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CHERYL MYERS
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ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 836
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
INSURANCE REGULATION

FILED
02/26/2024 12:22 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Rules implementing insurer and PBM reporting requirements of SB 192 (2023)

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 04/02/2024 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: 03/26/2024
TIME: 11:00 AM
OFFICER: Numi Giffith

IN-PERSON HEARING DETAILS
ADDRESS: Labor and Industries Building, 350 Winter St. NE, Basement, Conf Rm E, Salem, OR 97301

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 1-503-446-4951
CONFERENCE ID: 591485268

NEED FOR THE RULE(S)

The Department of Consumer and Business Services (DCBS) administers the Oregon Drug Price Transparency Program (DPT) under ORS 646A.680, 646A.683, and 646A.686-692. DPT collects a variety of data related to drug pricing from prescription drug manufacturers, insurers, and consumers.

Currently, insurers offering health benefit plans in the small group and individual markets report information about drug pricing to DPT as part of rate filings required under ORS 743.018. Senate Bill 192 (2023) decouples this report from the rate filing process, 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 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. 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, this rulemaking only relates to the new PBM reporting requirement and modified insurer reporting requirement. The other elements of the bill will be implemented in subsequent rulemaking.

In order to facilitate the new PBM reporting requirement, we propose creating a new rule in the series 836-200-0400 defining terms and establishing the form in which DCBS 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 RACIAL EQUITY IN THIS STATE

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 DCBS, no insurers 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:

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

(2)(a) The rule applies to health insurance carriers and pharmacy benefit managers. Based on financial filings made to DCBS, no insurers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated. DCBS does not have specific information about the number of employees or corporate structure of pharmacy benefit managers in the state, but it is unlikely that any pharmacy benefit managers meet the definition based on the information available to the department.

(2)(b) The rule applies to health insurance carriers and pharmacy benefit managers. Based on financial filings made to DCBS, no insurers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated. DCBS does not have specific information about the number of employees or corporate structure of pharmacy benefit managers in the state, but it is unlikely that any pharmacy benefit managers meet the definition based on the information available to the department. 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) The rule applies to health insurance carriers and pharmacy benefit managers. Based on financial filings made to DCBS, no insurers meet the definition of a small business under ORS 183.310, because no insurer is independently owned and operated. DCBS does not have specific information about the number of employees or corporate structure of pharmacy benefit managers in the state, but it is unlikely that any pharmacy benefit managers meet the definition based on the information available to the department. 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.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

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

RULES PROPOSED:
836-053-0473, 836-053-1630, 836-200-0418

AMEND: 836-053-0473

RULE SUMMARY: This rule describes the materials that must be filed by an insurer as part of a rate filing for small group and individual health benefit plans. The amendment removes the language related to annual reporting by insurers for the Drug Price Transparency program.

CHANGES TO RULE:

836-053-0473
Required Materials for Rate Filing for Individual or Small Employer Health Benefit Plans ¶

(1) Every insurer that offers a health benefit plan for small employers or an individual health benefit plan must file the information specified in section (2) of this rule when the insurer files with the director a schedule or table of

premium rates for approval.¶
(2) A schedule or table of base premium rates filed under section (1) of this rule must include sufficient information and data to allow the director to consider the factors set forth in ORS 743.018(4) and (5). The filing must include all of the following separately set forth and labeled as indicated:¶
(a) A filing description labeled "Filing Description." The filing description must:¶
(A) Be submitted in the form of a cover letter;¶
(B) Provide a summary of the reasons an insurer is requesting a rate change and the minimum and maximum rate impact to all groups or members affected by the rate change, including the anticipated change in number of enrollees if the proposed premium rate is approved;¶
(C) Explain the rate change in a manner understandable to the average consumer; and¶
(D) Include a description of any significant changes the insurer is making to the following:¶
(i) Rating factor changes; and¶
(ii) Benefit or administration changes.¶
(b) Rate tables and factors labeled "Rate Tables and Factors." The rate tables and factors must:¶
(A) Include base and geographic average rate tables;¶
(B) Identify factors used by the insurer in developing the rates;¶
(C) Explain how the information is used in the development of rates;¶
(D) Include a table of rating factors reflecting ages of employees and dependents and geographic area.¶
(E) Include rate tier tables if base rates are not provided by rating tier;¶
(F) Indicate whether the rate increases are the same for all policies;¶
(G) Explain how the rate increases apply to different policies;¶
(H) Provide the entire distribution of rate changes and the average of the highest and lowest rates resulting from the application of other rating factors;¶
(I) Within the geographic average rate table, include family type, geographic area and the average of the highest and lowest rates resulting from the application of other rating factors;¶
(J) Within the base rate table, include the base rates for each available plan and sufficient information for determination of rates for each health benefit plan, including but not limited to:¶
(i) Each age bracket;¶
(ii) Each geographic area;¶
(iii) Each rate tier;¶
(iv) Any other variable used to determine rates; and¶
(v) If the rates vary more frequently than annually, separate rates for each effective date of change or sufficient information to permit the determination of the rates and the justification for the variation in the rates.¶
(K) For a grandfathered small group health benefit plan, include the following factors if applied by the insurer:¶
(i) Contribution;¶
(ii) Level of participation;¶
(iii)Family composition;¶
(iv) The level at which enrollees or dependents engage in health promotion, disease prevention or wellness programs;¶
(v) Duration of coverage in force;¶
(vi) Any adjustment to reflect expected claims experience; and¶
(vii) Age.¶
(L) For a grandfathered individual health benefit plan, include the following factors to the extent applied by the insurer:¶
(i) Family composition; and¶
(ii) Age.¶
(M) For a nongrandfathered health benefit plan, include the following factors if applied by the insurer:¶
(i) Tobacco usage; and¶
(ii) The level at which enrollees or dependents engage in health promotion, disease prevention, or wellness programs.¶
(c) An actuarial memorandum consistent with the requirements of both state and federal law labeled "Actuarial Memorandum." The actuarial memorandum must include all of the following:¶
(A) A description of the benefit plan and a quantification of any changes to the benefit plan as set forth in subsection (e) of this section;¶
(B) A discussion of assumptions, factors, calculations, rate tables and any other information pertinent to the proposed rate, including an explanation of the impact of risk corridors, risk adjustment and state and federal reinsurance on the proposed rate;¶
(C) A description of any changes in rating methodology supported by sufficient detail to permit the department to evaluate the effect on rates and the rationale for the change;¶

(D) The range of rate impact to groups or members including the distribution of the impact on members;¶
(E) A cross-reference of all supporting documentation in the filing in the form of an index and citations;¶
(F) The dated signature of the qualified actuary or actuaries who reviewed and authorized the rate filing; and¶
(G) The contact information of the filer.¶
(d) A description of the development of the proposed rate change or base rate that is included as an exhibit to the filing and labeled "Exhibit 1: Development of Rate Change." The development of rate change is the core of the rate filing and must:¶
(A) Explain how the proposed rate or rate change was calculated using generally accepted actuarial rating principles for rating blocks of business;¶
(B) Include actual or expected membership information;¶
(C) Identify a proposed loss ratio for the rating period;¶
(D) Include a rate renewal calculation that:¶
(i) Begins with an assumed experience period of at least one year and ends within the immediately preceding year; or¶
(ii) If more recent data is available, uses the one-year period that ends with the most recent period for which data is available.¶
(E) Show adjustments to total premium earned during the experience period to yield premium adjusted to current rates;¶
(F) Include a projection of premiums and claims for the period during which the proposed rates are to be effective; and¶
(G) Provide a renewal projection using claims underlying the projection that reflect an assumed medical trend rate and other expected changes in claims cost, including but not limited to, the impact of benefit changes or provider reimbursement.¶
(e) A description of changes to covered benefits or health benefit plan design that is included as an exhibit to the rate filing and labeled "Exhibit 2: Covered Benefit or Plan Design Changes." The covered benefit or plan design changes must:¶
(A) Explain all applicable benefit and administrative changes with a rating impact, including but not limited to:¶
(i) Covered benefit level changes;¶
(ii) Member cost-sharing changes;¶
(iii) Elimination of plans;¶
(iv) Implementation of new plan designs;¶
(v) Provider network changes;¶
(vi) New utilization or prior authorization programs;¶
(vii) Changes to eligibility requirements; and¶
(viii) Changes to exclusions.¶
(B) Show any change in the plan offerings that impacts costs or coverage provided not otherwise provided pursuant to subsection (e)(A) of this section.¶
(f) The average annual rate change included as an exhibit to the filing and labeled "Exhibit 3: Average Annual Rate Change." The average annual rate change must:¶
(A) Provide the average, maximum and minimum annual rate changes for each effective date in the filing;¶
(B) Include a meaningful distribution of rate changes; and¶
(C) Provide an estimate of contributing factors to the annual rate change.¶
(g) Trend information and projection included as an exhibit to the filing and labeled "Exhibit 4: Trend Information and Projection." The trend information and projection must:¶
(A) Describe how the assumed future growth of medical claims (the medical trends rate) was developed based on generally accepted actuarial principles; and¶
(B) At a minimum, include historical monthly average claim costs for the two years immediately preceding the period for which the proposed rate is to apply. If the carrier's structure does not include claims cost, the carrier must submit this information based on allocated costs.¶
(h) A statement of administrative expenses and premium retention included as an exhibit to the filing and labeled "Exhibit 5: Statement of Administrative Expenses and Premium Retention." The statement of administrative expenses and premium retention must:¶
(A) Include a completed chart displaying the five-year trend of administrative costs and enumerating the insurer's administrative expenses detailed as follows:¶
(i) Salaries;¶
(ii) Rent;¶
(iii) Advertising;¶
(iv) General office expenses;¶
(v) Third party administration expenses;¶

(vi) Legal and other professional fees; and¶
(vii) Travel and other administrative costs not accounted for under a category in subsections (h)(B)(i)-(vi) of this section.¶
(B) Explain how the insurer allocates administrative expenses for the filed line of business;¶
(C) Include a description of the amount retained by the insurer to cover all of the insurer's non-claim costs including expected profit or contribution to surplus for a nonprofit entity reported on a percentage of premium and per member per month basis; and¶
(D) Demonstrate the total premium retention for the filing, including total administrative expenses reported under subsection (h)(B) of this section, commissions, taxes, assessments and margin.¶
(i) Plan relativities included as an exhibit to the filing and labeled "Exhibit 6: Plan Relativities." Plan relativities must:¶
(A) Explain the presentation of rates for each benefit plan;¶
(B) Explain the methodology of how the benefit plan relativities were developed; and¶
(C) Demonstrate the comparison and reasonableness of benefits and costs between plans.¶
(j) Information about the insurer's financial position included as an appendix to the filing and labeled "Appendix I: Insurer's Financial Position." The insurer's financial position may reference documents filed with the department and available to the public, including the insurer's annual statement. The insurer's financial position must include:¶
(A) Information about the insurer's financial position including but not limited to the insurer's:¶
(i) Profitability;¶
(ii) Surplus;¶
(iii) Reserves; and¶
(iv) Investment earnings.¶
(B) An analysis, explanation and determination of whether the proposed change in the premium rate is necessary to maintain the insurer's solvency or to maintain rate stability and prevent excessive rate increases in the future.¶
(k) Changes in the insurer's health care cost containment and quality improvement efforts included as an appendix to the filing and labeled "Appendix II: Cost Containment and Quality Improvement Efforts. The cost containment and quality improvement efforts must:¶
(A) Explain any changes the insurer has made in its health care cost containment efforts and quality improvement efforts since the insurer's last rate filing for the same category of health benefit plan;¶
(B) Describe significant new health care cost containment initiatives and quality improvement efforts;¶
(C) Include an estimate of the potential savings from the initiatives and efforts described in subsection (2)(g)(B) of this section together with an estimate of the cost or savings for the projection period; and¶
(D) Include information about whether the cost containment initiatives reduce costs by eliminating waste, improving efficiency, by improving health outcomes through incentives, by elimination or reduction of covered services or reduction in the fees paid to providers for services.¶
(l) ~~Information regarding prescription drug costs included as an appendix to the filing and labeled "Appendix III: Prescription Drug Costs." This document must include, for drugs reimbursed by the insurer under both pharmacy and medical benefits for policies or certificates issued in this state and for the experience period covered in the filing, all of the following:¶~~
~~(A) The 25 most frequently prescribed drugs;¶~~
~~(B) The 25 most costly drugs. In determining this list, the insurer must consider total annual spending, including the net impact of any rebates or other price concessions if applicable;¶~~
~~(C) The 25 drugs that have caused the greatest increase in total plan spending from one year to the next. In determining this list, the insurer must consider the net impact on total plan spending of any rebates or other price concessions if applicable; and¶~~
~~(D) The impact of the costs of prescription drugs on premium rates, on a per member, per month basis, including the net impact of any rebates or other price concessions if applicable.¶~~
~~(m)~~ Certification of compliance labeled "Certification of Compliance." The certification of compliance must:¶
(A) Comply with OAR 836-010-0011; and¶
(B) Certify that the filing complies with all applicable Oregon statutes, rules, product standards and filing requirements.¶
(~~n~~m) Third party filer's letter of authorization labeled "Third Party Authorization." If the filing is submitted by a person other than the insurer to which the filing applies, the filing must include a letter from the insurer that authorizes the third party to:¶
(A) Submit the filing to the department;¶
(B) Correspond with the department on matters pertaining to the rate filing; and¶
(C) Act on the insurer's behalf regarding all matters related to the filing.¶
(3) Insurers offering individual and small group health benefit plans that spend less than 12 percent of total

medical expenditures on payments for primary care must include with each health benefit plan rate filing a plan to increase spending on payments for primary care by at least one percentage point each year. Once an insurer has met the 12 percent benchmark for primary care spending, that fact must be disclosed with each health benefit plan rate filing including a disclosure of the current percentage of total medical expenditures on primary care. Insurers shall use the methodology outlined in the annual Primary Care Spending in Oregon report to calculate the percentage of primary care spending.
Statutory/Other Authority: ORS 743.018, 743.019, 743.020, ORS 731.244
Statutes/Other Implemented: ORS 743.018, 743.020, 742.003, 742.005, 742.007, 743.730, 743.767, ORS 743.025, ORS 735.537

ADOPT: 836-053-1630

RULE SUMMARY: This rule restates the language removed from OAR 836-053-0473 with slight modification to reflect the expanded reporting requirements. The draft rule describes the information that must be submitted by insurers annually to the Drug Price Transparency program.

CHANGES TO RULE:

836-053-1630
Drug Price Transparency Insurer Reporting
(1) For the purposes of this rule, "insurer" means a licensed insurance company, health care services contractor, or health maintenance organization that issues health benefit plans as defined in ORS 743B.005(16) in this state. ¶
(2) No later than May 1 of each year, an insurer with 200 or more enrollees in the state of Oregon must report to the department the information described in ORS 743.025(2) in the form and manner prescribed by the department. For drugs reimbursed by the insurer under both pharmacy and medical benefits in health benefit plans during the prior calendar year, the reporting must include all of the following:¶
(a) The 25 most frequently prescribed drugs.¶
(b) The 25 most costly drugs. In determining this list, the insurer must consider total annual spending, including the net impact of any rebates or other price concessions if applicable.¶
(c) The 25 drugs that have caused the greatest increase in total plan spending from one year to the next. In determining this list, the insurer must consider the net impact on total plan spending of any rebates or other price concessions if applicable.¶
(d) The impact of the costs of prescription drugs on premium rates, on a per member per month basis, including the net impact of any rebates or other price concessions if applicable.
Statutory/Other Authority: ORS 731.244
Statutes/Other Implemented: ORS 743.025, ORS 735.537

ADOPT: 836-200-0418

RULE SUMMARY: This rule describes the information that must be submitted to the department annually by Pharmacy Benefit Managers under SB 192 (2023 Oregon Laws, Chapter 466).

CHANGES TO RULE:

836-200-0418
Aggregated Rebate and Payment Reports
(1) For the purposes of this rule, "health benefit plan" has the meaning defined in ORS 743B.005(16).¶
(2) For the purposes of this rule, "pharmacy benefit manager" has the meaning defined in ORS 735.530.¶
(3) No later than June 1 of each year, a pharmacy benefit manager required to be registered with the Department of Consumer and Business Services must file a report using the form and manner prescribed by the department. The report must contain the following information for the immediately preceding calendar year:¶
(a) The aggregated amount of rebates, fees, price protection payments, and any other payments the pharmacy benefit manager received from manufacturers related to managing the pharmacy benefits for carriers issuing health benefit plans in this state.¶
(b) The aggregated amount of any payments, as described in subsection (3)(a) of this rule, that were passed on to carriers issuing health benefit plans in this state.¶
(c) The aggregated amount of any payments, as described in subsection (3)(a) of this rule, that were passed on to enrollees in a health benefit plan at the point of sale in this state.¶
(d) The aggregated amount of any payments, as described in subsection (3)(a) of this rule, that were retained as revenue by the pharmacy benefit manager. ¶
(4) The amount described in section (3)(a) of this rule should be equal to the sum of the amounts described in sections (3)(b), (3)(c), and (3)(d) of this rule.¶
(5) The amounts described in section (3) of this rule must include all payments that the pharmacy benefit manager received from manufacturers directly and any payments the pharmacy benefit manager received from manufacturers by the pharmacy benefit manager's subsidiaries, any other entities that the pharmacy benefit manager holds an ownership in, or any entities which hold an ownership interest in the pharmacy benefit manager.
Statutory/Other Authority: ORS 731.244
Statutes/Other Implemented: ORS 743.025, ORS 735.537