

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 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;
 - establish registration revocation and re-application procedures; and
 - notify certain individuals doing business with a person whose pharmacy benefit manager registration is revoked;
- ▶ authorizes administrative rules; and
- ▶ makes technical changes.

Money Appropriated in this Bill:



28 None

29 **Other Special Clauses:**

30 None

31 **Utah Code Sections Affected:**

32 ENACTS:

33 **58-86-101**, Utah Code Annotated 1953

34 **58-86-102**, Utah Code Annotated 1953

35 **58-86-103**, Utah Code Annotated 1953

36 **58-86-104**, Utah Code Annotated 1953

37 **58-86-105**, Utah Code Annotated 1953

38 REPEALS AND REENACTS:

39 **31A-22-640**, as last amended by Laws of Utah 2015, Chapter 258



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

42 Section 1. Section **31A-22-640** is repealed and reenacted to read:

43 **31A-22-640. Insurers using pharmacy benefit management services --**

44 **Registration required**

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

48 (2) A person may not use the pharmacy benefit management services of another if the
49 person knows or should know that the other does not have the registration required in
50 Subsection (1).

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

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

53 **58-86-101. Title.**

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

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

56 **58-86-102. Definitions.**

57 As used in this chapter:

58 (1) "Maximum allowable cost" means:

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

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

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

66 (3) "Pharmacy benefit manager" means a person or entity that provides pharmacy
67 benefit management services, as defined in Section 49-20-502, on behalf of an insurer, as
68 defined in Subsection 31A-22-636(1).

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

70 **58-86-103. Insurer and pharmacy benefit management services -- Registration --**
71 **Maximum allowable cost -- Audit restrictions.**

72 (1) An insurer and an insurer's pharmacy benefit manager are subject to the pharmacy
73 audit provisions of Section 58-17b-622.

74 (2) A pharmacy benefit manager may not use maximum allowable cost as a basis for
75 reimbursement to a pharmacy unless:

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

80 (b) the drug is:

81 (i) generally available for purchase in Utah from a national or regional wholesaler; and

82 (ii) not obsolete.

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

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

89 (a) include information identifying the national drug pricing compendia and other data

90 sources used to obtain the drug price data in the contract with the pharmacy;

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

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

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

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

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

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

104 (i) the reason for the denial; and

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

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

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

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

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

116 (ii) the name and contact information for the registered agent for the pharmacy benefit
117 manager; and

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

120 (c) The division may establish a fee, in accordance with Title 63J, Chapter 1,

121 Budgetary Procedures Act, for the initial registration and the annual renewal of the registration.

122 (d) The division shall:

123 (i) make rules, in accordance with Title 63G, Chapter 3, Utah Administrative

124 Rulemaking Act, to establish:

125 (A) an application process and an application form for registration under this chapter;

126 (B) procedures that allow a person whose registration has been revoked under Section

127 58-86-104 to apply for reinstatement of the registration; and

128 (C) criteria for reinstatement, in accordance with this Subsection (7)(d)(i); and

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

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

134 (i) a health care facility licensed under Title 26, Chapter 21, Health Care Facility

135 Licensing and Inspection Act;

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

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

138 and

139 (iv) a labor union.

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

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

144 **58-86-104. Self-audit and certification to division -- Complaints.**

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

147 (a) for the purpose of ensuring compliance with the provisions of this chapter, require a
148 self-audit and certification of a person:

149 (i) registered under this chapter; or

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

151 (b) create a form on which a person described in Subsection (1)(a):

152 (i) certifies that the person is in full compliance with each requirement of this chapter
153 and any other applicable laws, rules, regulations, or registration conditions; and

154 (ii) names each insurance carrier with which the person engages as a pharmacy benefit
155 manager; and

156 (c) establish procedures to:

157 (A) receive, evaluate, and investigate complaints regarding failures to comply with this
158 chapter by a person described in Subsection (1)(a); and

159 (B) revoke a pharmacy benefit manager registration, in accordance with Section
160 58-86-104.

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

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

164 **58-86-105. Revocation of registration -- Notification of insurance carriers.**

165 (1) The director or the director's designee shall promptly revoke a pharmacy benefit
166 manager's registration if, upon review of the self-audit, certification, or complaints described in
167 Section 58-86-103, and as part of an adjudicative proceeding under Title 63G, Chapter 4,
168 Administrative Procedures Act, the director or the director's designee finds that:

169 (a) the person has, on multiple occasions, violated provisions of this chapter, or a rule
170 or order issued with respect to this chapter;

171 (b) the violations are part of a pattern of noncompliance; and

172 (c) disciplinary action is appropriate.

173 (2) (a) When a registration is revoked under this section, the division shall promptly
174 give notice that the person's registration is revoked, stating the grounds for the revocation, and
175 that the person can no longer provide services as a pharmacy benefit manager under this
176 chapter.

177 (b) The division shall give notice to.

178 (i) the person for whom the registration is revoked;

179 (ii) each insurance carrier with which the person engages as a pharmacy benefit
180 manager, as identified by the person in accordance with Subsection 58-86-103(1)(b)(ii); and

181 (iii) the Insurance Department, to promote insurer compliance with Section
182 31A-22-640.

Legislative Review Note
Office of Legislative Research and General Counsel