

NOTICE OF PROPOSED RULEMAKING STATEMENT OF NEED AND FISCAL IMPACT

Filing caption: Updates to Pharmacy Benefit Manager Rules

Public comment deadline: Click or tap to enter a date.

Effective Date: Click or tap to enter a date.

HEARING:

Date: Click or tap to enter a date.

Time:

Officer:

Location: Labor & Industries Building
350 Winter St. NE
Basement, Conf Rm
Salem, OR 97301

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

NEED FOR RULEMAKING:

2024 Oregon House Bill 4149 makes a number of changes to the state laws regulating Pharmacy Benefit Managers (PBMs). Most significantly, the bill changes the law's existing requirement for PBMs to register with DCBS with a licensure regime and prohibits retaliation against pharmacies for certain actions. The bill also adds new required data elements to the recently adopted PBM transparency law. DCBS initially adopted rules to implement the PBM statutes in 2014 after passage of 2013 House Bill 2123, and made updates in 2017 and 2019 following subsequent legislation. DCBS also adopted rules in 2024 to implement portions of 2023 Senate Bill 192 related to mandatory PBM reporting of pharmaceutical manufacturer rebates.

PBM regulation has remained a topic of interest for the Oregon legislature, among concerns that PBM business practices are contributing to the closure of independent pharmacies throughout the state, leaving many areas of the state without a local pharmacy and placing a greater burden on the remaining pharmacies. DCBS has also received complaints and heard anecdotal reports that suggest that PBM market conduct requirements under the current laws and rules are unclear.

The proposed rule replaces references to registration throughout our current rules, encoded at OAR 836-200-401 *et seq* with references to licensure. It also adds new data elements to our

reporting rule and new market conduct requirements created by 2024 HB 4149, 2019 HB 2185, and 2023 HB 2725 that were not previously restated in rule. It also adds language clarifying the bar on retaliation against pharmacies, noting that a pharmacy claims audit may be considered retaliation under certain circumstances. Finally, the rule includes substantial revisions to the language related to pharmacy reimbursement in order to clarify expectations for PBMs when a pharmacy is reimbursed below acquisition cost under a maximum allowable cost schedule.

DCBS convened a rulemaking advisory Committee in October 2024, which has held three meetings. RAC membership included representatives for pharmacy benefit managers, insurers, patients, and pharmacies, including a small business pharmacy located in rural Oregon.

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 EQUITY IN THIS STATE:

The rule regulates the conduct of PBMs, and may have some ancillary impacts and benefits for pharmacies throughout the state. Advocates for PBM legislation have suggested that the regulation of PBMs will help reduce pharmacy closures in Oregon. Pharmacy closures have historically had a greater impact in rural areas of Oregon, and the rule could advance equity between urban and rural populations. This also has general impacts on patients that rely on prescription drugs who prefer to use a brick-and-mortar pharmacy to access their medications.

FISCAL AND ECONOMIC IMPACT:

Based on information available to DCBS, briefly discuss the cost of compliance for businesses, generally. State whether there are compliance costs for small businesses (independently owned and operated with fewer than 50 employees).

The rule regulates the conduct of PBMs. Based on the information available to DCBS, no pharmacy benefit manager meets the definition of a small business under ORS 183.310. There may be some ancillary impacts on independent pharmacies, which are likely to be considered small businesses. However, any administrative burden on pharmacies should be balanced against

the intended benefit for pharmacies in increased reimbursement and protection against certain PBM business practices.

COST OF COMPLIANCE FOR SMALL BUSINESSES:

(1) Identify any state agencies, units of local government, and members of the public (including specific interest groups) likely to be economically affected by the rulemaking.

(2)(a) Estimate the number and type of small businesses subject to the rule(s).

The rule regulates the conduct of PBMs. Based on the information available to DCBS, no pharmacy benefit manager meets the definition of a small business under ORS 183.310.

(2)(b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s).

The rule regulates the conduct of PBMs. Based on the information available to DCBS, no pharmacy benefit manager meets the definition of a small business under ORS 183.310.

(2)(c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

The rule regulates the conduct of PBMs. Based on the information available to DCBS, no pharmacy benefit manager meets the definition of a small business under ORS 183.310.

How were small businesses involved in the development of the rule?

Representatives of small businesses were invited to provide comment on the rule, including general business trade groups, pharmacy trade groups, and independent pharmacy owners.

Was an administrative rule advisory committee consulted? Yes.

RAC membership included representatives of the regulated industries, including pharmacy benefit managers, insurers, CCOs, and pharmacies. It also included multiple patient advocates. The RAC held three virtual meetings on October 30, November 11, and December 11.

Did membership of the RAC represent the interests of persons and communities likely to be affected by the rule? Yes.

RAC membership included representatives of the regulated industries, including pharmacy benefit managers, insurers, CCOs, and pharmacies. It also included multiple patient advocates. DCBS also invited representatives of general business interests, ethnic groups, LGBTQ+ populations, and other populations to participate in the RAC.

RULE NUMBER AND SUMMARY:

List each rule number and a short summary of what the rule does.

AMEND:
RULE SUMMARY:

ADOPT:
RULE SUMMARY:

STATUTORY REFERENCE:

STATUTORY/OTHER AUTHORITY:

STATUTES/OTHER IMPLEMENTED:

Andrew R. Stolfi, Insurance Commissioner

Signature Printed name Date

LEGISLATOR NOTICE:

If the rulemaking results from legislation passed within two years of this notice of proposed rulemaking, the agency must give notice to: 1) the legislator(s) who introduced the bill; and 2) the chair or co-chairs of all committees that reported the bill out. (Does not include referrals to other committees).

If the rule does not result from legislation within the last two years, notice shall be given to the chair or co-chairs of any interim or session committee with authority over the subject matter of the rule. If notice cannot be given to these individuals, notice shall be given to the Speaker of the House and the President of the Senate.

Name	Committee or Title	Email

RULEMAKING ADVISORY COMMITTEE:

Name	Organization	Email