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# NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 925
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
PRESCRIPTION DRUG AFFORDABILITY BOARD

**FILED**
05/23/2023 3:48 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Prescription Drug Affordability Review

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 06/29/2023 5:00 PM

*The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.*

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Salem,OR 97301

Filed By:
Jennifer Romadka-Healy
Rules Coordinator

HEARING(S)

*Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.*

DATE: 06/22/2023
TIME: 11:00 AM - 11:45 AM
OFFICER: Cortnee Whitlock

HEARING LOCATION
ADDRESS: Labor and Industries Building, 350 Winter St. NE, Basement, Conf Rm E, Salem, OR 97301

REMOTE MEETING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 543551605
SPECIAL INSTRUCTIONS:
A hybrid meeting conducted in-person and virtually via Microsoft Teams.

NEED FOR THE RULE(S)

The Prescription Drug Affordability Board (PDAB) was established as part of Senate Bill 844 (2021) within the Department of Consumer and Business Services with the purpose to protect consumers and other entities from the high cost of prescription drugs. The law provides authority for the PDAB to adopt rules necessary for the administration of the board ORS 646A.693(18).

Specifically, the law provides that the PDAB will adopt criteria by rule that will be used by the board to annually identify nine drugs and at least one insulin product that the board determines may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon. ORS 646A.694(1).

The prescription drug affordability review rule is needed to provide the framework and criteria for the board to conduct

drug affordability reviews. The rule informs the PDAB on the costs of prescription drugs by providing criteria for reviewing information from drug manufacturers, health insurance carriers, pharmacy benefit managers, and other sources. To carry out the statutory requirements, the PDAB will select drugs for review by considering criteria, including the wholesale acquisition costs (WAC), whether the drug had an expedited pathway for FDA approval, and determining therapeutic alternatives. Additionally, the rule requires the PDAB to consider if the pricing of prescription drugs contributes to health inequities and how price concessions, discounts, rebates, coupons, or patient assistant programs impact drug affordability.

A Rules Advisory Committee (RAC) met on April 5, 2023, and consisted of stakeholders from drug manufacturers, insurers, and pharmacy benefit managers (PBMs).

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Draft rules are available from Karen Winkel, Rules Coordinator, Division of Financial Regulation located at 350 Winter St. NE, Salem, OR 97301 and are available on the division's website: https://dfr.oregon.gov/laws-rules/Pages/proposed-rules.aspx.

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

The PDAB is tasked with evaluating the cost of prescription drugs, including ones that contribute to health inequities for communities of color.

Conducting an affordability review of prescription drugs can help ensure that individuals with lower incomes or limited access to healthcare are not disproportionately burdened by high drug costs. This can promote greater equity in terms of access to necessary medications. It is important for the PDAB to carefully consider the potential impacts of affordability reviews on equity and access to healthcare.

FISCAL AND ECONOMIC IMPACT:

Cost of compliance for business under this rulemaking would be minimal as most of the business compliance standards are governed through the Drug Price Transparency Program. The Drug Price Transparency Program collects the data required under ORS 646A.689 (2) and (6), and ORS 743.025, and provides that data to the PDAB to identify the nine drugs and insulin product.

The PDAB will also review information submitted by health insurance carriers in response to data calls issued under ORS 731.296. Information collected through these data calls will inform the PDAB's decisions in conducting affordability reviews. The rule does not impose compliance costs on carriers beyond the statutory requirements of ORS 731.296 and ORS 743.025.

Compliance costs for small businesses are not anticipated as a result of this rule.

COST OF COMPLIANCE:

*(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).*

(1) Based on currently available information, the proposed rule would not have a fiscal or economic impact on state agencies, local government units, or the general public beyond the statutory requirements. The requirement to conduct affordability reviews has a fiscal impact on the Department of Consumer and Business Services due to the staffing and

other resources required for this work. However, the rules solely provide detail and elaboration to this requirement and do not have a fiscal impact beyond the underlying statute.

(2)(a) The proposed rule specifies criteria for affordability reviews performed by the PDAB and does not impose additional requirements on businesses.

Drug manufacturers are required to provide the data used in the PDAB's review by ORS 646A.689. The proposed rule specifies additional uses for this data and does not impose additional requirements on manufacturers.

Health insurance carriers are required to provide the data used in PDAB's review by ORS 731.296 and ORS 743.025. The proposed rule specifies additional uses for this data and does not impose additional requirements on carriers.

The RAC included representatives of prescription drug manufacturers, health insurers, pharmacy benefit managers, pharmacies, and consumer and patient advocates. Committee feedback suggested that it is unlikely that any small businesses are affected by the proposed rule.

(2)(b) Based on the available information, including feedback from the RAC, the proposed rules do not impose additional compliance costs beyond the underlying statutory requirements.

(2)(c) Based on current information, including feedback from the RAC, the proposed rules do not impose additional costs for professional services, equipment supplies, labor, and increased administration beyond the underlying statutory requirements.

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DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

The rulemaking advisory committee was comprised of stakeholders within the pharmaceutical supply chain. This included representation of pharmacies and some pharmacies are small businesses.

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WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

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RULES PROPOSED:
925-200-0010, 925-200-0020

ADOPT: 925-200-0010

RULE SUMMARY: The methodology for the Prescription Drug Affordability Board (PDAB) to select a subset of prescription drugs to prioritize for an affordability review.

CHANGES TO RULE:

925-200-0010
Selecting Prescription Drugs for Affordability Reviews
The Prescription Drug Affordability Board (PDAB) will select from the list of eligible prescription drugs, provided by the Department of Consumer and Business Services pursuant to ORS 646A.694, a subset of drugs to prioritize for an affordability review under OAR 925-200-0020 by considering the following for the selection of prescription drugs:¶
(1) Whether any prescription drugs are on each of the insurer reported top 25 lists under ORS 743.025.¶
(2) Whether the prescription drug is included in the manufacturer new drug report or price increase report under ORS 646A.689 for the previous calendar year. ¶
(3) Historical and current manufacturer drug price increases, based on wholesale acquisition cost (WAC) information. For drugs with multiple nation drug codes (NDC), a measure of central tendency will be used for a price comparison.¶

(4) The date of U.S. Food and Drug Administration (FDA) approval of the prescription drug and whether the prescription drug was approved through an expedited pathway. Expedited approval includes fast track, priority review, accelerated approval, and breakthrough therapy designation. For brand-name drugs and biological products, whether there are any approved and marketed generic drugs or biosimilar drugs for the specific brand-name drug or biological product.¶
(5) Where there are therapeutic alternatives, the cost and availability of potential alternatives.¶
(6) Whether the prescription drugs have a patent expiration or data exclusivity expiration within 18 months.¶
(7) For insulin drugs marketed in the U.S. and available in Oregon, criteria for selection may include, but not limited to, those products with the highest insurer reported: ¶
(a) Overall spend; ¶
(b) Per-patient spend; and¶
(c) Patient out-of-pocket cost.
Statutory/Other Authority: ORS 646A.693, ORS 646A.694
Statutes/Other Implemented: ORS 646A.694

ADOPT: 925-200-0020

RULE SUMMARY: The process for the Prescription Drug Affordability Board (PDAB) to conduct an affordability review on a prioritized subset of prescription drugs.

CHANGES TO RULE:

925-200-0020
Conducting an Affordability Review
The Prescription Drug Affordability Board (PDAB) will conduct an affordability review on the prioritized subset of prescription drugs, selected under OAR 925-200-0010 to identify nine prescription drugs and at least one insulin product that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon. ¶
(1) 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.¶
(2) PDAB will conduct an affordability review by considering, to the extent practicable, the additional following factors:¶
(a) In addition to the criteria in subparagraph (1)(a): Whether the pricing of the prescription drug results in or has contributed to health inequities in:¶
(A) Under-resourced communities; or ¶
(B) Regions with limited pharmacy access. ¶
(b) In addition to the criteria in subparagraph (1)(b): Include off label use of prescription drugs used to treat other conditions. ¶
(c) In addition to the criteria in subparagraph (1)(f): Consider the estimated net price. 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. Therapeutic alternative is to mean a drug product that contains a different chemical structure than the drug prescribed, but is in the same pharmacologic or therapeutic class and can be expected to have a similar therapeutic effect and adverse reaction profile when administered to patients in a therapeutically equivalent dosage.¶
(d) In addition to the criteria in subparagraph (1)(d), (1)(e), and (1)(g): Consider information submitted by manufacturers related to patient assistant programs and coupons.¶
(e) Current wholesale acquisition cost of the prescription drug and changes in the prescription drug's net cost over time.¶
(f) Analysis to consider acquisition cost for pharmacies.¶
(g) Effect of price on consumers' access to the prescription drug by reviewing changes in pricing, expenditure, and utilization over time.¶
(h) Potential market for prescription drug for labeled and off-label indications and budget impact on various payors in the state.¶
(i) In addition to the criteria in subparagraph (1)(j): ¶

(A) 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. ¶
(B) To the extent such information can be quantified, the total cost of the disease and the drug price offset.¶
(j) In addition to the criteria in subparagraph (1)(k): Patient copayment or other cost sharing data, across different health benefit plan designs, including:¶
(A) Copayment and coinsurance impacts from:¶
(i) Patient assistance programs; and¶
(ii) Copay coupons;¶
(B) Deductible;¶
(C) Patient out-of-pocket costs; and¶
(D) Any other cost sharing data.¶
(k) Input from Specified Stakeholders:¶
(A) Patients and Caregivers:¶
(i) 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:¶
(I) The impact of the disease;¶
(II) Patient treatment preferences;¶
(III) Patient perspective on the benefits and disadvantages of using the prescription drug;¶
(IV) Caregiver perspective on the benefits and disadvantages of using the prescription drug; and¶
(V) Available patient assistance in purchasing the prescription drug.¶
(ii) In seeking additional information, attempt to gather a diversity of experience among patients from different socioeconomic backgrounds.¶
(B) 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, including:¶
(i) The impact of the disease;¶
(ii) Perspectives on benefits and disadvantages of the prescription drug, including comparisons with therapeutic alternatives if any exist; and ¶
(iii) Input regarding the prescription drug utilization in standard medical practice, as well as input regarding off label usage.¶
(C) Safety Net Providers: health care providers that care for uninsured patients and patients with low income and receive discounted prices on prescription drugs through section 340B of the federal Public Health Service Act (42 U.S.C. 256b):¶
(i) The utilization of the prescription drug by the safety net provider patients;¶
(ii) Whether safety net providers receive a 340B discount for the prescription drug;¶
(iii) Where safety net providers do not receive a discount, whether access to the prescription drug is impeded; and¶
(iv) Any other topics identified by safety net provider stakeholders.¶
(D) Payers¶
(i) Total cost of care for disease(s);¶
(ii) Cost of the prescription drug to the payer; ¶
(iii) The availability of therapeutic alternatives on the formulary;¶
(iv) Coverage mandates and impacts to per member per month or premiums;¶
(v) Affordability concerns of the prescription drug, from employer groups and other plan sponsors; and¶
(vi) Other costs to consider. ¶
(l) Rebates, Discounts, and Price Concessions:¶
(A) 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¶
(B) Financial assistance the manufacturer provides to pharmacies, providers, consumers, and other entities.¶
(m) Information from the Oregon Health Authority (OHA), Health Evidence Review Commission (HERC), and Pharmacy and Therapeutics Committee (P&T) that is relevant to the prescription drug or therapeutic alternative under review.
Statutory/Other Authority: ORS 646A.693, ORS 646A.694
Statutes/Other Implemented: ORS 646A.694