836-200-0401

Statement of Purpose; Authority; Applicability

Under the authority of section 1, chapter 570, Oregon Laws 2013, 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

Statutes/Other Implemented: ORS 735.530 to 735.552

History:

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

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

836-200-0406

Application Requirements for Pharmacy Benefit Manager

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

(2) An application for 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 ORS 735.533.

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

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

Statutory/Other Authority: ORS 731.244, 735.532,

Statutes/Other Implemented: ORS 735.530, 735.532 History:

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

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

836-200-0411

Renewal of Pharmacy Benefit License

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

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

Statutory/Other Authority: ORS 731.244, 735.532,

Statutes/Other Implemented: ORS 735.530, 735.532

History:

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

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

60

61 **836-200-0416**

62 **Licensure Requirements Not Exclusive**

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

69 Statutory/Other Authority: ORS 731.244, 735.532

70 Statutes/Other Implemented: ORS 735.530, 735.532

71 History:

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

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

74

75 **836-200-0418**

76 **Aggregated Rebate and Payment Reports**

77

78 (1) For the purposes of this rule, “health benefit plan” has the meaning defined in ORS
79 743B.005(16).

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

82 (3) For the purposes of this rule, “spread pricing” has the meaning defined in ORS
83 735.537(e).

84 (4) For the purposes of this rule “administrative fee” has the meaning defined in ORS
85 735.537(a).

86 (5) For the purposes of this rule, "dispensing fee" means any payment for services
87 associated with issuance of a prescribed quantity of an individual drug entity by a licensed
88 pharmacist;

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

93 (a) The aggregated amount of rebates, fees, price protection payments, and any other
94 payments the pharmacy benefit manager received from manufacturers related to
95 managing the pharmacy benefits for carriers issuing health benefit plans in this state. This
96 amount must include payments that the pharmacy benefit manager received from
97 manufacturers directly and payments the pharmacy benefit manager received from
98 manufacturers by the pharmacy benefit manager's subsidiaries, any other entities that the
99 pharmacy benefit manager holds an ownership in, or any entities which hold an ownership
100 interest in the pharmacy benefit manager. This includes:

101 (A) The aggregated amount of any payments, as described in subsection (6)(a) of this rule,
102 that were passed on to carriers issuing health benefit plans in this state.

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

105 (C) The aggregated amount of any payments, as described in subsection (6)(a) of this rule,
106 that were retained as revenue by the pharmacy benefit manager.

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

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

111 (d) The total dispensing fees paid to pharmacies in this state by the pharmacy benefit
112 manager.

113 (e) The total administrative fees received from manufacturers and carriers.

114 (f) The total administrative fees as described in subsection (e) that were retained by the
115 pharmacy benefit manager.

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

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.

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.

118 Statutory/Other Authority: ORS 731.244

119 Statutes/Other Implemented: ORS 743.025 & 735.537

120 History:

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

122

123 **836-200-0421**

124 **Service on Licensee**

125 The Director of the Department of Consumer and Business Services may direct notices and
126 inquiries to, and make service on a pharmacy benefit manager at, the address shown on
127 the current license of the pharmacy benefit manager on file with the director, in the manner
128 provided in ORS Chapter 183.

129 Statutory/Other Authority: ORS 731.244, 735.532

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

131 History:

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

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

134

135 **836-200-0436**

136 **Submission of Complaints**

137 (1) Any complaint filed with the Department of Consumer and Business Services by a
138 pharmacy, or by an entity acting on behalf of a pharmacy, alleging a violation of ORS
139 735.530 to 735.552, shall be in form as posted on the Department's Division of Financial
140 Regulation website.

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

143

144 Statutory/Other Authority: ORS 731.244, 735.532

145 Statutes/Other Implemented: ORS 735.530 to 735.552

146 History:

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

148

149 **836-200-0440**

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

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

158 (2) Except as provided in subsections (6) and (7) of this rule, a pharmacy benefit manager
159 may require a prescription for a specialty drug to be filled or refilled at a specialty pharmacy
160 as a condition for the reimbursement of the cost of a drug.

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

161 (3) For the purposes of subsection (2) of this section, the department will consider a
162 prescription drug to meet the definition of "specialty drug" under ORS 735.534 if, to be
163 properly dispensed according to standard industry practice, the drug:(a) Requires
164 specialized preparation, administration, handling, storage, inventory, reporting or
165 distribution;

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

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

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

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

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

181 (5) Nothing in subsection (4) of this section shall be construed to prohibit a pharmacy
182 benefit manager from specifying additional terms and conditions for a specialty pharmacy
183 network contract, including terms and conditions related to reimbursement.

184 (6) A pharmacy benefit manager shall reimburse the cost of a specialty drug that is filled or
185 refilled at a network pharmacy that is a long term care pharmacy, provided that the
186 specialty drug is dispensed to an enrollee who is a resident of a long term care facility
187 served by the long term care pharmacy.

188 (7) A pharmacy benefit manager may not require a prescription to be filled or refilled by a
189 mail order pharmacy as a condition for reimbursing the cost of the drug.

190 (8) A network pharmacy may appeal its reimbursement for a drug subject to maximum
191 allowable cost pricing if the pharmacy benefit manager's reimbursement to the pharmacy
192 is less than the net amount that the network pharmacy paid to the supplier of the drug.

193 (a) If the pharmacy benefit manager denies a pharmacy's appeal under this rule, it must
194 provide the reason for the denial and identify a national or regional wholesaler and national
195 drug code where the drug is generally available for purchase by similarly situated
196 pharmacies at a price equal to or less than the maximum allowable cost for the drug.

197 (A) For the purposes of this rule, "generally available for purchase" means a drug is
198 available for purchase in this state by a pharmacy from a national or regional wholesaler at
199 the time a claim for reimbursement is submitted by a network pharmacy. A drug is not
200 "generally available for purchase" if the drug:

201 (i) May only be dispensed in a hospital or inpatient care facility;

202 (ii) Is unavailable due to a shortage of the produce or an ingredient;

203 (iii) Is available to a pharmacy at a price at or below the maximum allowable cost only if
204 purchased in substantial quantities in excess of its business needs. For the purposes of
205 this subsection, a quantity in excess of the business needs of a network pharmacy is
206 defined as a purchase quantity greater than a 3-month supply based on the pharmacy's
207 total dispensing history over the most recent rolling 12 months. A pharmacy benefit
208 manager may require a network pharmacy appealing its reimbursement for a drug in
209 accordance with this subsection to submit applicable evidence of its dispensing history to
210 the pharmacy benefit manager as part of the appeal process.

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.

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

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

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

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

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.

217 (c) If an appeal is upheld under this rule, the pharmacy benefit manager must make an
218 adjustment for the appealing pharmacy from the date of initial adjudication forward and
219 allow the pharmacy to reverse the claim and resubmit an adjusted claim without any
220 charges.

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

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

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

230 (9) A pharmacy benefit manager may not retroactively deny or reduce payment on a claim
231 for reimbursement of the cost of services after the claim has been adjudicated by the
232 pharmacy benefit manager unless the:

233 (a) Adjudicated claim was submitted fraudulently. For the purposes of this section, “fraud”
234 has the meaning defined in ORS 735.540.

235 (b) The payment was incorrect because the pharmacy had already been paid for the
236 services; or

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

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

240 (10) A pharmacy benefit manager may not impose a fee for a particular claim on a
241 pharmacy after the point of sale. For the purposes of this subsection, “point-of-sale”
242 means the time that the claim was adjudicated.

243 (11) A pharmacy benefit manager may not penalize a network pharmacy for:

244 (a) Appealing the reimbursement of a drug to the pharmacy benefit manager;

245 (b) Filing a complaint against the pharmacy benefit manager with the Department;

246 (d) Engaging in the legislative process; or

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

248 (f) For the purposes of this subsection, "penalize" includes but is not limited any of the
249 following actions if applied to a network pharmacy that has engaged in the protected
250 conduct described in subsections (11)(a) to(e) of this rule differently from similarly situated
251 pharmacies that have not engaged in said protected conduct: imposing charges or fees,
252 requiring contract amendments, canceling or terminating contracts, demanding
253 recoupment, or conducting an unnecessary or unwarranted audit of a pharmacy.

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

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

256 Statutory/Other authority: ORS 735.534, ORS 735.536

257 Statutes/Other Implemented: ORS 735.534, ORS 735.536

258 History:

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