

NOTICE OF PROPOSED RULEMAKING STATEMENT OF NEED AND FISCAL IMPACT

Filing caption: Updates to Pharmacy Benefit Manager Rules

Public comment deadline: 5/29/2025

Effective Date: 6/29/2025

HEARING:

Date: 5/22/2025

Time: 1 PM PST

Officer: Numi Lee Griffith

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

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

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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 the Department of Consumer and Business Services (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.

We are also proposing an amendment to OAR 836-053-1630, which relates to the requirement that insurers annually report certain information about prescription drugs dispensed in the prior year. This rule was adopted in 2024 following the expansion of the reporting requirement to all health benefit plans in the state. As originally adopted, the rule requires insurers with 200 or more enrollees in the state of Oregon to report. However, following its review of the rule, the Office of Legislative Counsel notified the department that the statutory language does not support a reporting threshold. In order to rectify this error, we are proposing to delete the language related to a reporting threshold. Moving forward, the department will depend on its inherent enforcement discretion to manage the scope of insurer reporting of prescription drug information.

DCBS convened a Rulemaking Advisory Committee (RAC) in October 2024, which has held three meetings. RAC membership included representatives for pharmacy benefit managers, insurers, patients, and pharmacies, including an independent pharmacy located in rural Oregon. In May 2025, following the addition of changes to the insurer reporting bill, DCBS reconvened the RAC to address the modified text.

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 insurers, 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 and insurers. 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.

Based on information currently available to DCBS, the proposed rules would not have a fiscal or economic impact on state agencies, local government units, nor the public.

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

The rule regulates the conduct of PBMs and insurers. Based on the information available to DCBS, no pharmacy benefit manager or insurer 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 and insurers. Based on the information available to DCBS, no pharmacy benefit manager or insurer meets the definition of a small business under ORS 183.310. The rule generally makes minor changes and clarifications to existing market conduct requirements, but also expands the categories of data subject to annual reporting. Based on our understanding, the data requested is either already in the possession of PBMs or easily calculable. We expect that PBMs would have a minimal cost for reporting, recordkeeping, and administrative activities to comply with the rule.

(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 and insurers. Based on the information available to DCBS, no pharmacy benefit manager or insurer meets the definition of a small business under ORS 183.310. The rule generally makes minor changes and clarifications to existing market conduct requirements, but also expands the categories of data subject to annual reporting. Based on our understanding, the data requested is either already in the possession of PBMs or easily calculable. We expect that PBMs would have a minimal cost for professional services, equipment supplies, labor, and increased administration activities to comply with the rule.

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, 2024, November 11, 2024, and December 11, 2024.

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: 836-200-0406

RULE SUMMARY: Defines application requirements for pharmacy benefit managers to register with DCBS. The amendments replace registration language with equivalent language on licensure.

AMEND: 836-200-0411

RULE SUMMARY: Sets requirements for a pharmacy benefit manager to renew its registration with DCBS. The amendments replace registration language with equivalent language on licensure.

AMEND: 836-200-0416

RULE SUMMARY: states that registration as a PBM does not exempt an entity from other state licensure requirements. The amendments replace registration language with equivalent language on licensure and add a clarification that this also applies to licensure by DCBS as a third-party administrator.

AMEND: 836-200-0418

RULE SUMMARY: defines the timing, data elements and requirements for required annual reports from PBMs to DCBS. The amendments replace registration language with equivalent language on licensure and add new reporting categories created by 2024 HB 4149.

AMEND: 836-200-0421

RULE SUMMARY: describes service requirements on a registered PBM. The amendments replace registration language with equivalent language on licensure.

AMEND: 836-200-0440

RULE SUMMARY: describes restrictions on the conduct of licensed PBMs. The amendments replace registration language with equivalent language on licensure, add new requirements created by statute between 2019 and 2024, and reorder provisions to provide additional clarity about the department's expectations.

AMEND: 836-053-1630

RULE SUMMARY: delineates reporting requirements for insurers related to annual data collected on prescription drugs. The amendments delete language creating a minimum enrollee threshold for required reports, pursuant to review by the office of Legislative Counsel.

STATUTORY REFERENCE:

STATUTORY/OTHER AUTHORITY: ORS 731.244, 735.532, 2024 Oregon Laws Ch. 87

STATUTES/OTHER IMPLEMENTED: ORS 735.530-735.552, ORS 743.025, 2024 Oregon Laws Ch. 87

Andrew R. Stolfi, Insurance Commissioner

Signature	Printed name	Date
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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 cochairs 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
Rob Nosse	Chair, House Committee on Behavioral Health and Health Care	Rep.RobNosse@oregonlegislature.gov
Travis Nelson	Vice-Chair, House Committee on Behavioral Health and Health Care	Rep.TravisNelson@oregonlegislature.gov
Cyrus Javadi	Vice-Chair, House Committee on Behavioral Health and Health Care	Rep.CyrusJavadi@oregonlegislature.gov
Deb Patterson	Chair, Senate Committee on Health Care	Sen.DebPatterson@oregonlegislature.gov
Cedric Hayden	Vice Chair, senate Committee on Health Care	Sen.CedricHayden@oregonlegislature.gov
Nancy Nathanson	Representative, Chief-Sponsor 2023 HB 4149	Rep.NancyNathanson@oregonlegislature.gov
Christine Goodwin	Representative, Chief-Sponsor 2023 HB 4149	N/A – No longer in Office
Bobby Levy	Representative, Chief-Sponsor 2023 HB 4149	Rep.BobbyLevy@oregonlegislature.gov
Greg Smith	Representative, Chief-Sponsor 2023 HB 4149	Rep.GregSmith@oregonlegislature.gov
Sarah Gelser-Blouin	Senator, Chief-Sponsor 2023 HB 4149	Sen.SaraGelser@oregonlegislature.gov

James Manning Jr.	Senator, Chief-Sponsor 2023 HB 4149	Sen.JamesManning@oregonlegislature.gov
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RULEMAKING ADVISORY COMMITTEE:

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