

1 **836-200-0401**

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

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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, ~~Sec. 1, Ch. 570, OL 2013, Sec. 1-3, Ch.~~
10 ~~73, OL 2017 & 2017 Or Laws ch 73, §§ 1-3~~

11 Statutes/Other Implemented: ORS 735.530 to 735.552

12 History:

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

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

15

16 **836-200-0406**

17 **Application Requirements for Pharmacy Benefit Manager**

18

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

25 (2) An application for ~~registration licensure~~ as a pharmacy benefit manager shall include:

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

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

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

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

35 (e) Information relevant to a determination of the circumstances listed in ~~section 2(1),~~
36 ~~chapter 73, Oregon Laws 2017~~ORS 735.533.

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

40 (4) The application for registrationlicensure as a pharmacy benefit manager must include a
41 fee of \$1100.

42

43 Statutory/Other Authority: ORS 731.244, 735.532, ~~Sec. 2-3, Ch. 73, OL 2017 & 2017 Or~~
44 ~~Laws ch 73, §§ 1-3~~

45 Statutes/Other Implemented: ORS 735.530, 735.532 & ~~Sec. 2-5, Ch. 73, OL 2017~~

46 History:

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

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

49

50 **836-200-0411**

51 **Renewal of Pharmacy Benefit Registration**

52

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

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

63

64

65 Statutory/Other Authority: ORS 731.244, 735.532, ~~Sec. 2-3, Ch. 73, OL 2017 & 2017 Or~~
66 ~~Laws ch 73, §§ 1-3~~

67 Statutes/Other Implemented: ORS 735.530, 735.532 & ~~Sec. 2-5, Ch. 73, OL 2017~~

68 History:

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

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

71

72 **836-200-0416**

73 **RegistrationLicensure Requirements Not Exclusive**

74

75 Compliance with pharmacy benefit manager registrationlicensure requirements is
76 additional to and not in lieu of filing and other requirements established by law for the
77 purpose of doing business in this state, including but not limited to licensure as a third-
78 party administrator under ORS 744.700 et seq and compliance with registration
79 requirements of the Secretary of State applicable to assumed business names and
80 applicable to the business structure of an applicant.

81

82 Statutory/Other Authority: ORS 731.244, 735.532, ~~Sec. 2-3, Ch. 73, OL 2017 & 2017 Or~~
83 ~~Laws ch 73, §§ 1-3~~

84 Statutes/Other Implemented: ORS 735.530, 735.532 & ~~Sec. 2-5, Ch. 73, OL 2017~~

85 History:

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

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

88

89 **836-200-0418**

90 **Aggregated Rebate and Payment Reports**

91

92 (1) For the purposes of this rule, “health benefit plan” has the meaning defined in ORS
93 743B.005(16).

94

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

97

98 ~~(3)~~ For the purposes of this rule, “spread pricing” has the meaning defined in ORS
99 735.537.

100 ~~(4)~~ For the purposes of this rule “administrative fee has the meaning defined in ORS
101 735.537(a)

102

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

107

108 (a) The aggregated amount of rebates, fees, price protection payments, and any other
109 payments the pharmacy benefit manager received from manufacturers related to
110 managing the pharmacy benefits for carriers issuing health benefit plans in this state. This
111 amount must include payments that the pharmacy benefit manager received from
112 manufacturers directly and payments the pharmacy benefit manager received from
113 manufacturers by the pharmacy benefit manager’s subsidiaries, any other entities that the
114 pharmacy benefit manager holds an ownership in, or any entities which hold an ownership
115 interest in the pharmacy benefit manager.

116

117 (b) The aggregated amount of any payments, as described in subsection ~~(34)~~(a) of this rule,
118 that were passed on to carriers issuing health benefit plans in this state.

119

120 (c) The aggregated amount of any payments, as described in subsection (34)(a) of this rule,
121 that were passed on to enrollees in a health benefit plan at the point of sale in this state.

122

123 (d) The aggregated amount of any payments, as described in subsection (34)(a) of this rule,
124 that were retained as revenue by the pharmacy benefit manager.

125

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

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

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

131 ~~(e) The total administrative fees as described in subsection (g) that were retained by the~~
132 ~~PBM.~~

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

135

136 (5) The amount described in section (34)(a) of this rule should be equal to the sum of the
137 amounts described in sections (34)(b), (34)(c), and (34)(d) of this rule.

138

139 ~~(5) The amounts described in section (3) of this rule must include all payments that the~~
140 ~~pharmacy benefit manager received from manufacturers directly and any payments the~~
141 ~~pharmacy benefit manager received from manufacturers by the pharmacy benefit~~
142 ~~manager's subsidiaries, any other entities that the pharmacy benefit manager holds an~~
143 ~~ownership in, or any entities which hold an ownership interest in the pharmacy benefit~~
144 ~~manager.~~

145

146 Statutory/Other Authority: ORS 731.244

147 Statutes/Other Implemented: ORS 743.025 & 735.537

148 History:

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

150

151 **836-200-0421**

152 **Service on Registrant Licensee**

153

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

158

159 Statutory/Other Authority: ORS 731.244, 735.532, ~~Sec. 2-3, Ch. 73, OL 2017 & 2017 Or~~
160 ~~Laws ch 73, §§ 1-3~~

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

162 History:

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

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

165

166 **836-200-0436**

167 **Submission of Complaints**

168

169 (1) Any complaint filed with the Department of Consumer and Business Services by a
170 pharmacy, or by an entity acting on behalf of a pharmacy, alleging a violation of ORS
171 735.530 to 735.552, shall be in form as posted on the Department's Division of Financial
172 Regulation website.

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

175

176 Statutory/Other Authority: ORS 731.244, 735.532, ~~Sec. 2, Ch. 73, OL 2017 & 2017 Or Laws~~
177 ~~ch 73, §§ 1-3~~

178 Statutes/Other Implemented: ORS 735.530 to 735.552

179 History:

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

181

182 **836-200-0440**

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

184

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

192

193 (2) Except as provided in subsection (6) of this section, a pharmacy benefit manager may
194 require a prescription for a specialty drug to be filled or refilled at a specialty pharmacy as a
195 condition for the reimbursement of the cost of a drug.

196

197 (3) For the purposes of subsection (2) of this section, the department will consider a
198 prescription drug to meet the definition of "specialty drug" under ~~Oregon Laws 2019,~~
199 ~~chapter 526, section 4~~ ORS 735.534 if, to be properly dispensed according to standard
200 industry practice, the drug:

201

202 (a) Requires specialized preparation, administration, handling, storage, inventory, reporting
203 or distribution;

204

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

206

207 (c) Requires a pharmacist to manage the patient's use of the drug by monitoring, provide
208 disease or therapeutic support systems, provide care coordination including collaboration

209 with patients or other health care providers to manage adherence, identify side effects,
210 monitor clinical parameters, assess responses to therapy, or document outcomes.

211

212 (4) For the purposes of subsection (2) of this section, a pharmacy may demonstrate to the
213 department that it meets the definition of “specialty pharmacy” under ~~Oregon Laws 2019;~~
214 ~~chapter 526, section 4~~ORS 735.534 by showing that:

215

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

219

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

224

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

228

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

233

234 (7) A network pharmacy may appeal its reimbursement ~~from a pharmacy benefit manger~~
235 for a drug subject to maximum allowable cost pricing ~~if the pharmacy benefit manager’s~~
236 ~~reimbursement to the pharmacy is less than the net amount that the network pharmacy~~
237 ~~paid to the supplier of the drug.~~

238 ~~(a) If the pharmacy benefit manager denies a pharmacy’s appeal under this rule, it must~~
239 ~~provide the reason for the denial and a national drug code for the drug that may be~~

240 purchased by similarly situated pharmacies at a price equal to or less than the maximum
241 allowable cost for the drug.

242 (b) A network pharmacy may appeal a denial under subsection (a) of this rule, on the basis
243 that the drug is only available at the specified price if purchased in substantial quantities in
244 excess of its business needs. For the purposes of this subsection, a quantity in excess of
245 the business needs of a network pharmacy is defined as a purchase quantity greater than a
246 3-month supply based on the pharmacy’s total dispensing history over the most recent
247 rolling 12 months. A pharmacy benefit manager may require a network pharmacy appealing
248 its reimbursement for a drug in accordance with this subsection to submit applicable
249 evidence of its dispensing history to the pharmacy benefit manager as part of the appeal
250 process. ~~A pharmacy benefit manager’s compliance with this subsection is sufficient to~~
251 ~~demonstrate compliance with Oregon Laws 2019, chapter 526, section 4 (1)(a)(B)(iii).~~

252
253 ~~(c) If an appeal is upheld under subsection (7)(a) or (7)(b) of this rule, the pharmacy~~
254 ~~benefit manager must make an adjustment for the appealing pharmacy from the date of~~
255 ~~initial adjudication forward and allow the pharmacy to reverse the claim and resubmit an~~
256 ~~adjusted claim without any charges.~~

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

264
265 (8) A pharmacy benefit manager may not retroactively deny or reduce payment on a claim
266 for reimbursement of the cost of services after the claim has been adjudicated by the
267 pharmacy benefit manager unless the:

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

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

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

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

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

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

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

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

282 (d) Engaging in the legislative process; or

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

284 (f) For the purposes of this subsection, “penalize” includes but is not limited any of the
285 following actions if applied to a network pharmacy that has engaged in the conduct
286 described in subsections (11)(a) to(e) of this rule differently from network pharmacies that
287 have not engaged in similar conduct: imposing charges or fees, requiring contract
288 amendments, canceling or terminating contracts, demanding recoupment, or conducting
289 an audit of a pharmacy.

290 Statutory/Other Authority: ~~Or Laws 2019, ch 526~~ ORS 735.534, ORS 735.536

291 Statutes/Other Implemented: ~~Or Laws 2019, ch 526~~ ORS 735.534, ORS 735.536

292 History:

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