

Representative Bradley G. Last proposes the following substitute bill:

PHARMACY BENEFIT MANAGER AMENDMENTS

2016 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Bradley G. Last

Senate Sponsor: _____

LONG TITLE

General Description:

This bill creates registration and practice requirements for pharmacy benefit managers.

Highlighted Provisions:

This bill:

- ▶ defines terms;
- ▶ establishes the Pharmacy Benefit Manager Act;
- ▶ requires a person providing pharmacy benefit management services to:
 - register with the Division of Occupational and Professional Licensing (DOPL) in accordance with a certain process; and
 - self-certify compliance with applicable laws and rules;
- ▶ establishes certain requirements for the practice of a pharmacy benefit manager;
- ▶ requires DOPL to:
 - establish a registration process and requirements;
 - investigate noncompliance and complaints;
 - provide certain notice to the Insurance Department and insurance carriers regarding registrations; and
 - impose fines in certain circumstances;
- ▶ authorizes administrative rules; and



26 ▶ makes technical changes.

27 **Money Appropriated in this Bill:**

28 None

29 **Other Special Clauses:**

30 None

31 **Utah Code Sections Affected:**

32 AMENDS:

33 **31A-22-640**, as last amended by Laws of Utah 2015, Chapter 258

34 ENACTS:

35 **58-86-101**, Utah Code Annotated 1953

36 **58-86-102**, Utah Code Annotated 1953

37 **58-86-103**, Utah Code Annotated 1953

38 **58-86-104**, Utah Code Annotated 1953

39 **58-86-105**, Utah Code Annotated 1953



41 *Be it enacted by the Legislature of the state of Utah:*

42 Section 1. Section **31A-22-640** is amended to read:

43 **31A-22-640. Insurer and pharmacy benefit management services -- Registration**
44 **-- Maximum allowable cost -- Audit restrictions.**

45 (1) For purposes of this section:

46 (a) "Maximum allowable cost" means:

47 (i) a maximum reimbursement amount for a group of pharmaceutically and
48 therapeutically equivalent drugs; or

49 (ii) any similar reimbursement amount that is used by a pharmacy benefit manager to
50 reimburse pharmacies for multiple source drugs.

51 (b) "Obsolete" means a product that may be listed in national drug pricing compendia
52 but is no longer available to be dispensed based on the expiration date of the last lot
53 manufactured.

54 (c) (i) "Pharmacy benefit manager" means a person or entity that provides pharmacy
55 benefit management services as defined in Section **49-20-502** on behalf of an insurer as defined
56 in Subsection **31A-22-636(1)**.

57 (ii) "Pharmacy benefit manager" includes independent entities and
58 entities wholly or partially owned or controlled, either directly or indirectly, by:

59 (A) a retail pharmacy;

60 (B) a mail order pharmacy; or

61 (C) an insurer.

62 (2) ~~[An insurer and an insurer's]~~ A pharmacy benefit manager is subject to the
63 pharmacy audit provisions of Section [58-17b-622](#).

64 (3) A pharmacy benefit manager ~~[shall]~~ may not use maximum allowable cost as a
65 basis for reimbursement to a pharmacy unless:

66 (a) the drug is listed as "A" or "B" rated in the most recent version of the United States
67 Food and Drug Administration's approved drug products with therapeutic equivalent
68 evaluations, also known as the "Orange Book," or has an "NR" or "NA" rating or similar rating
69 by a nationally recognized reference; and

70 (b) the drug is ~~[(i)]~~ generally available for purchase in ~~[this state]~~ Utah from a national
71 or regional wholesaler~~;~~ ~~and (ii)]~~ and is not obsolete.

72 (4) ~~[The]~~ A pharmacy benefit manager may determine maximum allowable cost ~~[may~~
73 ~~be determined]~~ by using comparable and current data on drug prices obtained from multiple
74 nationally recognized, comprehensive data sources, including wholesalers, drug file vendors,
75 and pharmaceutical manufacturers for drugs that are available for purchase by pharmacies in
76 ~~[the state]~~ Utah.

77 (5) For every drug for which the pharmacy benefit manager uses maximum allowable
78 cost to reimburse a contracted pharmacy, the pharmacy benefit manager shall:

79 (a) include ~~[in the contract with the pharmacy]~~ information identifying the national
80 drug pricing compendia and other data sources used to obtain the drug price data in the contract
81 with the pharmacy;

82 (b) review and make necessary adjustments to the maximum allowable cost, using the
83 most recent data sources identified in Subsection (5)(a), at least once per week;

84 (c) provide a process for the contracted pharmacy to appeal the maximum allowable
85 cost in accordance with Subsection (6); and

86 (d) include ~~[in each contract with a contracted pharmacy]~~ a process to obtain an update
87 to the pharmacy product pricing files used to reimburse the pharmacy, in each contract with a

88 contracted pharmacy, in a format that is readily available and accessible.

89 (6) (a) ~~[The right to appeal in]~~ (i) A contracted pharmacy may appeal the maximum
90 allowable cost in accordance with Subsection (5)(c) ~~[shall be: (i) limited to]~~ within 21 days
91 following the initial claim adjudication~~[, and]~~.

92 (ii) ~~[investigated and resolved by the]~~ The pharmacy benefit manager shall investigate
93 and resolve the appeal within 14 business days.

94 (b) If an appeal is denied, the pharmacy benefit manager shall provide the contracted
95 pharmacy with:

96 (i) the reason for the denial; and

97 (ii) the identification of the national drug code of the drug for which the pharmacy
98 appealed that may be purchased by the pharmacy at a price at or below the price determined by
99 the pharmacy benefit manager.

100 (7) The contract with each pharmacy shall contain a dispute resolution mechanism in
101 the event either party breaches the terms or conditions of the contract.

102 ~~[(8)(a) To conduct business in the state, a pharmacy benefit manager shall register~~
103 ~~with the Division of Corporations and Commercial Code within the Department of Commerce~~
104 ~~and annually renew the registration. To register under this section, the pharmacy benefit~~
105 ~~manager shall submit an application which shall contain only the following information:]~~

106 ~~[(i) the name of the pharmacy benefit manager;]~~

107 ~~[(ii) the name and contact information for the registered agent for the pharmacy benefit~~
108 ~~manager; and]~~

109 ~~[(iii) if applicable, the federal employer identification number for the pharmacy benefit~~
110 ~~manager.]~~

111 ~~[(b) The Department of Commerce may establish a fee in accordance with Title 63J,~~
112 ~~Chapter 1, Budgetary Procedures Act, for the initial registration and the annual renewal of the~~
113 ~~registration, which may not exceed \$100 per year.]~~

114 ~~[(c) The following entities do not have to register as a pharmacy benefit manager under~~
115 ~~Subsection (8)(a) when the entity is providing formulary services to its own patients,~~
116 ~~employees, members, or beneficiaries:]~~

117 ~~[(i) a health care facility licensed under Title 26, Chapter 21, Health Care Facility~~
118 ~~Licensing and Inspection Act;]~~

119 ~~[(ii) a pharmacy licensed under Title 58, Chapter 17b, Pharmacy Practice Act;]~~
 120 ~~[(iii) a health care professional licensed under Title 58, Occupations and Professions;]~~
 121 ~~[(iv) a health insurer; and]~~
 122 ~~[(v) a labor union.]~~

123 ~~[(9) This section does not apply to a pharmacy benefit manager when the pharmacy~~
 124 ~~benefit manager is providing pharmacy benefit management services on behalf of the state~~
 125 ~~Medicaid program.]~~

126 (8) (a) A person may not perform, offer to perform, or advertise any service as a
 127 pharmacy benefit manager in Utah without a valid registration under Title 58, Chapter 86,
 128 Pharmacy Benefit Manager Act.

129 (b) A person may not use the pharmacy benefit management services of another if the
 130 person knows or should know that the other does not have the registration required in
 131 Subsection (8)(a).

132 Section 2. Section **58-86-101** is enacted to read:

133 **CHAPTER 86. PHARMACY BENEFIT MANAGER ACT**

134 **58-86-101. Title.**

135 This chapter is known as the "Pharmacy Benefit Manager Act."

136 Section 3. Section **58-86-102** is enacted to read:

137 **58-86-102. Definitions.**

138 As used in this chapter, "pharmacy benefit manager" means the same as that term is
 139 defined in Section [31A-22-640](#).

140 Section 4. Section **58-86-103** is enacted to read:

141 **58-86-103. Pharmacy benefit manager registration.**

142 (1) (a) To conduct business in the state, a pharmacy benefit manager shall register with
 143 the division and renew the registration annually.

144 (b) To register under this chapter, the pharmacy benefit manager shall submit to the
 145 division an application containing:

146 (i) the name of the pharmacy benefit manager;

147 (ii) the name and contact information for the registered agent for the pharmacy benefit
 148 manager; and

149 (iii) if applicable, the federal employer identification number for the pharmacy benefit

150 manager.

151 (2) The division may establish a fee, in accordance with Title 63J, Chapter 1,
152 Budgetary Procedures Act, for the initial registration and the annual renewal of the registration.

153 (3) The division shall:

154 (a) make rules, in accordance with Title 63G, Chapter 3, Utah Administrative
155 Rulemaking Act, to establish an application process and an application form for registration
156 under this chapter; and

157 (b) retain the registration fees imposed under Subsection (2) as a dedicated credit to the
158 division to pay for the cost of administering this chapter.

159 (4) The following entities are not required to register as a pharmacy benefit manager
160 under Subsection (7)(a) when the entity is providing formulary services to the entity's patients,
161 employees, members, or beneficiaries:

162 (a) a health care facility licensed under Title 26, Chapter 21, Health Care Facility
163 Licensing and Inspection Act;

164 (b) a pharmacy licensed under Title 58, Chapter 17b, Pharmacy Practice Act;

165 (c) a health care professional licensed under Title 58, Occupations and Professions; and

166 (d) a labor union.

167 (5) This section does not apply to a pharmacy benefit manager when the pharmacy
168 benefit manager is providing pharmacy benefit management services on behalf of:

169 (a) the state Medicaid program;

170 (b) a motor vehicle insurer; or

171 (c) a workers' compensation insurer.

172 Section 5. Section **58-86-104** is enacted to read:

173 **58-86-104. Self-certification to division -- Complaints.**

174 (1) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah
175 Administrative Rulemaking Act, that:

176 (a) for the purpose of ensuring compliance with the provisions of this section, require a
177 self-certification of a person:

178 (i) registered under this chapter; or

179 (ii) who engages in activities that require registration under this chapter;

180 (b) create a form on which a person described in Subsection (1)(a) certifies that the

181 person is in full compliance with each requirement of this section and any other applicable
182 laws, rules, regulations, or registration conditions; and

183 (c) establish procedures to:

184 (i) receive, evaluate, and investigate complaints regarding failures to comply with this
185 section by a person described in Subsection (1)(a), including, if applicable, adjudicative
186 procedures under Title 63G, Chapter 4, Administrative Procedures Act; and

187 (ii) provide the notice described in Section 58-86-105.

188 (2) A person described in Subsection (1)(a) shall honestly and in good faith complete
189 the self-certification process described in Subsections (1)(a) and (b).

190 Section 6. Section **58-86-105** is enacted to read:

191 **58-86-105. Notification of Insurance Department and insurance carriers.**

192 (1) (a) The division shall give the notice described in Subsection (1)(b) to the person
193 who is the subject of the complaint described in Subsection (1)(a)(i) when, through procedures
194 established under Subsection 58-86-104(1)(c), the division:

195 (i) receives a complaint that a person who is not registered, as required in Subsection
196 58-86-103(1), is conducting business as a pharmacy benefit manager or providing pharmacy
197 benefit management services, as defined in Section 49-20-502; and

198 (ii) determines that the complaint described in Subsection (1)(a)(i) is true.

199 (b) The division shall ensure that the notice required in Subsection (1)(a) contains a
200 statement:

201 (i) that the person is not registered as a pharmacy benefit manager as required by this
202 chapter; and

203 (ii) that the person is prohibited from providing services as a pharmacy benefit
204 manager, unless the person registers, as required in this chapter, within 30 days of the date of
205 the notice.

206 (2) (a) The division shall give the notice described in Subsection (2)(b) when the
207 person who is the subject of the complaint described in Subsection (1)(a)(i) does not register,
208 as required in Subsection 58-86-103(1), within 30 days of the date of the notice described in
209 Subsection (1)(b).

210 (b) The division shall:

211 (i) ensure that the notice required in Subsection (2)(a) contains a statement that the

212 person is:

213 (A) not registered as a pharmacy benefit manager, as required by Subsection

214 58-86-103(1); and

215 (B) subject to fines, in accordance with Subsection (3), if the person provides services

216 as a pharmacy benefit manager; and

217 (ii) give the notice required in Subsection (2)(a) to:

218 (A) each insurance carrier with which the division has reason to believe the person

219 engages as a pharmacy benefit manager; and

220 (B) the Insurance Department, to promote insurer compliance with Section

221 31A-22-640.

222 (3) (a) The division shall impose the escalating fines described in Subsection (3)(b)

223 upon a person that is the subject of a notice described in Subsection (2) if:

224 (i) the person does not register as required in Subsection 58-86-103(1) within 30 days

225 of the date of the notice; and

226 (ii) the person provides services as a pharmacy benefit manager after the 30-day period

227 described in Subsection (3)(a)(i).

228 (b) In accordance with Subsection (3)(a), until the person registers as required in

229 Subsection 58-86-103(1) the division shall impose escalating fines as follows:

230 (i) beginning on the 31st day until the 60th day after the date of the original notice

231 described in Subsection (1)(b), a fine of \$50 per day;

232 (ii) beginning on the 61st day until the 90th day after the date of the original notice

233 described in Subsection (1)(b), a fine of \$250 per day; and

234 (iii) beginning on the 91st day until the 120th day after the date of the original notice

235 described in Subsection (1)(b), a fine of \$1,000 per day.

236 (4) A person that is the subject of a notice described in Subsection (2) may not provide

237 services as a pharmacy benefit manager beginning on the 121st day after the date of the original

238 notice described in Subsection (1)(b) until the person registers as required in Subsection

239 58-86-103(1).

240 (5) The division shall retain the fines imposed under this section as a dedicated credit

241 to the division to pay for the cost of administering this chapter.

242 (6) To promote insurer compliance with Section 31A-22-640, the division shall, at

243 least once every three months, provide the Insurance Department with a list of all current and
244 valid registrations under this chapter.