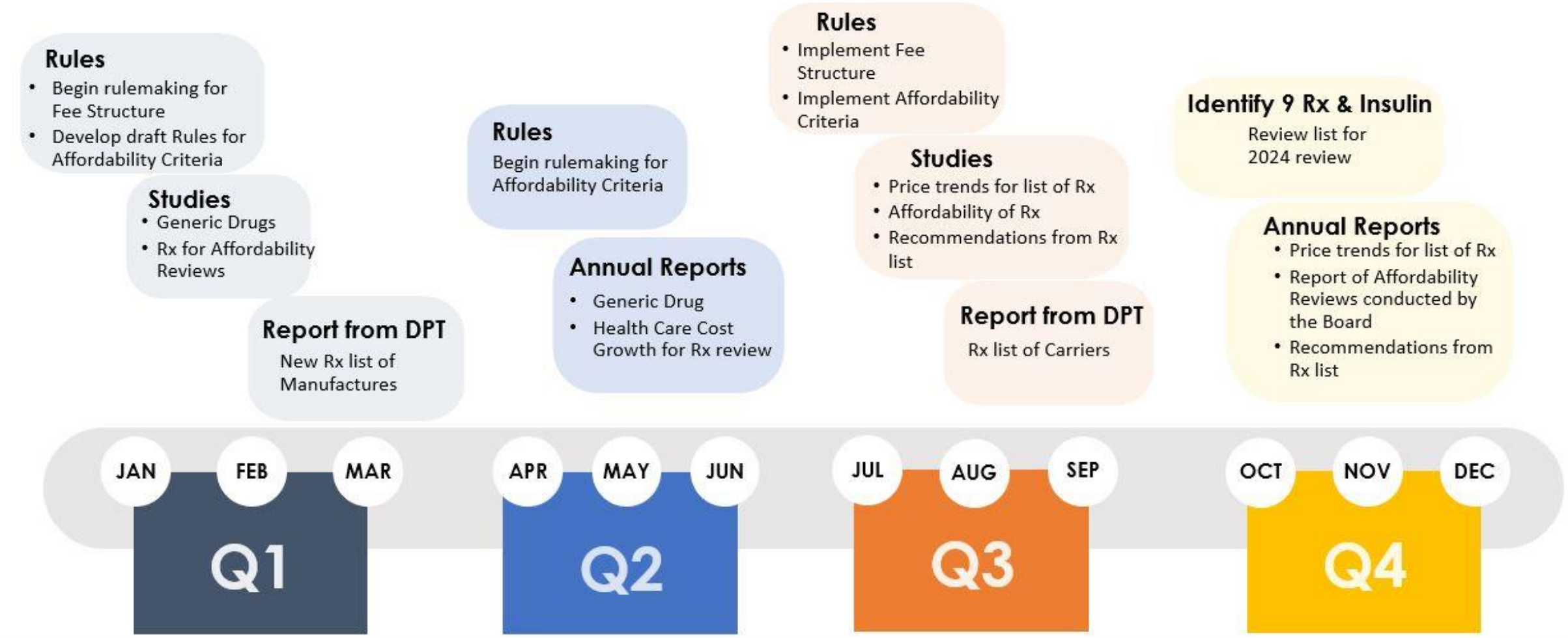
Drug affordability reviews – criteria development

Criteria

- Average price concession, discount, or rebate from manufacturer to plans and PBMs for therapeutic alternatives
- Estimated costs to insurance plans
- Impact on patient access to the drug
- Financial impacts to health, medical, or social services costs as compared to therapeutic alternatives
- Patient co-payment or other cost sharing
- Any information from a manufacturer
- Any other factors as determined by the board

PDAB roadmap for 2023

PDAB ROADMAP for 2023



Where we are today – level setting

- Inaugural PDAB meeting was June 23
  - Meeting monthly
- Improving our understanding the complexities of pharmaceutical purchasing and supply chain
- Recognition there is a lot to learn
- This is just the beginning
  - New PDAB – not fully seated
  - New team – still building
- Embracing challenge

Opportunities for Synergy - DPT and PDAB

- Inherent value in understanding the marketplace to develop new policy recommendations that promote accountability and offer cost containment strategies for government and private sector purchasers.
- Lack of drug pricing transparency is not singularly focused on drug manufacturers. It includes:
  - PBMs
  - Insurance carriers
  - Drug wholesalers
  - Pharmacies
  - Others

Analytic opportunities to inform policy

- Identify the most expensive drugs by utilization
- Determine which drugs have shown significant price increases, contributed to raised carrier operating costs and consumer premiums and co-pays
- Extrapolate information to identify how rebates and incentives drive cost and impact consumers

Upcoming PDAB meetings and presentations

Wednesday, Oct. 19

Perspectives on PDAB Upper Payment Limit (UPL) implementations

Lila Cummings, PDAB Director, State of Colorado

Andrew York, PharmD., JD, Executive Director, Maryland PDAB

Wednesday, Nov. 16

Overview of Prescription Drug Patent Law

Tahir Amin, Cofounder and Co-Executive Director; I-MAK.org

Register for board updates and meetings: **dfr.oregon.gov/pdab**

Next steps

- DPT results and recommendations to legislature report – Dec. 2022
- DPT public hearing – Dec. 2022
- PDAB policy recommendations and reports to Legislature – Dec. 2022
- PDAB will begin rule development for affordability reviews – Jan. 2023
- PDAB affordability reviews – July to Dec. 2023

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Inflation Reduction Act (IRA) Medicare Drug Negotiations and Changes for Oregon Medicare Beneficiaries

Presenter: Ralph Magrish

Medicare Part D negotiations

- Gives Medicare powers to negotiate prices on select numbers of the costliest drugs for the first time and provide important relief to Medicare Part D beneficiaries
- By 2025, it would cap out-of-pocket costs for Medicare Part D beneficiaries (the prescription drug pharmacy benefit) at $2,000
- By 2024, it would eliminate a 5 percent co-pay on drugs for catastrophic coverage, saving thousands of dollars for patients with serious diseases (cancer, hepatitis C, multiple sclerosis, etc.) who require very expensive drugs

Inflation Reduction Act and Medicare Part D

- Beginning in 2023, drug companies would be required to pay rebates if drug prices rise faster than inflation
- The first negotiated prices would take effect on 10 drugs in 2026, 15 additional drugs in 2027, 15 more in 2028 and 20 more in 2029
- Through negotiations and other provisions, the bill is expected to equal net revenue for the government of $288 billion over 10 years

IRA and Part D implications For Oregonians

Eliminates 5% co-insurance above the Part D catastrophic threshold	Establishes the $2,000 out of pocket spending cap for Part D	Expands income eligibility for full Part D low-income subsidies	Eliminates cost sharing for adult vaccines covered under Part D
14,190	20,360	5,300	69,440

Kaiser Family Foundation – How Would the Prescription Drug Provisions in the Senate Reconciliation Proposal Affect Medicare Beneficiaries?
https://www.kff.org/medicare/issue-brief/how-would-the-prescription-drug-provisions-in-the-senate-reconciliation-proposal-affect-medicare-beneficiaries/

Questions?

Questions

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