

**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: \_\_\_\_\_

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**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 Corporations and Commercial Code 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 the Division of Corporations and Commercial Code 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           **16-18-101**, Utah Code Annotated 1953

36           **16-18-102**, Utah Code Annotated 1953

37           **16-18-103**, Utah Code Annotated 1953

38           **16-18-104**, Utah Code Annotated 1953

39           **16-18-105**, Utah Code Annotated 1953



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

42           Section 1. Section **16-18-101** is enacted to read:

43                           **CHAPTER 18. PHARMACY BENEFIT MANAGER ACT**

44           **16-18-101. Title.**

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

46           Section 2. Section **16-18-102** is enacted to read:

47           **16-18-102. Definitions.**

48           As used in this chapter:

49           (1) "Division" means the Division of Corporations and Commercial Code, created in

50 Section **13-1-2**.

51           (2) "Maximum allowable cost" means the same as that term is defined in Section

52 **31A-22-640**.

53           (3) "Obsolete" means the same as that term is defined in Section **31A-22-640**.

54           (4) "Pharmacy benefit manager" means the same as that term is defined in Section

55 **31A-22-640**.

56           Section 3. Section **16-18-103** is enacted to read:

57 **16-18-103. Pharmacy benefit manager registration.**58 (1) (a) To conduct business in the state, a pharmacy benefit manager shall register with  
59 the division and renew the registration annually.60 (b) To register under this chapter, the pharmacy benefit manager shall submit to the  
61 division an application containing:62 (i) the name of the pharmacy benefit manager;63 (ii) the name and contact information for the registered agent for the pharmacy benefit  
64 manager; and65 (iii) if applicable, the federal employer identification number for the pharmacy benefit  
66 manager.67 (2) The division may establish a fee, in accordance with Title 63J, Chapter 1,  
68 Budgetary Procedures Act, for the initial registration and the annual renewal of the registration.69 (3) The division shall:70 (a) make rules, in accordance with Title 63G, Chapter 3, Utah Administrative  
71 Rulemaking Act, to establish an application process and an application form for registration  
72 under this chapter; and73 (b) retain the registration fees imposed under Subsection (2) as a dedicated credit, as  
74 defined in Section 51-5-3, to the division to pay for the cost of administering this chapter.75 (4) The following entities are not required to register as a pharmacy benefit manager  
76 under Subsection (7)(a) when the entity is providing formulary services to the entity's patients,  
77 employees, members, or beneficiaries:78 (a) a health care facility licensed under Title 26, Chapter 21, Health Care Facility  
79 Licensing and Inspection Act;80 (b) a pharmacy licensed under Title 58, Chapter 17b, Pharmacy Practice Act;81 (c) a health care professional licensed under Title 58, Occupations and Professions; and82 (d) a labor union.83 (5) This section does not apply to a pharmacy benefit manager when the pharmacy  
84 benefit manager is providing pharmacy benefit management services on behalf of:85 (a) the state Medicaid program;86 (b) a motor vehicle insurer; or87 (c) a workers' compensation insurer.

88 Section 4. Section **16-18-104** is enacted to read:

89 **16-18-104. Self-certification to division -- Complaints.**

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

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

94 (i) registered under this chapter; or

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

96 (b) create a form on which a person described in Subsection (1)(a) certifies that the  
97 person is in full compliance with each requirement of this section and any other applicable  
98 laws, rules, regulations, or registration conditions; and

99 (c) establish procedures to:

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

103 (ii) provide the notice described in Section [16-18-105](#).

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

106 Section 5. Section **16-18-105** is enacted to read:

107 **16-18-105. Notification of Insurance Department and insurance carriers.**

108 (1) (a) The division shall give the notice described in Subsection (1)(b) to the person  
109 who is the subject of the complaint described in Subsection (1)(a)(i) when, through procedures  
110 established under Subsection [16-18-104](#)(1)(c), the division:

111 (i) receives a complaint that a person who is not registered, as required in Subsection  
112 [16-18-103](#)(1), is conducting business as a pharmacy benefit manager or providing pharmacy  
113 benefit management services, as defined in Section [49-20-502](#); and

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

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

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

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

122 (2) (a) The division shall give the notice described in Subsection (2)(b) when the  
123 person who is the subject of the complaint described in Subsection (1)(a)(i) does not register,  
124 as required in Subsection 16-18-103(1), within 30 days of the date of the notice described in  
125 Subsection (1)(b).

126 (b) The division shall:

127 (i) ensure that the notice required in Subsection (2)(a) contains a statement that the  
128 person is:

129 (A) not registered as a pharmacy benefit manager, as required by Subsection  
130 16-18-103(1); and

131 (B) subject to fines, in accordance with Subsection (3), if the person provides services  
132 as a pharmacy benefit manager; and

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

134 (A) each insurance carrier with which the division has reason to believe the person  
135 engages as a pharmacy benefit manager; and

136 (B) the Insurance Department, to promote insurer compliance with Section  
137 31A-22-640.

138 (3) (a) The division shall impose the escalating fines described in Subsection (3)(b)  
139 upon a person that is the subject of a notice described in Subsection (2) if:

140 (i) the person does not register as required in Subsection 16-18- 103(1) within 30 days  
141 of the date of the notice; and

142 (ii) the person provides services as a pharmacy benefit manager after the 30-day period  
143 described in Subsection (3)(a)(i).

144 (b) In accordance with Subsection (3)(a), until the person registers as required in  
145 Subsection 16-18-103(1) the division shall impose escalating fines as follows:

146 (i) beginning on the 31st day until the 60th day after the date of the original notice  
147 described in Subsection (1)(b), a fine of \$50 per day;

148 (ii) beginning on the 61st day until the 90th day after the date of the original notice  
149 described in Subsection (1)(b), a fine of \$250 per day; and

150 (iii) beginning on the 91st day until the 120th day after the date of the original notice  
151 described in Subsection (1)(b), a fine of \$1,000 per day.

152 (4) A person that is the subject of a notice described in Subsection (2) may not provide  
153 services as a pharmacy benefit manager beginning on the 121st day after the date of the original  
154 notice described in Subsection (1)(b) until the person registers as required in Subsection  
155 16-18-103(1).

156 (5) The division shall retain the fines imposed under this section as a dedicated credit  
157 to the division to pay for the cost of administering this chapter.

158 (6) To promote insurer compliance with Section 31A-22-640, the division shall, at  
159 least once every three months, provide the Insurance Department with a list of all current and  
160 valid registrations under this chapter.

161 Section 6. Section 31A-22-640 is amended to read:

162 **31A-22-640. Insurer and pharmacy benefit management services -- Registration**  
163 **-- Maximum allowable cost -- Audit restrictions.**

164 (1) For purposes of this section:

165 (a) "Maximum allowable cost" means:

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

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

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

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

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

178 (A) a retail pharmacy;

179 (B) a mail order pharmacy; or

180 (C) an insurer.

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

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

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

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

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

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

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

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

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

205 (d) include ~~[in each contract with a contracted pharmacy]~~ a process to obtain an update  
206 to the pharmacy product pricing files used to reimburse the pharmacy, in each contract with a  
207 contracted pharmacy, in a format that is readily available and accessible.

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

211 (ii) ~~[investigated and resolved by the]~~ The pharmacy benefit manager shall investigate

212 and resolve the appeal within 14 business days.

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

215 (i) the reason for the denial; and

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

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

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

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

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

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

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

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

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

238 ~~[(ii) a pharmacy licensed under Title 58, Chapter 17b, Pharmacy Practice Act;]~~

239 ~~[(iii) a health care professional licensed under Title 58, Occupations and Professions;]~~

240 ~~[(iv) a health insurer; and]~~

241 ~~[(v) a labor union.]~~

242 [(9) This section does not apply to a pharmacy benefit manager when the pharmacy



243 ~~benefit manager is providing pharmacy benefit management services on behalf of the state~~  
244 ~~Medicaid program.]~~

245 (8) (a) A person may not perform, offer to perform, or advertise any service as a  
246 pharmacy benefit manager in Utah without a valid registration under Title 16, Chapter 18,  
247 Pharmacy Benefit Manager Act.

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