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CHERYL MYERS
DEPUTY SECRETARY OF STATE
AND TRIBAL LIAISON

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

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

TEMPORARY ADMINISTRATIVE ORDER
INCLUDING STATEMENT OF NEED & JUSTIFICATION

ID 42-2024
CHAPTER 836
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES
INSURANCE REGULATION

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ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Temporary rules to implement 2024 HB 4149

EFFECTIVE DATE: 01/01/2025 THROUGH 06/29/2025

AGENCY APPROVED DATE: 12/19/2024

CONTACT: Karen Winkel
503-947-7694
dfr.rules@dcbs.oregon.gov

350 Winter St. NE
Salem,OR 97301

Filed By:
Karen Winkel
Rules Coordinator

NEED FOR THE RULE(S):

2024 Oregon House Bill 4149 made updates to the statutes regulating the conduct of pharmacy benefit managers (PBMs). Most significantly, it changed the existing requirement that PBMs register with the Oregon Department of Consumer and Business Services (DCBS) to a licensure requirement. There are extensive references to “registration” in DCBS’s existing rule that will need to be updated to “licensure” language. The law also expanded transparency requirements on PBMs, and new language is needed in the respective rule to reflect the addition of new data elements.

Additionally, some stakeholders have raised concerns that PBMs are not in full compliance with existing law. We are proposing updates throughout the PBM rules to provide additional clarity on existing requirements related to “maximum allowable cost” (MAC) lists, and adding new language reflecting market conduct requirements for PBMs that were created under 2019 HB 2185 and 2023 HB 2725.

JUSTIFICATION OF TEMPORARY FILING:

The pharmacy industry is complex and the regulations in question are highly technical. In drafting these proposed rules, DBCS convened a Rulemaking Advisory Committee (RAC) including representatives of patients, insurers, PBMs, and pharmacies. The RAC met three times in 2024 and engaged in extensive discussion about the content of the proposed rules. After these discussions, the draft language reflects stakeholder consensus for the rule content. We expect that the language contained in this temporary filing is almost identical to the final rules that we plan to have effective before the expiration of these emergency rules.

Unfortunately, due to the time needed for stakeholder deliberation, it was not possible to complete the required notice and comment process in time for a January 1, effective date when HB 4149 becomes law.

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:

dfr.oregon.gov/laws-rules/Pages/proposed-rules.aspx.

RULES:

836-200-0401, 836-200-0406, 836-200-0411, 836-200-0416, 836-200-0418, 836-200-0421, 836-200-0436, 836-200-0440

AMEND: 836-200-0401

RULE SUMMARY: Amendments update statutory references to reflect assignment of ORS numbers since the last time these rules were revised.

CHANGES TO RULE:

836-200-0401
Statement of Purpose; Authority; Applicability ¶

Under the authority of ~~section 1, chapter 570, Oregon Laws 2013~~Oregon Laws 2013, chapter 570, section 1, ORS 735.530 to 735.552 shall be administered and enforced in accordance with the Insurance Code. The rules promulgated under ORS 735.530 to 735.552 are authorized and reasonably necessary for, or as an aid to, the effectuation of the Insurance Code.
Statutory/Other Authority: ORS 731.244, 735.532~~, Sec. 1, Ch. 570, OL 2013, Sec. 1-3, Ch. 73, OL 2017, 2017 Or Laws ch 73, 1-3~~
Statutes/Other Implemented: ORS 735.530 ~~to~~ - 735.552

AMEND: 836-200-0406

RULE SUMMARY: Describes application requirements for Pharmacy Benefit Manager licensure.

CHANGES TO RULE:

836-200-0406
Application Requirements for Pharmacy Benefit Manager ¶

(1) Each pharmacy benefit manager conducting business in Oregon must ~~register with~~obtain a license to transact business as a pharmacy benefit manager from the Department of Consumer and Business Services. To ~~register as a pharmacy benefit manager~~obtain a license under this rule, an applicant must submit a Pharmacy Benefit Manager Application, in form as posted on the ~~D~~department's Division of Financial Regulation website.¶
(2) An application for ~~registration~~licensure as a pharmacy benefit manager shall include:¶
(a) The name, address and FEIN of the pharmacy benefit manager;¶
(b) The names, business addresses and job titles of the principal officers of the pharmacy benefit manager;¶
(c) The name, business address, business telephone number, business e-mail address and job title of the officer or employee who should be contacted regarding any pharmacy benefit manager regulatory compliance concerns;¶
(d) The business telephone number and business e-mail address where pharmacy benefit manager personnel directly responsible for the processing of appeals may be contacted; and,¶
(e) Information relevant to a determination of the circumstances listed in ~~section 2(1), chapter 73, Oregon Laws 2017~~ORS 735.533(1).¶
(3) A pharmacy benefit manager shall provide the ~~D~~department with written notification of any change to its ~~registration~~licensure information not later than 30 days after the date of change.¶
(4) The application for ~~registration~~licensure as a pharmacy benefit manager must include a fee of $1100.
Statutory/Other Authority: ORS 731.244, 735.532~~, Sec. 2-3, Ch. 73, OL 2017, 2017 Or Laws ch 73, 1-3~~
Statutes/Other Implemented: ORS 735.530, 735.532~~, Sec. 2-5, Ch. 73, OL 2017~~

AMEND: 836-200-0411

RULE SUMMARY: Describes requirements for renewal of Pharmacy Benefit Manager license.

CHANGES TO RULE:

836-200-0411
Renewal of Pharmacy Benefit ~~Registration ¶~~
License
(1) All pharmacy benefit manager ~~registration~~licenses expire annually on September 1 unless renewed on or before that date. A pharmacy benefit manager must apply for renewal of the ~~registration~~license by submitting a renewal application, in form as posted on the ~~D~~department's Division of Financial Regulation website, to the ~~D~~director of the Department of Consumer and Business Services. The application to renew a ~~registration~~license to transact business as a pharmacy benefit manager must include a renewal fee of $1100.¶
(2) A pharmacy benefit manager shall provide the ~~D~~department with written notification of any change to its ~~registration~~licensure information not later than 30 days after the date of change.
Statutory/Other Authority: ORS 731.244, 735.532~~, Sec. 2-3, Ch. 73, OL 2017, 2017 Or Laws ch 73, 1-3~~
Statutes/Other Implemented: ORS 735.530, 735.532~~, Sec. 2-5, Ch. 73, OL 2017~~

AMEND: 836-200-0416

RULE SUMMARY: States that PBM licensure requirement is in addition to, and not exclusive of, other Oregon licensure or registration requirements.

CHANGES TO RULE:

836-200-0416
~~Registration~~Licensure Requirements Not Exclusive ¶

Compliance with pharmacy benefit manager ~~registration~~licensure requirements is additional to and not in lieu of filing and other requirements established by law for the purpose of doing business in this state, including but not limited to licensure as a third-party administrator under ORS 744.700 et seq and compliance with registration requirements of the Secretary of State applicable to assumed business names and applicable to the business structure of an applicant.
Statutory/Other Authority: ORS 731.244, 735.532~~, Sec. 2-3, Ch. 73, OL 2017, 2017 Or Laws ch 73, 1-3~~
Statutes/Other Implemented: ORS 735.530, 735.532~~, Sec. 2-5, Ch. 73, OL 2017~~

AMEND: 836-200-0418

RULE SUMMARY: Describes annual reporting requirements for Pharmacy Benefit Managers.

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) For the purposes of this rule "administrative fee" has the meaning defined in ORS 735.537(a).¶
(4) For the purposes of this rule, "dispensing fee" means an amount paid to a pharmacy for dispensing a prescription in addition to reimbursement for the cost of the drug; ¶
(5) No later than June 1 of each year, a pharmacy benefit manager required to be ~~register~~licensed 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. This amount must include payments that the pharmacy benefit manager received from manufacturers directly and 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. This includes:¶
(~~b~~A) The aggregated amount of any payments, as described in subsection (~~3~~5)(a) of this rule, that were passed on to carriers issuing health benefit plans in this state.¶
(~~c~~B) The aggregated amount of any payments, as described in subsection (~~3~~5)(a) of this rule, that were passed on to enrollees in a health benefit plan at the point of sale in this state.¶
(~~d~~C) The aggregated amount of any payments, as described in subsection (~~3~~5)(a) of this rule, that were retained as revenue by the pharmacy benefit manager.¶
(4b) The amount described in section (~~3~~5)(a) of this rule should be equal to the sum of the amounts described in sections (~~3~~5)(A)(~~b~~a), (~~3~~5)(A)(~~c~~b), and (~~3~~5)(A)(~~d~~c) of this rule.¶
(~~5~~c) The ~~amounts described in section (3) of this rule must include all payments that~~total dispensing fees paid to 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 an~~in this state from insurers, coordinated care organizations, and the Oregon Prescription Drug Program.¶
(d) The total dispensing fees paid to pharmacies in this state by the pharmacy benefit manager.¶
(e) The total administrative fees received from manufacturers and carriers.¶
(f) The total administrative fees as described in subsection (e) that were retained by the pharmacy benefit manager.¶
(g) The total amount of revenue received by the pharmacy ben~~tities which hold an ownership interest in the pharmacy benefit manager~~efit manager through spread pricing, pay-for-performance arrangements, or similar means.
Statutory/Other Authority: ORS 731.244, 743.025
Statutes/Other Implemented: ORS ~~743.025,~~ 735.537

AMEND: 836-200-0421

RULE SUMMARY: Describes service requirements for Pharmacy Benefit Managers.

CHANGES TO RULE:

836-200-0421
Service on ~~Registrant~~Licensee ¶

The ~~D~~ddirector of the Department of Consumer and Business Services may direct notices and inquiries to, and make service on a pharmacy benefit manager at, the address shown on the current ~~registration~~license of the pharmacy benefit manager on file with the director, in the manner provided in ORS Chapter 183.
Statutory/Other Authority: ORS 731.244, 735.532~~, Sec. 2-3, Ch. 73, OL 2017, 2017 Or Laws ch 73, 1-3~~
Statutes/Other Implemented: ORS 73~~5.530 to 735.552~~1.236, 731.296, ORS 73~~1.236, 731.296~~5.530 - 735.552

AMEND: 836-200-0436

RULE SUMMARY: Describes process for pharmacies and their agents to submit complaints related to the Pharmacy Benefit Manager statutes.

CHANGES TO RULE:

836-200-0436
Submission of Complaints
(1) Any complaint filed with the Department of Consumer and Business Services by a pharmacy, or by an entity acting on behalf of a pharmacy, alleging a violation of ORS 735.530 to 735.552, shall be in form as posted on the ~~D~~department's Division of Financial Regulation website.¶
(2) A complaint shall include documentation of the alleged violation and of all efforts made to resolve the alleged violation prior to filing of the complaint.
Statutory/Other Authority: ORS 731.244, 735.532~~, Sec. 2, Ch. 73, OL 2017, 2017 Or Laws ch 73, 1-3~~
Statutes/Other Implemented: ORS 735.530 ~~to~~ - 735.552

AMEND: 836-200-0440

RULE SUMMARY: Describes market conduct requirements for licensed pharmacy benefit managers.

CHANGES TO RULE:

836-200-0440
Market Conduct Requirements for Pharmacy Benefit Managers
(1) A pharmacy benefit manager shall allow a network pharmacy to mail, ship or deliver prescription drugs to its patients as an ancillary service. A contract between a pharmacy benefit manager and a network pharmacy may establish limits and parameters on the pharmacy's mail, shipment and/or delivery of prescription drugs on the request of enrollees based on the pharmacy's total prescription volume. A pharmacy benefit manager is not required to reimburse a delivery fee charged by a network pharmacy unless the fee is specified in the contract between the pharmacy benefit manager and the pharmacy.¶
(2) Except as provided in subsections (6) and (7) of this ~~section~~rule, a pharmacy benefit manager may require a prescription for a specialty drug to be filled or refilled at a specialty pharmacy as a condition for the reimbursement of the cost of a drug.¶
(3) For the purposes of subsection (2) of this section, the department will consider a prescription drug to meet the definition of "specialty drug" under O~~regon Laws 2019, chapter 526, section~~ RS 735.534 if, to be properly dispensed according to standard industry practice, the drug:¶
(a) Requires specialized preparation, administration, handling, storage, inventory, reporting or distribution;¶
(b) Is associated with difficult or unusual data collection or administrative requirements; or¶
(c) Requires a pharmacist to manage the patient's use of the drug by monitoring, provide disease or therapeutic support systems, provide care coordination including collaboration with patients or other health care providers to manage adherence, identify side effects, monitor clinical parameters, assess responses to therapy, or document outcomes.¶
(4) For the purposes of subsection (2) of this section, a pharmacy may demonstrate to the department that it meets the definition of "specialty pharmacy" under O~~regon Laws 2019, chapter 526, section~~ RS 735.534 by showing that:¶
(a) Its business is primarily providing specialty drugs and specialized, disease-specific clinical care and services for people with serious or chronic health conditions requiring complex medication therapies; or¶
(b) It has been validated for meeting quality, safety and accountability standards for specialty pharmacy practice through accreditation in specialty pharmacy by a nationally recognized, independent accreditation organization such as URAC or the Accreditation Commission for Health Care (ACHC).¶
(5) Nothing in subsection (4) of this section shall be construed to prohibit a pharmacy benefit manager from specifying additional terms and conditions for a specialty pharmacy network contract, including terms and conditions related to reimbursement.¶
(6) A pharmacy benefit manager shall reimburse the cost of a specialty drug that is filled or refilled at a network pharmacy that is a long term care pharmacy, provided that the specialty drug is dispensed to an enrollee who is a resident of a long term care facility served by the long term care pharmacy.¶
(7) A ~~network pharmacy may appeal its reimbursement from a~~pharmacy benefit manager may not require a prescription to be filled or refilled by a mail order pharmacy as a condition for reimbursing the cost of the drug.¶
(8) A network pharmacy may appeal its reimbursement for a drug subject to maximum allowable cost pricing if the pharmacy benefit manager ~~for a drug subject to maximum allowable cost pricing on the basis that the drug is only available at the specified price~~'s reimbursement to the pharmacy is less than the net amount that the network pharmacy paid to the supplier of the drug.¶
(a) If the pharmacy benefit manager denies a pharmacy's appeal under this rule, it must provide the reason for the denial and identify a national drug code for the drug, generally available for purchase by similarly situated pharmacies, and national or regional wholesalers where that national drug code was listed at a price equal to or less than the maximum allowable cost for the drug at the time that the claim in question was adjudicated.¶
(A) For the purposes of this rule, "generally available for purchase" means a drug is available for purchase in this state by a pharmacy from a national or regional wholesaler at the time a claim for reimbursement is submitted by a network pharmacy. A drug is not "generally available for purchase" if the drug:¶
(i) May only be dispensed in a hospital or inpatient care facility;¶
(ii) Is unavailable due to a shortage of the produce or an ingredient;¶
(iii) Is available to a pharmacy at a price at or below the maximum allowable cost only if purchased in substantial quantities in excess of its business needs. For the purposes of this subsection, a quantity in excess of the business needs of a network pharmacy is defined as a purchase quantity greater than a 3-month supply based on the pharmacy's total dispensing history over the most recent rolling 12 months. A pharmacy benefit manager may require a network pharmacy appealing its reimbursement for a drug in accordance with this subsection to submit

applicable evidence of its dispensing history to the pharmacy benefit manager as part of the appeal process. A pharmacy benefi¶
(iv) Is sold at a discount due to a short expiration date on the drug; or¶
(v) Is the subject of an active or pending recall.¶
(b) The appeals process required by ORS 735.534(4) must provide the pharmacy the opportunity to rebut manager's compliance with this subsection is sufficient to demonstrate compliance with Oregon Laws 2019, chapter 526, section 4 (1)(a)(B)(iii) appeal on the basis that the NDC provided in the denial is not generally available for purchase for similarly situated pharmacies for one of the reasons described in subsection (8)(a)(A) of this rule.¶
(c) If an appeal is upheld under this rule, the pharmacy benefit manager must make an adjustment for the appealing pharmacy from the date of initial adjudication forward and allow the pharmacy to reverse the claim and resubmit an adjusted claim without any charges.¶
(8d) If a prescription drug subject to a specified maximum allowable cost is available at that price if purchased in quantities that are consistent with the business needs of some pharmacies but inconsistent with the business needs of others, nothing in subsection (78) shall be construed to prohibit a pharmacy benefit manager from applying the maximum allowable cost to pharmacies that can purchase the drug in the necessary quantities consistent with their business needs.¶
(e) If the request for an adjustment has come from a "critical access pharmacy", as defined by the Oregon Health Authority in OAR 431-121-2000, the adjustment approved under subsection (8) of this rule is only required to apply to critical access pharmacies.¶
(9) A pharmacy benefit manager may not retroactively deny or reduce payment on a claim for reimbursement of the cost of services after the claim has been adjudicated by the pharmacy benefit manager unless the:¶
(a) Adjudicated claim was submitted fraudulently. For the purposes of this section, "fraud" has the meaning defined in ORS 735.540.¶
(b) The payment was incorrect because the pharmacy had already been paid for the services;¶
(c) Services were improperly rendered by the pharmacy in violation of state or federal law; or¶
(d) The payment was incorrect due to an error that the pharmacy and pharmacy benefit manager agree was a clerical error.¶
(10) A pharmacy benefit manager may not impose a fee for a particular claim on a pharmacy after the point of sale. For the purposes of this subsection, "point-of-sale" means the time that the claim was adjudicated.¶
(11) A pharmacy benefit manager may not penalize a network pharmacy for:¶
(a) Appealing the reimbursement of a drug to the pharmacy benefit manager;¶
(b) Filing a complaint against the pharmacy benefit manager with the department;¶
(c) Engaging in the legislative process; or¶
(d) Challenging the pharmacy benefit manager's practices or agreements.¶
(12) For the purposes of subsection (11) of this rule, "penalize" includes but is not limited any of the following actions if applied to a network pharmacy that has engaged in the protected conduct described in subsections (11)(a) to (d) of this rule differently from similarly situated pharmacies that have not engaged in said protected conduct: imposing charges or fees, requiring contract amendments, canceling or terminating contracts, demanding recoupment, or conducting an unnecessary or unwarranted audit of a pharmacy.¶
(13) A pharmacy benefit manager may not charge a fee to a pharmacy for submitting claims or for the adjudication of claims.¶
(14) Nothing in subsections (9) and (13) of this rule shall be construed as limiting a pharmacy benefit manager from conducting a pharmacy claims audit that is in compliance with the requirements of ORS 735.540 to 735.552.
Statutory/Other Authority: Or Laws 2019, ch 52RS 735.534, 735.536
Statutes/Other Implemented: Or Laws 2019, ch 52RS 735.534, 735.536