1 **836-200-0401**

2 **Statement of Purpose; Authority; Applicability**

3

4 Under the authority of section 1, chapter 570, Oregon Laws 2013, ORS 735.530 to 735.552
5 shall be administered and enforced in accordance with the Insurance Code. The rules
6 promulgated under ORS 735.530 to 735.552 are authorized and reasonably necessary for,
7 or as an aid to, the effectuation of the Insurance Code.

8

9 Statutory/Other Authority: ORS 731.244, 735.532

10 Statutes/Other Implemented: ORS 735.530 to 735.552

11 History:

12 ID 16-2017, amend filed 12/28/2017, effective 01/01/2018

13 ID 12-2014, f. & cert. ef. 7-21-14

14

15 **836-200-0406**

16 **Application Requirements for Pharmacy Benefit Manager**

17

18 (1) Each pharmacy benefit manager conducting business in Oregon must obtain a license
19 to transact business as a pharmacy benefit manager from the Department of Consumer
20 and Business Services. To obtain a license under this rule, an applicant must submit a
21 Pharmacy Benefit Manager Application, in form as posted on the Department's Division of
22 Financial Regulation website.

23 (2) An application for licensure as a pharmacy benefit manager shall include:

24 (a) The name, address and FEIN of the pharmacy benefit manager;

25 (b) The names, business addresses and job titles of the principal officers of the pharmacy
26 benefit manager;

27 (c) The name, business address, business telephone number, business e-mail address and
28 job title of the officer or employee who should be contacted regarding any pharmacy
29 benefit manager regulatory compliance concerns;

30 (d) The business telephone number and business e-mail address where pharmacy benefit
31 manager personnel directly responsible for the processing of appeals may be contacted;
32 and,

33 (e) Information relevant to a determination of the circumstances listed in ORS 735.533.

34 (3) A pharmacy benefit manager shall provide the Department with written notification of
35 any change to its licensure information not later than 30 days after the date of change.

36 (4) The application for licensure as a pharmacy benefit manager must include a fee of
37 $1100.

38

39 Statutory/Other Authority: ORS 731.244, 735.532,

40 Statutes/Other Implemented: ORS 735.530, 735.532 History:

41 ID 16-2017, amend filed 12/28/2017, effective 01/01/2018

42 ID 12-2014, f. & cert. ef. 7-21-14

43

44 **836-200-0411**

45 **Renewal of Pharmacy Benefit License~~Registration~~**

46

47 (1) All pharmacy benefit manager licenses expire annually on September 1 unless renewed
48 on or before that date. A pharmacy benefit manager must apply for renewal of the license
49 by submitting a renewal application, in form as posted on the Department's Division of
50 Financial Regulation website, to the Director of the Department of Consumer and Business
51 Services. The application to renew a license to transact business as a pharmacy benefit
52 manager must include a renewal fee of $1100.

53 (2) A pharmacy benefit manager shall provide the Department with written notification of
54 any change to its licensure information not later than 30 days after the date of change.

55

56

57 Statutory/Other Authority: ORS 731.244, 735.532,

58 Statutes/Other Implemented: ORS 735.530, 735.532

59 History:

60 ID 16-2017, amend filed 12/28/2017, effective 01/01/2018

61 ID 12-2014, f. & cert. ef. 7-21-14

62

63 **836-200-0416**

64 **Licensure Requirements Not Exclusive**

65

66 Compliance with pharmacy benefit manager licensure requirements is additional to and
67 not in lieu of filing and other requirements established by law for the purpose of doing
68 business in this state, including but not limited to licensure as a third-party administrator
69 under ORS 744.700 *et seq* and compliance with registration requirements of the Secretary
70 of State applicable to assumed business names and applicable to the business structure
71 of an applicant.

72

73 Statutory/Other Authority: ORS 731.244, 735.532

74 Statutes/Other Implemented: ORS 735.530, 735.532

75 History:

76 ID 16-2017, amend filed 12/28/2017, effective 01/01/2018

77 ID 12-2014, f. & cert. ef. 7-21-14

78

79 **836-200-0418**

80 **Aggregated Rebate and Payment Reports**

81

82 (1) For the purposes of this rule, “health benefit plan” has the meaning defined in ORS
83 743B.005(16).

84

85 (2) For the purposes of this rule, “pharmacy benefit manager” has the meaning defined in
86 ORS 735.530.

87 (3) For the purposes of this rule, “spread pricing” has the meaning defined in ORS
88 735.537(e).~~.~~

89 (4) For the purposes of this rule “administrative fee” has the meaning defined in ORS
90 735.537(a)~~.)~~

91

92 (5) For the purposes of this rule, “dispensing fee” means any payment for services
93 associated with issuance of a prescribed quantity of an individual drug entity by a licensed
94 pharmacist;

95 (6~~4~~) No later than June 1 of each year, a pharmacy benefit manager required to be licensed
96 with the Department of Consumer and Business Services must file a report using the form
97 and manner prescribed by the department. The report must contain the following
98 information for the immediately preceding calendar year:

99

100 (a) The aggregated amount of rebates, fees, price protection payments, and any other
101 payments the pharmacy benefit manager received from manufacturers related to
102 managing the pharmacy benefits for carriers issuing health benefit plans in this state. This
103 amount must include payments that the pharmacy benefit manager received from
104 manufacturers directly and payments the pharmacy benefit manager received from
105 manufacturers by the pharmacy benefit manager’s subsidiaries, any other entities that the
106 pharmacy benefit manager holds an ownership in, or any entities which hold an ownership
107 interest in the pharmacy benefit manager. This includes:

108 (A

109 ~~(b~~) The aggregated amount of any payments, as described in subsection (6~~4~~)(a) of this rule,
110 that were passed on to carriers issuing health benefit plans in this state.

111 (B

112 ~~(c~~) The aggregated amount of any payments, as described in subsection (6~~4~~)(a) of this rule,
113 that were passed on to enrollees in a health benefit plan at the point of sale in this state.

114 (C

115 ~~(d~~) The aggregated amount of any payments, as described in subsection (6~~4~~)(a) of this rule,
116 that were retained as revenue by the pharmacy benefit manager.

117 (b) The amount described in section (6)(a) of this rule should be equal to the sum of the
118 amounts described in sections (6)(A), (6)(B), and (6)(C) of this rule.

Commented [GNL1]: Draft definition for clarity on expectations. This borrows language from the OHA OARS related to reimbursement for OPDP.

Commented [GNL2R1]: We believe that this definition, as applied to fees received by PBMs, is still confusing. However, statutory changes may be necessary to clarify legislative intent in this area.

Commented [GNL3]: After discussing this with program staff and DOJ, I’ve reorganized this section to be more similar to the original rule. The text is largely unchanged, but the nesting of subsections is substantially reorganized. This effectively preserves the existing rule as-is for reporting requirements established by 2023 SB 192.

(c) The total ~~(e) The total~~ dispensing fees paid ~~in this state~~ to the pharmacy benefit manager in this state from~~by~~ insurers, coordinated care organizations, and the Oregon Prescription Drug Program.~~;~~

(d~~f~~) The total dispensing fees paid to pharmacies in this state by the pharmacy benefit manager.~~;~~

(e~~g~~) The total administrative fees received~~obtained~~ from manufacturers and carriers.

(f~~h~~) The total administrative fees as described in subsection (e~~g~~) that were retained by the pharmacy benefit manager~~PBM~~.

(g~~f~~) The total amount of revenue received~~obtained~~ by the pharmacy benefit manager through spread pricing, pay-for-performance arrangements, or similar means.

~~(i) The amount described in section (4)(a) of this rule should be equal to the sum of the amounts described in sections (4)(b), (4)(c), and (4)(d) of this rule.~~

Statutory/Other Authority: ORS 731.244

Statutes/Other Implemented: ORS 743.025 & 735.537

History:

ID 3-2024, adopt filed 04/29/2024, effective 05/01/2024

836-200-0421

Service on Licensee

The Director 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 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

Statutes/Other Implemented: ORS 735.530 to 735.552, ORS 731.236 & 731.296

Commented [GNL4]: I searched both the OARs and ORS for a definition and found none. There are references to the term in 442.392 and 943-120-0350 but little guidance is given as to meaning. We did not receive any comments that proposed definitions.

Commented [GNL5]: The new reporting elements are now split out into separate subsections under subsection (6), distinct from the requirements created by 192. Since these new requirements do not refer back to Health Benefit Plans (unlike 192), we believe the scope of business subject to these reports is wider. Will discuss.

148 History:

149 ID 16-2017, amend filed 12/28/2017, effective 01/01/2018

150 ID 12-2014, f. & cert. ef. 7-21-14

151

152 **836-200-0436**

153 **Submission of Complaints**

154

155 (1) Any complaint filed with the Department of Consumer and Business Services by a
156 pharmacy, or by an entity acting on behalf of a pharmacy, alleging a violation of ORS
157 735.530 to 735.552, shall be in form as posted on the Department's Division of Financial
158 Regulation website.

159 (2) A complaint shall include documentation of the alleged violation and of all efforts made
160 to resolve the alleged violation prior to filing of the complaint.

161

162 Statutory/Other Authority: ORS 731.244, 735.532

163 Statutes/Other Implemented: ORS 735.530 to 735.552

164 History:

165 ID 16-2017, adopt filed 12/28/2017, effective 01/01/2018

166

167 **836-200-0440**

168 **Market Conduct Requirements for Pharmacy Benefit Managers**

169 (1) A pharmacy benefit manager shall allow a network pharmacy to mail, ship or deliver
170 prescription drugs to its patients as an ancillary service. A contract between a pharmacy
171 benefit manager and a network pharmacy may establish limits and parameters on the
172 pharmacy's mail, shipment and/or delivery of prescription drugs on the request of
173 enrollees based on the pharmacy's total prescription volume. A pharmacy benefit manager
174 is not required to reimburse a delivery fee charged by a network pharmacy unless the fee is
175 specified in the contract between the pharmacy benefit manager and the pharmacy.

176

177 (2) Except as provided in subsectionssubsection (6) and (7) of this rule, section, a
178 pharmacy benefit manager may require a prescription for a specialty drug to be filled or
179 refilled at a specialty pharmacy as a condition for the reimbursement of the cost of a drug.

180

181 (3) For the purposes of subsection (2) of this section, the department will consider a
182 prescription drug to meet the definition of "specialty drug" under ORS 735.534 if, to be
183 properly dispensed according to standard industry practice, the drug:(:

184 (a) Requires specialized preparation, administration, handling, storage, inventory, reporting
185 or distribution;

186

187 (b) Is associated with difficult or unusual data collection or administrative requirements; or

188

189 (c) Requires a pharmacist to manage the patient's use of the drug by monitoring, provide
190 disease or therapeutic support systems, provide care coordination including collaboration
191 with patients or other health care providers to manage adherence, identify side effects,
192 monitor clinical parameters, assess responses to therapy, or document outcomes.

193

194 (4) For the purposes of subsection (2) of this section, a pharmacy may demonstrate to the
195 department that it meets the definition of "specialty pharmacy" under ORS 735.534 by
196 showing that:

197

198 (a) Its business is primarily providing specialty drugs and specialized, disease-specific
199 clinical care and services for people with serious or chronic health conditions requiring
200 complex medication therapies; or

201

202 (b) It has been validated for meeting quality, safety and accountability standards for
203 specialty pharmacy practice through accreditation in specialty pharmacy by a nationally
204 recognized, independent accreditation organization such as URAC or the Accreditation
205 Commission for Health Care (ACHC).

206

Commented [GNL6]: Added reference clarifying exclusion for mail order requirements and interaction with specialty pharmacy clauses.

(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 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~~(7~~) A network pharmacy may appeal its reimbursement for a drug subject to maximum allowable cost pricing if the pharmacy benefit manager'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 or regional wholesaler and~~a~~ national drug code where~~for~~ the drug is generally available for purchase~~that may be purchased~~ by similarly situated pharmacies at a price equal to or less than the maximum allowable cost for the drug.

(~~b)~~ A) For the purposes~~ network pharmacy may appeal a denial under subsection (a)~~ of this rule, "generally ~~on the basis that the drug is only~~ 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:~~specified price~~

(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

Commented [GNL7]: Moved this up to make drafting relationship with specialty pharmacy language more clear.

Commented [GNL8]: I've significantly reorganized this section again. More detail to be provided in meeting. Specifically, I've removed the secondary clause expressly allowing a second right of appeal, but clarified that an opportunity to rebut is needed.

Commented [GNL9]: Added based on feedback at last meeting.

Commented [GNL10]: Structured as terms defining the "generally available for purchase" requirement in statute, and providing clarity as to expectations rather than creating additional process requirements.

239 accordance with this subsection to submit applicable evidence of its dispensing history to
240 the pharmacy benefit manager as part of the appeal process.

241 (iv) Is sold at a discount due to a short expiration date on the drug; or

242 (v) Is the subject of an active or pending recall.

243 (b) The appeals process required by ORS 735.534(4) must provide the pharmacy the
244 opportunity to rebut an appeal on the basis that the NDC provided in the denial is not
245 generally available for purchase for similarly situated pharmacies for one of the reasons
246 described in subsection (8)(a)(A) of this rule.

247 (c) If an appeal is upheld under ~~subsection (7)(a) or (7)(b) of~~ this rule, the pharmacy benefit
248 manager must make an adjustment for the appealing pharmacy from the date of initial
249 adjudication forward and allow the pharmacy to reverse the claim and resubmit an
250 adjusted claim without any charges.

251

252 (d) If a prescription drug subject to a specified maximum allowable cost is available at that
253 price if purchased in quantities that are consistent with the business needs of some
254 pharmacies but inconsistent with the business needs of others, nothing in subsection (7)
255 shall be construed to prohibit a pharmacy benefit manager from applying the maximum
256 allowable cost to pharmacies that can purchase the drug in the necessary quantities
257 consistent with their business needs.

258 (e) If the request for an adjustment has come from a "critical access pharmacy", as defined
259 by the Oregon Health Authority in OAR 431-121-2000, the adjustment approved under
260 subsection (8) of this rule is only required to apply to critical access pharmacies.

261 (9~~(8~~) A pharmacy benefit manager may not retroactively deny or reduce payment on a claim
262 for reimbursement of the cost of services after the claim has been adjudicated by the
263 pharmacy benefit manager unless the:

264 (a) Adjudicated claim was submitted fraudulently. For the purposes of this section, "fraud"
265 has the meaning defined in ORS 735.540.

266 (b) The payment was incorrect because the pharmacy had already been paid for the
267 services;

268

269 ~~**~~or

270 (c) Services were improperly rendered by the pharmacy in violation of state or federal law.

Commented [GNL11]: Current Language, nested within statutory language added in this draft.

Commented [GNL12]: Adding expectation of opportunity to rebut, rather than framing as a requirement for multiple stage appeals. We view this as a clarification of the existing regime established in rulemaking after HB 2185 rather than a new requirement.

Commented [GNL13]: Added language from statute limiting scope of adjustment when MAC appeal comes from a critical access pharmacy.

(d~~(c~~) The payment was incorrect due to an error that the pharmacy and pharmacy benefit manager agree was a clerical error.

(10~~9~~) 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.

~~(10) 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.~~

(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;

(d) Engaging in the legislative process; or

(e) Challenging the pharmacy benefit manager’s practices or agreements.

(f) For the purposes of this subsection, “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(e) of this rule differently from similarly situated pharmacies that have not engaged in said protected~~similar~~ conduct: imposing charges or fees, requiring contract amendments, canceling or terminating contracts, demanding recoupment, or conducting an ~~[~~unnecessary or unwarranted~~]~~ audit of a pharmacy.

(g) May not charge a fee to a pharmacy for submitting claims or for the adjudication of claims.

Commented [GNL14]: Added language in 4149 that was not added at first pass.

Statutory/Other authority~~Authority~~: ORS 735.534, ORS 735.536

Statutes/Other Implemented: ORS 735.534, ORS 735.536

History:

ID 10-2020, adopt filed 12/18/2020, effective 01/01/2021