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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

09/28/2022 3:37 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Model Rules for Rulemaking and Public Records Requests

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/01/2022 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.

CONTACT: Karen Winkel
503-947-7694
karen.j.winkel@dcbs.oregon.gov

350 Winter St. NE
Salem, OR 97301

Filed By:
Karen Winkel
Rules Coordinator

HEARING(S)

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

DATE: 10/25/2022

TIME: 1:00 PM

OFFICER: Cassie Soucy and Cortnee Whitlock

ADDRESS: Labor & Industries Building

350 Winter St. NE

Basement, Conf Rm E

Salem, OR 97301

SPECIAL INSTRUCTIONS:

This is a hybrid meeting conducted in-person and virtually via Microsoft Teams:

Join on your computer, mobile app or room device

Meeting ID: 279 814 617 663

Passcode: DYmV6M

Or call in (audio only)

+1 503-446-4951,,187471096# United States, Portland

Phone Conference ID: 187 471 096#

NEED FOR THE RULE(S)

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 board (ORS 646A.693(18)).

The Administrative Procedures Act requires state agencies and boards to adopt rules related to the procedure. The

Attorney General's Office has provided model rules for agencies and boards to utilize for creating the process to engage in these crucial functions (ORS 183.341). The Attorney General's Office recommends that all agencies and boards adopt the model rules for procedure around rulemaking to comply with the Administrative Procedures Act.

On June 23, 2022, the first rulemaking action that the PDAB conducted was to approve temporary rules that adopt the model rules for rulemaking and public records requests:

OAR 925-100-0001 provides a legal framework for the PDAB to engage in rulemaking as authorized by SB 844 (2021), consistent with authorities granted under ORS 183.341.

OAR 925-100-0002 defines requirements for notification of rulemaking by the PDAB.

OAR 925-100-0003 adopts Oregon's Public Records Law (ORS 192) requirements into PDAB rules.

A rules advisory committee met on August 25, 2022, and consisted of stakeholders from drug manufacturers, insurers, and 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

Based on currently available information, the rules will not directly affect racial equity in this state because the rules are for standard rulemaking and public record processes. The PDAB is tasked with evaluating the cost of prescription drugs including ones that contribute to health inequities for communities of color. These model rules allow the PDAB to function within its statutory authority and evaluate the impacts of prescription drug costs on communities of color.

FISCAL AND ECONOMIC IMPACT:

ORS 646A.693 has a significant economic impact on prescription drug manufacturers. The permanent rules proposed however are related to the administrative processes for rulemaking, rulemaking notices, and public records. These rules are unlikely to have an impact on prescription drug manufacturers or on any small businesses based on information available to the board.

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 rules would not have a fiscal or economic impact on state agencies, local government units, or the general public beyond the statutory requirements. The proposed rules do not add any new requirements on public entities, but instead clarify the board's administrative processes pertaining to rulemaking, rulemaking notice, and public records.

(2)(a) Based on the information available to the board, it is unlikely that the proposed rules will impose compliance costs on small businesses. Pharmaceutical manufacturers are the primary business directly subject to the underlying statute. The board does not have data on the specific number of employees employed by pharmaceutical manufacturers.

Regardless, the rule amendments proposed relate to administrative processes for the board and do not have an impact on manufacturers beyond the underlying statutory requirements.

DCBS convened a Rulemaking Advisory Committee (RAC), which 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 of the manufacturers or other businesses are small businesses.

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

(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.

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. This included representation of pharmacies and some pharmacies are small businesses.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

925-100-0001, 925-100-0002, 925-100-0003

ADOPT: 925-100-0001

RULE SUMMARY: Provides a legal framework for the Prescription Drug Affordability Board (PDAB) to engage in rulemaking as authorized by SB 844 (2021), consistent with authorities granted under ORS 183.341.

CHANGES TO RULE:

925-100-0001

Model Rules for Rulemaking

The Model Rules for Rulemaking, OAR 137-001-0005 through 137-001-0100, in effect on Jan. 1, 2008, adopted by the Oregon Department of Justice under ORS 183.341, are adopted as the rules of procedure for rulemaking actions of the Prescription Drug Affordability Board. The full text of the Model Rules is available from the Department of Justice, the Prescription Drug Affordability Board, or on the Oregon State Archives website at:

<https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=291164>

Statutory/Other Authority: ORS 646A.693 - 646A.697

Statutes/Other Implemented: ORS 183.325 - 183.410

ADOPT: 925-100-0002

RULE SUMMARY: Defines requirements for notification of rulemaking by the PDAB.

CHANGES TO RULE:

925-100-0002

Notice of Rulemaking

(1) Except when adopting a temporary rule, the Prescription Drug Affordability Board will give prior public notice of the proposed adoption, amendment, or repeal of any rule by:

(a) Publishing notice of the proposed rulemaking action in the Secretary of State's Oregon Bulletin at least 21 days before the effective date of the rule;

(b) Notifying interested people and organizations on the Prescription Drug Affordability Board's notification lists of proposed rulemaking actions under ORS 183.335; and

(c) Providing notice to legislators as required by ORS 183.335(15).

(2) A person or organization may elect to receive email or hard-copy notification of proposed rulemaking actions of the Prescription Drug Affordability Board.

(a) A person or organization may elect to subscribe to the Prescription Drug Affordability Board's email notification service at:

https://public.govdelivery.com/accounts/ORDCBS/subscriber/new?topic_id=ORDCBS_732.

(b) A person or organization may elect to receive hard-copy notification by sending a request in writing, including the person or organization's full name and mailing address, to the following address:

Rules Coordinator

Prescription Drug Affordability Board

350 Winter St. NE

P.O. Box 14480

Salem, OR 97309-0405

Statutory/Other Authority: ORS 646A.693 - 646A.697

Statutes/Other Implemented: ORS 84.022, 183.335

RULE SUMMARY: Adopts requirements found in Oregon's Public Records Law (ORS 192) into PDAB rules.

CHANGES TO RULE:

925-100-0003

Public Records Requests

- (1) Oregon's Public Records Law (ORS 192) provides that every person has a right to inspect any public records of a public body, except records that are exempt from disclosure.¶
 - (2) A public record request may be submitted in person, by U.S. Mail, fax or by email to the Prescription Drug Affordability Board (Board). The written request must include:¶
 - (a) The name and address of the person requesting the public record;¶
 - (b) The telephone number or other contact information of the person requesting the public record;¶
 - (c) A sufficiently detailed description of the record(s) requested to allow the Board to search for and identify responsive records; and the¶
 - (d) Date and signature of the person requesting the public record.¶
 - (3) Public records, except those exempt from disclosure, will be made available upon request for review and copies will be provided at a fee reasonably calculated.¶
 - (4) The Oregon Public Records Law allows agencies to recover their actual costs in fulfilling a public records request including actual costs for supplies, research, compilation, postage, shipping and staff time.¶
 - (5) Fees will be payable prior to fulfilling a public records request. If the fee is estimated to be greater than \$25:¶
 - (a) The Board staff will provide the requestor with a written notice of the estimated amount of the fee.¶
 - (b) The public records request will not be fulfilled until the requestor confirms in writing that the requestor wants to proceed with the request.¶
 - (6) Standard fees for Public Records:¶
 - (a) Per page fees reflect current Oregon Department of Administrative Services policy;¶
 - (b) \$5 for each true notarized certification;¶
 - (c) Other applicable fees: actual costs or best estimate of costs; and¶
 - (d) Miscellaneous fees may include archive retrieval costs, costs of software companies/contracts; other third party costs.¶
 - (e) No charge for the first 30 minutes of staff time for processing request. The hourly rate charged for additional staff time is based on the level of skill or expertise required to complete the work performed not the employee-level of the individual actually fulfilling the request.¶
 - (f) Clerical labor charges are \$25 per hour; Managerial labor charges are \$40 per hour; Professional (IT, HR, high-level Analyst) \$75 per hour; and DOJ, special attorney and other applicable legal fees: at the actual hourly rate charged for Public Records Request-related services. Fees are subject to statutory limitation described in ORS 192.324.¶
 - (7) The Board may furnish copies of public information without charge or at a reduced fee if it is determined that the waiver or reduction of fees is in the public interest because providing access primarily benefits the general public under ORS 192.324.¶
 - (8) A person desiring a waiver or reduction in fees must submit a written request for a waiver.¶
 - (9) The Board Executive Director will consider each request on a case-by-case basis based on the information provided by the requestor and the totality of the circumstance at the time of the request.¶
 - (10) The Board Executive Director will make fee waiver or reduction decisions based on the guidelines outlined in the Oregon Department of Administrative Services Statewide Standardized Fee Process.
- Statutory/Other Authority: ORS 646A.693 - 646A.697
Statutes/Other Implemented: ORS 192.324