Hearing Officer's Report to Agency on Rulemaking Hearing

Date: 7/20/2023

To: Department of Consumer and Business Services

From: Cortnee Whitlock, Hearing Officer

Subject: Prescription Drug Affordability Board prescription drug affordability review rules

Hearing Date/Time:	June 22, 2023 / 11:00 am
Hearing Location:	Labor and Industries Building Hybrid meeting conducted in person at Labor and Industries Building and virtually on Microsoft Teams
Comment Period End:	June 29, 2023

Background

The Prescription Drug Affordability Board (PDAB) was enacted as part of Senate Bill 844 (2021) within the Department of Consumer and Business Services (DCBS) 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 PDAB (ORS 646A.693(18)).

Specifically, the law provides that the PDAB will adopt criteria by rule that will be used by the PDAB to annually identify nine drugs and at least one insulin product that the PDAB 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 rules provide the criteria to be used by PDAB in conducting affordability reviews of prescription drugs.

1. OAR 925-200-0010 provides the criteria for the PDAB to select a subset of prescription drugs to prioritize for an affordability review. This rule supports the statutory requirements to identify nine prescription drugs and at least one insulin product.
2. OAR 925-200-0020 provides additional criteria the PDAB may use to conduct an affordability review.

There was a rules advisory committee meeting held on April 5, 2023, and consisted of stakeholders from drug manufacturers, insurers, and pharmacy benefit managers.

Hearing and Summary of Oral Comments

Public comment was provided by Eric Lohnes with Pharmaceutical Research and Manufacturers of America (PhRMA). Mr. Lohnes stated that PhRMA has asked for several items to be considered in previous submissions on the proposed rules including:

- Provide clear and meaningful methodologies and details regarding the review selection process
- How the review process will be operationalized
- Procedures for evaluating the reliability of information
- Procedure for stakeholder feedback
- Protections against the use of Quality Adjusted Life Years (QALYs)
- Clear standards on how the PDAB will maintain confidentiality of manufacturer data

Mr. Lohnes stated that that PhRMA will submit written comment by the submission deadline.

There were no additional oral comments provided at the hearing.

Summary of Written Comments

Pharmaceutical Research and Manufacturers of America (PhRMA) submitted written comment on June 23, providing the following feedback about the affordability review rules:

- Clear and meaningful standards for how the drug selection and affordability review processes will be conducted. Provide a specific methodology to be used in the drug selection and affordability review processes.
- Procedures for evaluating the reliability of information. Adopt specific procedures for reviewing and evaluating accuracy and completeness of the information the PDAB will consider.
- Procedures for stakeholder feedback. Adopt greater procedural protections to allow impacted stakeholders to provide feedback on PDAB processes and decision.
- Protections against the use of QALYs. Adopt this prohibition in the regulations and provide clear safeguards to restrict the PDAB from directly or indirectly considering QALYs and similar measures.
- Clear standards on how the PDAB will maintain confidentiality of manufacturer data. The proposed rules do not address how the PDAB will ensure the confidentiality of the materials it reviews in accordance with applicable law, including those in the PDAB statute.

Biotechnology Innovation Organization (BIO) submitted written comment on June 29, providing the following feedback about the affordability review rules:

- Rules must explicitly exclude rare disease drugs from consideration per the statute.
- Affordability should be defined more holistically to include value to the healthcare system generated by innovative therapies. This definition should account for savings resulting from reduced hospitalizations, acute care episodes, and other medical costs.
- Carefully consider utility of information about accelerated approval drugs to protect investments in treatments for rare diseases.
- Consider additional levers available to reduce out-of-pocket costs for patients, such as controlling PBMs through banning of spread pricing and allowing patients to spread their out-of-pocket costs throughout the benefit year.
- Accurately define out-of-pocket costs, co-insurance, cost-sharing, copayment, and other terms.
- Modify the therapeutic alternative definition to:

  Therapeutic alternative is to mean a drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved for the same indication with the same pharmacological or therapeutic class and has been shown through peer-reviewed studies to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose or has been recommended as consistent with standard medical practice by medical professional association guidelines.
- Remove the cost effectiveness metric, given that the statutory provision regarding insulin appears to be a moot issue.
- Establish a process that manufacturers can identify their confidential proprietary and trade secret information pursuant to State and Federal law.
- Data from 340B covered entities should reflect how they are using the discounts and the charity care they are providing.

Discussion

Regarding PhRMA comments:

The rules set forth the criteria to be considered in the affordability review. With these criteria, the PDAB will publicly and transparently deliberate their review of data and information to identify nine drugs and at least one insulin product.

ORS 646A.694 includes provisions addressing QALYs. The proposed rules implement the statutes and it is not necessary to include all statutory provisions in the rules.

Regarding BIO comments:

OAR 925-200-0020 was revised to include provision on rare disease drugs.

The PDAB statutes, ORS 646A.693 and ORS 646A.694, include provisions addressing confidentiality of information. The proposed rules implement the statutes and it is not necessary to include all statutory provisions in the rules.

The PDAB is required pursuant to ORS 646A.694 to identify at least one insulin drug through the affordability review.

The PDAB reviewed the comment about the definition for "therapeutic alternative" and decided to update the definition to:

> Therapeutic alternative is to mean a drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved, compendia-recognized as off-label use for the same indication, or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose.

Recommendation

Having fully considered all written and oral submissions, the hearing officer recommends the rules be adopted with the following additional changes to OAR 925-200-0020:

- Additional grammar and formatting changes were added to improve readability and clarity.
- The therapeutic alternative definition was updated and is defined in the discussion section above.
- Language was added to the rule for rare disease in Section 1, subsection (m) and Section 2, subsection (n).

Cortnee Whitlock
Hearing Officer
Division of Financial Regulation

This Summary and Recommendation are reviewed and adopted.

Signed this 2 day of August, 2022.

Andrew R. Stolfi
Insurance Commissioner and Director
Department of Consumer and Business Services