

**Representative Paul Ray** proposes the following substitute bill:

**PHARMACY BENEFIT MANAGER AMENDMENTS**

2016 GENERAL SESSION

STATE OF UTAH

**Chief Sponsor: Bradley G. Last**

Senate Sponsor: \_\_\_\_\_

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**LONG TITLE**

**General Description:**

This bill creates registration 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)
- instead of the Division of Corporations and Commercial Code; and
- self-audit and 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; and
    - provide certain notice to the Insurance Department and insurance carriers

regarding registrations;

- ▶ authorizes administrative rules; and
- ▶ makes technical changes.



26 **Money Appropriated in this Bill:**

27 None

28 **Other Special Clauses:**

29 None

30 **Utah Code Sections Affected:**

31 AMENDS:

32 **31A-22-640**, as last amended by Laws of Utah 2015, Chapter 258

33 ENACTS:

34 **58-86-101**, Utah Code Annotated 1953

35 **58-86-102**, Utah Code Annotated 1953

36 **58-86-103**, Utah Code Annotated 1953

37 **58-86-104**, Utah Code Annotated 1953

38 **58-86-105**, Utah Code Annotated 1953



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

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

42 **31A-22-640. Insurer and pharmacy benefit management services -- Registration**  
43 **-- Maximum allowable cost -- Audit restrictions.**

44 (1) For purposes of this section:

45 (a) "Maximum allowable cost" means:

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

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

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

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

56 (ii) "Pharmacy benefit manager" does not mean a person:

- 57           (A) that is primarily domiciled in a state other than Utah;
- 58           (B) that does not meet the definition of insurer in Section [31A-22-636](#); or
- 59           (C) that is subject to the requirements of Title 58, Chapter 86, Pharmacy Benefit
- 60 Manager Act.

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

63           (3) A pharmacy benefit manager shall not use maximum allowable cost as a basis for  
64 reimbursement to a pharmacy unless:

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

69           (b) the drug is:

70           (i) generally available for purchase in this state from a national or regional wholesaler;  
71 and

72           (ii) not obsolete.

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

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 drug  
80 pricing compendia and other data sources used to obtain the drug price data;

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

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

85           (d) include in each contract with a contracted pharmacy a process to obtain an update  
86 to the pharmacy product pricing files used to reimburse the pharmacy in a format that is readily  
87 available and accessible.

88 (6) (a) The right to appeal in Subsection (5)(c) shall be:

89 (i) limited to 21 days following the initial claim adjudication; and

90 (ii) investigated and resolved by the pharmacy benefit manager within 14 business  
91 days.

92 (b) If an appeal is denied, the pharmacy benefit manager shall provide the contracted  
93 pharmacy with the reason for the denial and the identification of the national drug code of the  
94 drug that may be purchased by the pharmacy at a price at or below the price determined by the  
95 pharmacy benefit manager.

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

98 (8) (a) To conduct business in the state, a pharmacy benefit manager shall register with  
99 the Division of Corporations and Commercial Code within the Department of Commerce and  
100 annually renew the registration. To register under this section, the pharmacy benefit manager  
101 shall submit an application which shall contain only the following information:

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

103 (ii) the name and contact information for the registered agent for the pharmacy benefit  
104 manager; and

105 (iii) if applicable, the federal employer identification number for the pharmacy benefit  
106 manager.

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

110 (c) The following entities do not have to register as a pharmacy benefit manager under  
111 Subsection (8)(a) when the entity is providing formulary services to its own patients,  
112 employees, members, or beneficiaries:

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

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

116 (iii) a health care professional licensed under Title 58, Occupations and Professions;

117 (iv) a health insurer; and

118 (v) a labor union.

119 (9) This section does not apply to a pharmacy benefit manager when the pharmacy  
120 benefit manager is providing pharmacy benefit management services on behalf of the state  
121 Medicaid program.

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

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

124 **58-86-101. Title.**

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

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

127 **58-86-102. Definitions.**

128 As used in this chapter:

129 (1) "Maximum allowable cost" means:

130 (a) a maximum reimbursement amount for a group of pharmaceutically and  
131 therapeutically equivalent drugs; or

132 (b) any similar reimbursement amount that is used by a pharmacy benefit manager to  
133 reimburse pharmacies for multiple source drugs.

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

137 (3) (a) "Pharmacy benefit manager" means a person or entity that provides pharmacy  
138 benefit management services, as defined in Section [49-20-502](#), on behalf of an insurer, as  
139 defined in Subsection [31A-22-636\(1\)](#).

140 (b) "Pharmacy benefit manager" does not mean a person:

141 (i) that is primarily domiciled in a state other than Utah;

142 (ii) that does not meet the definition of insurer in Section [31A-22-636](#); and

143 (iii) that is subject to the requirements of this chapter.

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

145 **58-86-103. Insurer and pharmacy benefit management services -- Registration --**  
146 **Maximum allowable cost -- Audit restrictions.**

147 (1) An insurer's pharmacy benefit manager is subject to the pharmacy audit provisions  
148 of Section [58-17b-622](#).

149 (2) A pharmacy benefit manager may not use maximum allowable cost as a basis for

150 reimbursement to a pharmacy unless:

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

155 (b) the drug is:

156 (i) generally available for purchase in Utah from a national or regional wholesaler; and  
157 (ii) not obsolete.

158 (3) A pharmacy benefit manager shall determine maximum allowable cost by using  
159 comparable and current data on drug prices obtained from multiple nationally recognized,  
160 comprehensive data sources, including wholesalers, drug file vendors, and pharmaceutical  
161 manufacturers for drugs that are available for purchase by pharmacies in Utah.

162 (4) For every drug for which the pharmacy benefit manager uses maximum allowable  
163 cost to reimburse a contracted pharmacy, the pharmacy benefit manager shall:

164 (a) include information identifying the national drug pricing compendia and other data  
165 sources used to obtain the drug price data in the contract with the pharmacy;

166 (b) review and make necessary adjustments to the maximum allowable cost, using the  
167 most recent data sources identified in Subsection (4)(a), at least once per week;

168 (c) provide a process for the contracted pharmacy to appeal the maximum allowable  
169 cost, in accordance with Subsection (5); and

170 (d) include a process to obtain an update to the pharmacy product pricing files used to  
171 reimburse the pharmacy, in each contract with a contracted pharmacy, in a format that is  
172 readily available and accessible.

173 (5) (a) (i) A contracted pharmacy may appeal the maximum allowable cost, in  
174 accordance with Subsection (4)(c), within 21 days following the initial claim adjudication.

175 (ii) The pharmacy benefit manager shall investigate and resolve the appeal within 14  
176 business days.

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

179 (i) the reason for the denial; and

180 (ii) the identification of the national drug code of the drug for which the pharmacy

181 appealed that may be purchased by the pharmacy at a price at or below the price determined by  
182 the pharmacy benefit manager.

183 (6) The pharmacy benefit manager shall ensure that the contract with each pharmacy  
184 contains a dispute resolution mechanism to be used if either party breaches the terms or  
185 conditions of the contract.

186 (7) (a) To conduct business in the state, a pharmacy benefit manager shall register with  
187 the division and renew the registration annually.

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

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

191 (ii) the name and contact information for the registered agent for the pharmacy benefit  
192 manager; and

193 (iii) if applicable, the federal employer identification number for the pharmacy benefit  
194 manager.

195 (c) The division may establish a fee, in accordance with Title 63J, Chapter 1,  
196 Budgetary Procedures Act, which may not exceed \$100 per year, for the initial registration and  
197 the annual renewal of the registration.

198 (d) The division shall:

199 (i) make rules, in accordance with Title 63G, Chapter 3, Utah Administrative  
200 Rulemaking Act, to establish an application process and an application form for registration  
201 under this chapter; and

202 (ii) retain the registration fees imposed under Subsection (7)(c) as a dedicated credit, as  
203 defined in Section 51-5-3, to the division to pay for the cost of administering this chapter.

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

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

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

210 (iii) a health care professional licensed under Title 58, Occupations and Professions;

211 (iv) a health insurer; and

212 (v) a labor union.

213 (8) This section does not apply to a pharmacy benefit manager when the pharmacy  
214 benefit manager is providing pharmacy benefit management services on behalf of the state  
215 Medicaid program.

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

217 **58-86-104. Certification to division -- Complaints.**

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

220 (a) for the purpose of ensuring compliance with the provisions of Section  
221 58-86-103(7), require a certification of a person:

222 (i) registered under Section 58-86-103(7); or

223 (ii) who engages in activities that require registration under Section 58-86-103(7);

224 (b) create a form on which a person described in Subsection (1)(a) certifies that the  
225 person is in full compliance with each requirement of Section 58-86-103(7) and any other  
226 applicable laws, rules, regulations, or registration conditions; and

227 (c) establish procedures to provide the notice described in Section 58-86-105.

228 (2) A person described in Subsection (1)(a) shall honestly and in good faith complete  
229 the certification process described in Subsections (1)(a) and (b).

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

231 **58-86-105. Notification of Insurance Department, insurance carriers.**

232 (1) (a) The division shall give the notice described in Subsection (1)(b) when, through  
233 procedures established under Subsection 58-86-104(1)(c), the division:

234 (i) receives a complaint that a person that is not registered in compliance with this  
235 section is conducting business as a pharmacy benefit manager or providing pharmacy benefit  
236 management services, as defined in Section 49-20-502; and

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

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

240 (i) that the person is not registered as a pharmacy benefit manager as required by this  
241 section; and

242 (ii) that the person is prohibited from providing services as a pharmacy benefit



243 manager in Utah, unless the person registers within 60 days of receipt of the notice.

244 (c) The division shall give the notice required in Subsection (1)(a) to:

245 (i) the person who is the subject of the complaint described in Subsection (1)(a);

246 (ii) each insurance carrier with which the division has reason to believe the person

247 engages as a pharmacy benefit manager; and

248 (iii) the Insurance Department, to promote insurer compliance with Section

249 [31A-22-640](#).

250 (2) To promote insurer compliance with Section [31A-22-640](#), the division shall, at

251 least once every three months, provide the Insurance Department with a list of all current and

252 valid registrations under this chapter.