

NOTICE OF PROPOSED RULEMAKING

STATEMENT OF NEED AND FISCAL IMPACT

Filing caption: Rules implementing insurer and PBM reporting requirements of 2023 SB 192

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 E
Salem, OR 97301

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

NEED FOR RULEMAKING:

The Department of Consumer and Business Services (DCBS) Division of Financial Regulation (DFR) administers the Oregon Drug Price Transparency Program (DPT) under ORS 646A.680-692. DPT collects a variety of data related to drug pricing from prescription drug manufacturers, insurers, and consumers. DCBS-DFR is also home to the Oregon Prescription Drug Affordability Board (PDAB), established by ORS 646A.693-697. PDAB is directed to perform affordability reviews of drugs that have been identified as presenting affordability challenges for consumers, health systems, or the state.

Currently, insurers offering health benefit plans in the small group and individual markets report information about drug pricing to DPT as part of the annual rate review process. 2023 SB 192 decouples this report from rate review, and instead requires all insurers to report the same information to DPT once annually. This change effectively expands the requirement to large group fully insured plans, but also leaves this requirement without a fixed due date. DCBS-DFR also has oversight over pharmacy benefit managers (PBMs). PBMs are required to register with DCBS and are subject to a number of market conduct restrictions, mostly related to pharmacy audits and standards for reimbursement of pharmaceutical claims. 2023 SB 192

requires PBMs required to register with DCBS to report specific information about rebates and other payments they receive from pharmaceutical manufacturers to the department annually. While SB 192 makes other changes to the law, some requiring implementation by DCBS-DFR, this rulemaking only relates to the new PBM reporting requirement and modified insurer reporting requirement. The other elements of the bill will be implemented by PDAB or DPT staff.

In order to facilitate the new PBM reporting requirement, we propose creating a new rule in the series 836-200-400 defining terms and establishing the form in which DFR expects the new reports from PBMs to be submitted. In order to facilitate the changes to the insurer reporting requirements, we propose removing the text describing the contents of DPT insurer reports from OAR 836-053-0473, and creating a new rule under a separate caption with the same text. The new rule would also define a due date for these reports, since they would no longer be submitted in connection with the annual rate filing process.

DCBS convened a Rulemaking Advisory Committee on November 13, 2023, which met a second time on December 18, 2023. DCBS invited stakeholders to participate including insurance carriers, pharmacy benefit managers, pharmaceutical manufacturers, independent pharmacies, patient organizations, consumer advocates, and representatives of general business interests. Of the groups which participated, DCBS is aware that many pharmacies operating in Oregon are considered small businesses.

Based on the information available to DCBS, the proposed rules would not have any additional fiscal or economic impact on state agencies, local governments, the public, nor small businesses beyond the underlying statutory requirements.

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:

(Who is this going to impact and how might it impact one group of people differently than others?)

The rule changes and new rules proposed in this proceeding both relate to expanded transparency for pharmaceutical pricing and reimbursement, with respect to information currently held by pharmacy benefit managers and insurance companies. The information gathered through these provisions may inform future policy decisions that have some impact on the cost of prescription drugs to individual consumers or the state of Oregon. However, these rules themselves do not have a substantive impact on the cost of prescription drugs, and no particular impact to equity is expected as a result of adopting these rules.

FISCAL AND ECONOMIC IMPACT:

Based on financial filings made to DFR, no insurers or pharmacy benefit managers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated. While many pharmacies in Oregon would be considered small businesses under ORS 183.310, the conduct of pharmacies is not directly regulated by these rules and there is no anticipated cost of compliance to pharmacies.

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 rule would not (or does 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).

Based on financial filings made to DFR, no insurers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated.

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

Based on financial filings made to DFR, no insurers or pharmacy benefit managers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated. While many pharmacies in Oregon would be considered small businesses under ORS 183.310, the conduct of pharmacies is not directly regulated by these rules and there is no anticipated cost of compliance to pharmacies.

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

Based on financial filings made to DFR, no insurers or pharmacy benefit managers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated. While many pharmacies in Oregon would be considered small businesses under ORS 183.310, the conduct of pharmacies is not directly regulated by these rules and there is no anticipated cost of compliance to pharmacies.

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

Representatives of small businesses were invited to participate in the Rulemaking Advisory Committee and to provide comment on the rule. This included both representatives of independent pharmacies operating in Oregon and general business interests representing small business owners, who may be interested as purchasers of group health coverage in Oregon.

Was an administrative rule advisory committee consulted? Yes.

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

The rules proposed in this proceeding directly regulate the conduct of health insurance companies and pharmacy benefit managers. Other interested parties could include consumers and small businesses as purchasers of insurance, pharmacies, and patients who rely on prescription drugs.

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