# DRAFT OUTLINE

**Affordability Reviews for Eligible Prescription Drugs**

(1) The purpose of this rule is to establish the methodology and process for the Prescription Drug Affordability Board (PDAB) to annually conduct an affordability review that identify nine prescription drugs and at least one insulin product that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon.

(2) **Eligible Prescription Drugs for Affordability Reviews**

Each calendar quarter PDAB will be provided from the Department of Consumer and Business Services a list of prescription drugs included in reports submitted to the department under ORS 646A.689 (2) and (6), a list of drugs included in reports submitted to the department under ORS 743.025, and a list of insulin drugs marketed in this state during the previous calendar year. From these lists, annually PDAB will identify nine drugs and at least one insulin product through an affordability review.

(3) **Selecting Prescription Drugs for Affordability Reviews**

PDAB will select from the eligible prescription drugs in subsection (2) a subset of drugs to prioritize for an affordability review under subsection (4) of this rule, by considering the following:

(a) Class of the Prescription Drug and Therapeutic Equivalents:

(A) Determine the date of FDA approval of the eligible prescription drug and whether the prescription drug was approved through an expedited pathway.

(B) For brand-name drugs and biological products, determine the class and whether there are any approved and marketed generic drugs or biosimilar drugs for the specific brand-name drug or biological product.

(C) Where there are therapeutic equivalents, PDAB may consider for each equivalent the cost and availability by considering utilization data and spending data.

(b) Aggregated Data:

(A) Health equity impact, including whether the prescription drug is utilized to treat a condition disproportionately experienced by priority populations;

(B) Historical and current pricing data, including wholesale acquisition cost and average sales price of the prescription drug;

(C) Expenditures associated with the prescription drug, including expenditures identified in APAC data;

(D) Utilization associated with the prescription drug, including utilization identified in APAC data; and

(E) Information regarding the estimated manufacturer net-cost and net-sales amounts for eligible prescription drugs.

(c) Average Patient Out-Of-Pocket Cost: Consideration of the average patient out-of-pocket cost for the prescription drug, which may include copayment amounts, cost-sharing amounts, coinsurance amounts, and other information relevant to out-of-pocket costs.

(4) **Conducting an Affordability Review**

PDAB will conduct an affordability review on the prioritized subset of prescription drugs selected under subsection (3) to identify nine prescription drugs and at least one insulin product that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon.

(a) PDAB will conduct an affordability review by considering, to the extent practicable, the following criteria set forth in ORS 646A.694:

(A) Whether the prescription drug has led to health inequities in communities of color;

(B) The number of residents in this state prescribed the prescription drug;

(C) The price for the prescription drug sold in this state;

(D) The estimated average monetary price concession, discount or rebate the manufacturer provides to health insurance plans in this state or is expected to provide to health insurance plans in this state, expressed as a percentage of the price for the prescription drug under review;

(E) The estimated total amount of the price concession, discount or rebate the manufacturer provides to each pharmacy benefit manager registered in this state for the prescription drug under review, expressed as a percentage of the prices;

(F) The estimated price for therapeutic alternatives to the drug that are sold in this state;

(G) The estimated average price concession, discount or rebate the manufacturer provides or is expected to provide to health insurance plans and pharmacy benefit managers in this state for therapeutic alternatives;

(H) The estimated costs to health insurance plans based on patient use of the drug consistent with the labeling approved by the United States Food and Drug Administration and recognized standard medical practice;

(I) The impact on patient access to the drug considering standard prescription drug benefit designs in health insurance plans offered in this state;

(J) The relative financial impacts to health, medical or social services costs as can be quantified and compared to the costs of existing therapeutic alternatives;

(K) The estimated average patient copayment or other cost-sharing for the prescription drug in this state; and

(L) Any information a manufacturer chooses to provide.

(b) PDAB conducts an affordability review by considering, to the extent practicable, the additional following criteria:

(A) In addition to the criteria in subparagraph (a)(A): Health Equity Factors: Whether the pricing of the prescription drug results in or has contributed to health inequities in under resourced communities and pharmacy deserts.

(B) In addition to the criteria in subparagraph (a)(B): Include off label use of prescription drugs used to treat other conditions.

(C) Current wholesale acquisition cost of the prescription drug and changes in the prescription drug's wholesale acquisition cost over time.

(D) In addition to the criteria in subparagraph (a)(C): Cost and availability of therapeutic alternatives to the prescription drug in the state, including any relevant data regarding costs, expenditures, availability, and utilization related to the prescription drug and its therapeutic alternatives.

(E) Price Effect on Oregon Consumer Access: Effect of price on consumers' access to the prescription drug by reviewing changes in pricing, expenditure, and utilization over time.

(F) In addition to the criteria in subparagraph (a)(J): Relative Financial Effects of the Prescription Drug on Health, Medical, or Social Services Costs:

i. To the extent such information can be quantified, the relative financial

effects of the prescription drug on broader health, medical, or social services costs, compared with therapeutic alternatives or no treatment.

ii. Identify if the sources it relies on use a quality-adjusted life-year analysis or a similar formula that takes into account a patient's age or severity of illness or disability, to identify subpopulations for which a prescription drug would be less cost-effective. PDAB may not use quality-adjusted life year analysis or a similar formula to evaluate relative financial effects.

(G) In addition to the criteria in subparagraph (a)(K): Patient copayment or other cost sharing data, across different health benefit plan designs, to the degree such information is available in the APAC, including:

i. Copayment;

ii. Coinsurance;

iii. Deductible; and/or

iv. Any other copayment and cost sharing data.

(H) Impact on Safety Net Providers: When the prescription drug is available through section 340B of the federal Public Health Service Act (42 U.S.C. 256b):

i. Information regarding safety net providers participating in the 340B, including information to assist with gathering input to assess the impact to safety net providers for a prescription drug under review that is available through Section 340B of the Federal "Public Health Service Act", Pub.L. 78-410;

ii. The utilization of the prescription drug by the safety net provider's patients;

iii. Whether the safety net provider receives a 340B discount for the prescription drug;

iv. Where the safety net provider does not receive a discount, whether access to the prescription drug is impeded; and

v. Any other topics identified by safety net provider stakeholders for discussion.

(I) Input from Specified Stakeholders:

i. Patients and Caregivers

1. Seek input from patients and caregivers affected by a condition or disease that is treated by the prescription drug under review by gathering information related to:

a) The impact of the disease,

b) Patient treatment preferences,

c) Patient perspective on the benefits and disadvantages of using the prescription drug,

d) Caregiver perspective on the benefits and disadvantages of using the prescription drug, and/or

e) Available patient assistance in purchasing the prescription drug.

2. In seeking additional information, attempt to gather a diversity of experience among patients from different socioeconomic backgrounds.

ii. Individuals with Scientific or Medical Training: Seek input from individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review by PDAB, including:

1. The impact of the disease,

2. Perspectives on benefits and disadvantages of the prescription drug, including comparisons with therapeutic alternatives if any exist, and/or

3. Input regarding the prescription drug utilization in standard medical practice, as well as input regarding off label usage.

(J) Rebates, Discounts, and Price Concessions:

i. To the extent practicable, estimated manufacturer net-sales or estimated net-cost amounts (including rebates, discounts, and price concessions) for the prescription drug and therapeutic alternatives; and

ii. Manufacturer financial assistance the manufacturer provides to pharmacies, providers, consumers, and other entities.

(K) Information from the Oregon Health Authority (OHA), Health Evidence Review Commission (HERC), and Pharmacy and Therapeutics Committee (P&T):

i. Additional analyses conducted that is relevant to the prescription drug or therapeutic alternative under review.

(L) Non-adherence and Utilization Management Information: Information regarding non-adherence to the prescription drug, as well as information related to utilization management restrictions placed on the prescription drug.

(M) PDAB may consider any document and research related to the introductory price or price increase of a prescription drug, including life cycle management, net average price in this state, market competition and context, projected revenue and the estimated value or cost-effectiveness of the prescription drug.

(c) After consideration of the criteria in subparagraphs (a) and (b), PDAB shall identify nine prescription drugs and at least one insulin product that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon.

(d) Report of Affordability Review: No later than December 31 of each year, PDAB shall include in its report to the Health Care Cost Growth Target program established in ORS 442.386 and to the interim committees of the Legislative Assembly related to health the prescription drugs that were reviewed under this rule with the following information:

(A) Price trends for the list of prescription drugs provided to the board by the Department of Consumer and Business Services under ORS 646A.694 (1);

(B) The prescription drugs that were reviewed under ORS 646A.694 (1); and

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

(e) Confidentiality:

(A) To the extent the information submitted to PDAB contains confidential, trade secret or proprietary information, PDAB will meet in executive session to discuss the information pursuant to ORS 192.660.

(B) PDAB will not disclose confidential, trade secret or proprietary information in an open meeting, its public meeting materials, or any reports.

(C) A manufacturer, carrier, pharmacy benefit manager, or other entity that voluntarily submits information for PDAB's consideration shall clearly designate the specific information it deems to be confidential, pursuant to ORS 192.355(4).