

1 **PHARMACY BENEFIT MANAGER AMENDMENTS**

2 2014 GENERAL SESSION

3 STATE OF UTAH

4 **Chief Sponsor: Bradley G. Last**

5 Senate Sponsor: _____

6

7 **LONG TITLE**

8 **General Description:**

9 This bill amends the Insurance Code to create a license for pharmacy benefit managers.

10 **Highlighted Provisions:**

11 This bill:

- 12 ▶ establishes the Pharmacy Benefit Manager Act;
- 13 ▶ defines terms;
- 14 ▶ requires a license to operate as a pharmacy benefit manager;
- 15 ▶ establishes:
 - 16 • a license application process; and
 - 17 • general requirements for a license;
- 18 ▶ provides for license probation, termination, or surrender under certain conditions;
- 19 ▶ establishes general duties regarding:
 - 20 • maximum allowable cost reimbursement to a contracted pharmacy; and
 - 21 • average reimbursement rates for multisource drugs;
- 22 ▶ permits the Insurance Department to establish fees to pay the cost of administering
- 23 the licensing chapter and designates the fee as a dedicated credit to the department;
- 24 ▶ authorizes the commissioner of insurance to impose penalties for a violation of the
- 25 chapter and designates the penalties as a dedicated credit to the department; and
- 26 ▶ authorizes administrative rules.

27 **Money Appropriated in this Bill:**



28 None

29 **Other Special Clauses:**

30 This bill takes effect on July 1, 2014.

31 **Utah Code Sections Affected:**

32 ENACTS:

33 31A-44-101, Utah Code Annotated 1953

34 31A-44-102, Utah Code Annotated 1953

35 31A-44-201, Utah Code Annotated 1953

36 31A-44-202, Utah Code Annotated 1953

37 31A-44-203, Utah Code Annotated 1953

38 31A-44-204, Utah Code Annotated 1953

39 31A-44-205, Utah Code Annotated 1953

40 31A-44-206, Utah Code Annotated 1953

41 31A-44-301, Utah Code Annotated 1953

42 31A-44-302, Utah Code Annotated 1953

43 31A-44-303, Utah Code Annotated 1953

44 31A-44-401, Utah Code Annotated 1953

45 31A-44-402, Utah Code Annotated 1953

46 31A-44-403, Utah Code Annotated 1953

47 31A-44-404, Utah Code Annotated 1953

48 31A-44-405, Utah Code Annotated 1953

49

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

51 Section 1. Section 31A-44-101 is enacted to read:

52 **CHAPTER 44. PHARMACY BENEFIT MANAGER ACT**

53 **Part 1. General Provisions**

54 **31A-44-101. Title.**

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

56 Section 2. Section 31A-44-102 is enacted to read:

57 **31A-44-102. Definitions.**

58 For purposes of this chapter:

59 (1) "Contracted pharmacy" or "pharmacy" means a pharmacy, as defined in Section
60 58-17b-102, participating in the network of a pharmacy benefit manager through a direct
61 contract or through a contract with a pharmacy services administration organization or group
62 purchasing organization.

63 (2) "Dispense" or "dispensed" is as defined in Section 58-17b-102.

64 (3) "Drug" is as defined in Section 58-37-2.

65 (4) "Generic exclusivity period" means the period designated by the Food and Drug
66 Administration following a successful challenge of an existing patent for an innovator drug
67 during which a subsequent manufacturer of a pharmaceutically and therapeutically equivalent
68 version of the innovator drug may market the pharmaceutically and therapeutically equivalent
69 version without competition from other multiple source drug manufacturers.

70 (5) "Maximum allowable cost" means:

71 (a) a maximum reimbursement amount for a group of pharmaceutically and
72 therapeutically equivalent multiple source drugs that are listed in the most recent edition of the
73 Approved Drug Products with Therapeutic Equivalence Evaluations published by the Food and
74 Drug Administration and for which there are no less than three nationally available equivalent
75 drug products; or

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

78 (6) "Multiple source drug" means a drug for which there are three or more drug
79 products that are:

80 (a) rated by the Food and Drug Administration as therapeutically equivalent or
81 bioequivalent;

82 (b) determined by the Food and Drug Administration to be pharmaceutically equivalent
83 or bioequivalent; and

84 (c) sold or marketed in the United States during the same calendar quarter.

85 (7) "Nationally available" means a product that is available for purchase in package
86 sizes commonly purchased by retail pharmacies or chain-operated warehouses in sufficient
87 supply from national pharmaceutical wholesalers and is not obsolete or temporarily
88 unavailable.

89 (8) "Obsolete" means a product that may be listed in national drug pricing compendia

90 but is no longer actively marketed by the product manufacturer or labeler.

91 (9) "Pharmacy benefit manager" means a person or entity that provides pharmacy
92 benefit management services on behalf of a self-insured employer, insurance company, health
93 maintenance organization, or other plan sponsor as defined by administrative rule adopted by
94 the commissioner.

95 (10) "Pharmacy benefit manager service" means any of the following services provided
96 to a health benefit plan, or to a participant of the health benefit plan:

97 (a) negotiating the amount to be paid by a health benefit plan for a prescription drug; or

98 (b) administering or managing prescription drug benefits provided by the health benefit
99 plan for the benefit of a participant of the health benefit plan, including:

100 (i) mail service pharmacy;

101 (ii) specialty pharmacy;

102 (iii) claims processing;

103 (iv) payment of a claim;

104 (v) retail network management;

105 (vi) clinical formulary development;

106 (vii) clinical formulary management services;

107 (viii) rebate contracting;

108 (ix) rebate administration;

109 (x) a participant compliance program;

110 (xi) a therapeutic intervention program;

111 (xii) a disease management program; or

112 (xiii) a service that is similar to, or related to, a service described in Subsection (10)(a)
113 or Subsections (10)(b)(i) through (xii).

114 (11) "Prescription" is as defined in Section 58-37-2.

115 (12) "Prescription drug" means a drug that is provided by prescription.

116 (13) "Temporarily unavailable" means a product that is experiencing short-term supply
117 interruptions, and only an inconsistent or intermittent supply is available in the current market.

118 Section 3. Section 31A-44-201 is enacted to read:

119 **Part 2. Licensing**

120 **31A-44-201. License required.**

121 (1) A person may not perform, offer to perform, or advertise any service as a pharmacy
122 benefit manager in Utah without a valid license as a pharmacy benefit manager.

123 (2) A person may not utilize the services of another person as a pharmacy benefit
124 manager if the person knows or has reason to know that the other person does not have a
125 license as required under Subsection (1).

126 Section 4. Section **31A-44-202** is enacted to read:

127 **31A-44-202. Application for license.**

128 (1) To obtain a license as a pharmacy benefit manager, a person shall:

129 (a) make an application for a license to the commissioner on forms and in a manner
130 established by the commissioner, by rule, made in accordance with Title 63G, Chapter 3, Utah
131 Administrative Rulemaking Act; and

132 (b) pay a nonrefundable application fee.

133 (2) The application described in Subsection (1)(a) shall:

134 (a) state the applicant's:

135 (i) name;

136 (ii) address;

137 (iii) Social Security number or federal employer identification number; and

138 (iv) personal history, experience, education, and business record;

139 (b) if the applicant is a natural person, state whether the applicant is 18 years of age or
140 older;

141 (c) state whether the applicant has committed an act that is a ground for denial,
142 suspension, or revocation described in Section 31A-44-301; and

143 (d) include any other information required by rule.

144 (3) The commissioner may require the applicant to submit documentation that is
145 reasonably necessary to verify the information contained in the application.

146 (4) An applicant's Social Security number contained in an application filed under this
147 section is a private record under Section 63G-2-302.

148 Section 5. Section **31A-44-203** is enacted to read:

149 **31A-44-203. General requirements for issuing a license.**

150 (1) The commissioner shall issue a license to act as a pharmacy benefit manager to a
151 person who:

- 152 (a) satisfies the character requirements described in Section 31A-44-204;
153 (b) has not committed an act that is a ground for denial, suspension, or revocation
154 under Section 31A-44-301;
155 (c) if a nonresident, complies with Section 31A-44-205; and
156 (d) pays the applicable fees under Sections 31A-3-103 and 31A-44-202.
157 (2) A person who is a licensed pharmacy benefit manager or who is an applicant for a
158 pharmacy benefit manager license shall, in accordance with Subsection (3), provide a report to
159 the commissioner of:
160 (a) any administrative action taken against the person:
161 (i) in another jurisdiction; or
162 (ii) by another regulatory agency in this state; and
163 (b) any criminal prosecution brought against the person in any jurisdiction.
164 (3) A person who is required to file a report described in Subsection (2) shall:
165 (a) file the report:
166 (i) at the time the person applies for a pharmacy benefit manager license; and
167 (ii) if an administrative action or prosecution described in Subsection (2) occurs after
168 the person applies for a pharmacy benefit manager license:
169 (A) for an administrative action, within 30 days after the day on which the final
170 disposition of the administrative action occurs; or
171 (B) for a criminal prosecution, within 30 days after the day on which the initial
172 appearance before a court occurs; and
173 (b) include a copy of the complaint and other legal documents relating to the initiation
174 or disposition of the action or prosecution described in Subsection (2).
175 (4) (a) The department may require a person who applies for a pharmacy benefit
176 manager license to submit to a criminal background check as a condition of receiving a license.
177 (b) A person, if required to submit to a criminal background check under Subsection
178 (4)(a), shall:
179 (i) submit a fingerprint card in a form acceptable to the department; and
180 (ii) consent to a fingerprint background check by:
181 (A) the Utah Bureau of Criminal Identification; and
182 (B) the Federal Bureau of Investigation.

183 (c) The department may request the following relating to a person who submits to a
184 criminal background check under this Subsection (4):

185 (i) criminal background information maintained pursuant to Title 53, Chapter 10, Part
186 2, Bureau of Criminal Identification, from the Bureau of Criminal Identification; and

187 (ii) complete Federal Bureau of Investigation criminal background checks through the
188 national criminal history system.

189 (d) Information obtained by the department from the review of criminal history records
190 received under this Subsection (4) shall be used by the department for the purposes of:

191 (i) determining if a person satisfies the character requirements described in Section
192 31A-44-204 for issuance or renewal of a license;

193 (ii) determining if a person has failed to maintain the character requirements described
194 in Section 31A-44-204; and

195 (iii) preventing a person who violates the federal Violent Crime Control and Law
196 Enforcement Act of 1994, 18 U.S.C. Sec. 1033, from providing pharmacy benefit management
197 services in the state.

198 (e) If the commissioner requests the criminal background information described in this
199 Subsection (4), the commissioner shall:

200 (i) pay to the Department of Public Safety the costs incurred by the Department of
201 Public Safety in providing the commissioner criminal background information described in
202 Subsection (4)(c)(i);

203 (ii) pay to the Federal Bureau of Investigation the costs incurred by the Federal Bureau
204 of Investigation in providing the department criminal background information described in
205 Subsection (4)(c)(ii); and

206 (iii) charge the person applying for a license, or for consent to provide pharmacy
207 benefit management services in the state, a fee equal to the aggregate of Subsections (4)(e)(i)
208 and (ii).

209 (5) The commissioner may deny a license application to act as a licensed pharmacy
210 benefit manager to a person who:

211 (a) fails to satisfy the requirements of this section; or

212 (b) commits an act that is a ground for denial, suspension, or revocation described in
213 Section 31A-44-301.

214 Section 6. Section **31A-44-204** is enacted to read:

215 **31A-44-204. Character requirements.**

216 An applicant for a license under this chapter shall demonstrate to the commissioner
217 that:

218 (1) the applicant has the good faith intent to engage in business as a pharmacy benefit
219 manager; and

220 (2) (a) if the applicant is a natural person, the applicant is:

221 (i) competent and trustworthy; and

222 (ii) at least 18 years old; or

223 (b) if the applicant is an entity, the entity and all partners, directors, principal officers,
224 or persons having comparable power over the entity are trustworthy.

225 Section 7. Section **31A-44-205** is enacted to read:

226 **31A-44-205. Nonresident jurisdictional agreement.**

227 (1) The commissioner shall waive any license requirement for a license under this
228 chapter and issue a nonresident pharmacy benefit manager license to a person who is a
229 nonresident pharmacy benefit manager, if:

230 (a) the person has a valid license from the person's home state;

231 (b) the person applies for a nonresident pharmacy benefit manager license;

232 (c) the person submits to the commissioner a copy of the application for a pharmacy
233 benefit manager license that the nonresident license applicant submitted to the applicant's home
234 state;

235 (d) the person pays the applicable fees under Sections 31A-3-103 and 31A-44-202;

236 (e) the nonresident license applicant's license in the applicant's home state is in good
237 standing; and

238 (f) the nonresident license applicant's home state awards nonresident pharmacy benefit
239 manager licenses to residents of this state on the same basis as this state awards licenses to
240 residents of that home state.

241 (2) A nonresident applicant shall execute, in a form acceptable to the commissioner, an
242 agreement to be subject to the jurisdiction of the Utah commissioner and courts on any matter
243 related to the applicant's pharmacy benefit manager activities and insurance activities in Utah,
244 on the basis of:

- 245 (a) service of process under Sections 31A-2-309 and 31A-2-310; or
 246 (b) other service authorized in the Utah Rules of Civil Procedure.
 247 (3) The commissioner may verify the pharmacy benefit manager's licensing status
 248 through any applicable database.
 249 (4) The commissioner may not assess a greater fee for an insurance license or related
 250 service to a person not residing in this state based solely on the fact that the person does not
 251 reside in this state.

252 Section 8. Section **31A-44-206** is enacted to read:

253 **31A-44-206. Form and contents of license.**

- 254 (1) A license issued under this chapter shall be in a form prescribed by the
 255 commissioner and shall include:
 256 (a) the name, address, and telephone number of the licensee;
 257 (b) the date of license issuance; and
 258 (c) any other information the commissioner considers advisable.
 259 (2) A pharmacy benefit manager doing business under any name other than the
 260 pharmacy benefit manager's legal name shall notify the commissioner before using the assumed
 261 name in this state.
 262 (3) (a) An organization shall be licensed as an agency if the organization acts as a
 263 pharmacy benefit manager.
 264 (b) An agency license issued under Subsection (3)(a) shall include the names of each
 265 natural person licensed under this chapter who is authorized to act as a pharmacy benefit
 266 manager for, or on behalf of, the organization in this state.

267 Section 9. Section **31A-44-301** is enacted to read:

268 **Part 3. License Probation and Termination**

269 **31A-44-301. Revocation, suspension, surrender, lapsing, limiting, or otherwise**
 270 **terminating a license -- Rulemaking for renewal and reinstatement.**

- 271 (1) A license issued under this chapter remains in force until:
 272 (a) revoked or suspended under Subsection (4) or Section 31A-4-302;
 273 (b) surrendered to the commissioner and accepted by the commissioner in lieu of
 274 administrative action;
 275 (c) the licensee dies or is adjudicated incompetent as defined under:

276 (i) Title 75, Chapter 5, Part 3, Guardians of Incapacitated Persons; or
277 (ii) Title 75, Chapter 5, Part 4, Protection of Property of Persons Under Disability and
278 Minors;
279 (d) lapsed under Section 31A-44-303; or
280 (e) voluntarily surrendered.
281 (2) The following may be reinstated within one year after the day on which the license
282 is no longer in force:
283 (a) a lapsed license; or
284 (b) a voluntarily surrendered license, except that a voluntarily surrendered license may
285 not be reinstated after the license period in which the license is voluntarily surrendered.
286 (3) Unless otherwise stated in the written agreement for the voluntary surrender of a
287 license, submission and acceptance of a voluntary surrender of a license does not prevent the
288 department from pursuing additional disciplinary or other action authorized under:
289 (a) this title; or
290 (b) rules made under this title in accordance with Title 63G, Chapter 3, Utah
291 Administrative Rulemaking Act.
292 (4) (a) If the commissioner makes a finding under Subsection (4)(b), as part of an
293 adjudicative proceeding under Title 63G, Chapter 4, Administrative Procedures Act, the
294 commissioner may, with respect to the license or license application to which the finding
295 relates:
296 (i) revoke the license;
297 (ii) suspend the license for a specified period of 12 months or less;
298 (iii) limit the license in whole or in part; or
299 (iv) deny the license application.
300 (b) The commissioner may take an action described in Subsection (4)(a) if the
301 commissioner finds that the licensee or applicant:
302 (i) is unqualified for a license under Section 31A-44-202, 31A-44-203, or 31A-44-204;
303 (ii) has violated:
304 (A) an insurance statute, including a statute in this chapter;
305 (B) a rule that is valid under Subsection 31A-2-201(3); or
306 (C) an order that is valid under Subsection 31A-2-201(4);

- 307 (iii) is insolvent or the subject of receivership, conservatorship, rehabilitation, or other
308 delinquency proceedings in any state;
- 309 (iv) fails to pay a final judgment rendered against the person in this state within 60
310 days after the day on which the judgment becomes final;
- 311 (v) is an affiliate of, or under the same general management or interlocking directorate
312 or ownership as, another pharmacy benefit manager that transacts business in this state without
313 a license;
- 314 (vi) refuses:
- 315 (A) to be examined; or
- 316 (B) to produce its accounts, records, and files for examination;
- 317 (vii) has an officer who refuses to:
- 318 (A) give information with respect to the pharmacy benefit manager's affairs; or
- 319 (B) perform any other legal obligation as to an examination;
- 320 (viii) provides information in a license application that is:
- 321 (A) incorrect;
- 322 (B) misleading;
- 323 (C) incomplete; or
- 324 (D) materially untrue;
- 325 (ix) has violated an insurance law, valid rule, or valid order of the insurance
326 department of another state, district, or territory of the United States;
- 327 (x) has violated a law, rule, or order of another state, province, district, or territory of
328 the United States that relates to regulation of a pharmacy benefit manager;
- 329 (xi) has obtained or attempted to obtain a license through misrepresentation or fraud;
- 330 (xii) has improperly withheld, misappropriated, or converted money or properties
331 received in the course of doing business as a pharmacy benefit manager;
- 332 (xiii) has intentionally misrepresented the terms of an actual or proposed contract;
- 333 (xiv) has been convicted of a felony;
- 334 (xv) has admitted, or been found to have committed, an insurance unfair trade practice
335 or fraud;
- 336 (xvi) in the conduct of business in this state or elsewhere has:
- 337 (A) used fraudulent, coercive, or dishonest practices; or

338 (B) demonstrated incompetence, untrustworthiness, or financial irresponsibility;
339 (xvii) has had an insurance license, a pharmacy benefit manager license, or their
340 equivalent, denied, suspended, or revoked in any other state, province, district, or territory of
341 the United States;
342 (xviii) has forged another's name to a document relating to the provision of a pharmacy
343 benefit management service;
344 (xix) has improperly used notes or any other reference material to complete an
345 examination for a license;
346 (xx) has knowingly accepted a pharmacy benefit management service from an
347 individual who is not licensed;
348 (xxi) has failed to comply with an administrative or court order imposing a child
349 support obligation;
350 (xxii) has failed to:
351 (A) pay state income tax; or
352 (B) comply with an administrative or court order directing payment of state income
353 tax;
354 (xxiii) has violated or permitted others to violate the federal Violent Crime Control and
355 Law Enforcement Act of 1994, 18 U.S.C. Sec. 1033; or
356 (xxiv) has engaged in methods and practices in the conduct of business that endanger
357 the legitimate interests of customers and the public.
358 (c) For purposes of this section, if a license is held by an agency, both the agency itself
359 and any individual designated under the license are considered to be the holders of the agency
360 license.
361 (d) If an individual designated under the agency license commits an act or fails to
362 perform a duty that is a ground for suspending, revoking, or limiting the individual's license,
363 the commissioner may suspend, revoke, or limit the license of:
364 (i) the individual;
365 (ii) the agency, if the agency:
366 (A) is reckless or negligent in the agency's supervision of the individual; or
367 (B) knowingly participated in the act or failure to act that is the grounds for
368 suspending, revoking, or limiting the license; or

369 (iii) (A) the individual; and
370 (B) the agency, if the agency meets the requirements of Subsection (4)(d)(ii).
371 (5) A licensee under this chapter is subject to the penalties for acting as a licensee
372 without a license if:
373 (a) the licensee's license is:
374 (i) revoked;
375 (ii) suspended;
376 (iii) limited;
377 (iv) surrendered in lieu of administrative action;
378 (v) lapsed; or
379 (vi) voluntarily surrendered; and
380 (b) the licensee:
381 (i) continues to act as a licensee; or
382 (ii) violates the terms of the license limitation.
383 (6) A licensee under this chapter shall immediately report to the commissioner:
384 (a) any revocation, suspension, or limitation of the person's license in any other state,
385 province, district, or territory of the United States;
386 (b) the imposition of a disciplinary sanction imposed on that person by any other state,
387 province, district, or territory of the United States; or
388 (c) a judgment or injunction entered against the person on the basis of conduct
389 involving:
390 (i) fraud;
391 (ii) deceit;
392 (iii) misrepresentation; or
393 (iv) a violation of an insurance or pharmacy benefit manager law or rule.
394 (7) (a) An order revoking a license under Subsection (4) or an agreement to surrender a
395 license in lieu of administrative action may specify a time, not to exceed five years, within
396 which the former licensee may not apply for a new license.
397 (b) If no time is specified in the order or agreement described in Subsection (7)(a), the
398 former licensee may not apply for a new license for five years from the day on which the order
399 or agreement is made without the express written approval of the commissioner.

400 (8) The commissioner shall promptly withhold, suspend, restrict, or reinstate the use of
401 a license issued under this part if so ordered by the court.

402 (9) The commissioner shall, by rule, prescribe the license renewal and reinstatement
403 procedures in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act.

404 Section 10. Section 31A-44-302 is enacted to read:

405 **31A-44-302. Probation -- Grounds for revocation.**

406 (1) The commissioner may place a licensee on probation for a period not to exceed 24
407 months as follows:

408 (a) after an adjudicative proceeding under Title 63G, Chapter 4, Administrative
409 Procedures Act, for any circumstances that would justify a suspension under Section
410 31A-44-301; or

411 (b) at the issuance of a new license:

412 (i) with an admitted violation under 18 U.S.C. Sec. 1033; or

413 (ii) with a response to a background information question on a new license application
414 indicating that:

415 (A) the person has been convicted of a crime that is listed by rule made in accordance
416 with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, as a crime that is grounds for
417 probation;

418 (B) the person is currently charged with a crime that is listed by rule made in
419 accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, as a crime that is
420 grounds for probation, regardless of whether adjudication is withheld;

421 (C) the person has been involved in an administrative proceeding regarding any
422 professional or occupational license; or

423 (D) any business in which the person is or was an owner, partner, officer, or director
424 has been involved in an administrative proceeding regarding any professional or occupational
425 license.

426 (2) The commissioner may place a licensee on probation for a specified period no
427 longer than 24 months if the licensee has admitted to a violation under 18 U.S.C. Sec. 1033.

428 (3) A probation order under this section shall state the conditions for retention of the
429 license, which shall be reasonable.

430 (4) A violation of the probation is grounds for revocation pursuant to any proceeding

431 authorized under Title 63G, Chapter 4, Administrative Procedures Act.

432 Section 11. Section **31A-44-303** is enacted to read:

433 **31A-44-303. License lapse and voluntary surrender.**

434 (1) A license issued under this chapter shall lapse if the licensee fails to:

435 (a) timely pay a fee under Sections 31A-3-103 and 31A-44-202;

436 (b) submit a completed renewal application as required by Section 31A-44-202; and

437 (c) maintain an active license in a resident state if the licensee is a nonresident licensee.

438 (2) A licensee whose license lapses due to the following may request an action

439 described in Subsection (3):

440 (a) military service;

441 (b) voluntary service for a period of time designated by the person for whom the

442 licensee provides voluntary service; or

443 (c) other extenuating circumstances, such as long-term medical disability.

444 (3) A licensee described in Subsection (2) may request:

445 (a) reinstatement of the license no later than one year after the day on which the license

446 lapses; and

447 (b) waiver of any of the following imposed for failure to comply with renewal

448 procedures:

449 (i) an examination requirement;

450 (ii) reinstatement fees set under Section 31A-3-103; or

451 (iii) other sanctions imposed for failure to comply with renewal procedures.

452 (4) If a license issued under this chapter is voluntarily surrendered, the license may be

453 reinstated:

454 (a) during the license period in which the license is voluntarily surrendered; and

455 (b) no later than one year after the day on which the license is voluntarily surrendered.

456 Section 12. Section **31A-44-401** is enacted to read:

457 **Part 4. General Duties - Enforcement**

458 **31A-44-401. Maximum allowable cost reimbursement -- Appeal process.**

459 (1) Prior to the expiration of any generic exclusivity period, a pharmacy benefit

460 manager shall not use maximum allowable cost as a basis for reimbursement to a pharmacy for

461 a multiple source drug.

- 462 (2) A pharmacy benefit manager may use maximum allowable cost as a basis for
463 reimbursement to a pharmacy for a drug if:
- 464 (a) there are at least three or more therapeutically equivalent multiple source drugs that
465 have been coded as A rated by the Food and Drug Administration; and
- 466 (b) the drugs identified in Subsection (2)(a) are available at a significant cost
467 difference.
- 468 (3) The maximum allowable cost shall be determined using comparable and current
469 data on drug prices obtained from multiple nationally recognized, comprehensive data sources,
470 including wholesalers, drug file vendors, and pharmaceutical manufacturers for drugs that are
471 nationally available and readily available for purchase by all pharmacies in the state.
- 472 (4) For every drug for which the pharmacy benefit manager uses maximum allowable
473 cost to reimburse a contracted pharmacy, the pharmacy benefit manager shall:
- 474 (a) include in the contract with the pharmacy:
- 475 (i) information identifying the national drug pricing compendia and other data sources
476 used to obtain the drug price data; and
- 477 (ii) the methodology used to calculate the maximum allowable cost;
- 478 (b) notify the contracted pharmacy at least 30 days prior to the initial implementation
479 of a maximum allowable cost for a specific drug;
- 480 (c) notify the contracted pharmacy at least 30 days prior to the discontinuation of a
481 maximum allowable cost for a specific drug;
- 482 (d) review and make necessary adjustments to the maximum allowable cost, using the
483 most recent data sources identified in Subsection (4)(a)(i), at least once per week, and notify
484 the contracted pharmacy of all adjustments within three business days of the adjustment;
- 485 (e) provide a process for the contracted pharmacy to appeal the maximum allowable
486 cost in accordance with Subsection (5); and
- 487 (f) include in the contract with a contracted pharmacy a process to provide a weekly
488 update to the pharmacy product pricing files used to reimburse the pharmacy.
- 489 (5) (a) The right to appeal in Subsection (4)(e) shall be:
- 490 (i) limited to 60 days following the initial claim adjudication; and
- 491 (ii) investigated and resolved by the pharmacy benefit manager within seven business
492 days.

493 (b) If the appeal is denied, the pharmacy benefit manager shall provide the contracted
494 pharmacy the reason for the denial and notify the contracted pharmacy where the drug product
495 may be purchased at a price at or below the maximum allowable cost.

496 (c) If the appeal is not denied:

497 (i) the pharmacy benefit manager shall make a payment adjustment to a pharmacy
498 retroactively to the date of the claim adjudication, if it is determined that the maximum
499 allowable cost has been applied incorrectly; and

500 (ii) when the change in maximum allowable cost for an adjusted cost rate becomes
501 effective, all pharmacies in the pharmacy network shall be informed that the adjudicated claim
502 may be submitted for payment again at the adjusted cost rate.

503 Section 13. Section **31A-44-402** is enacted to read:

504 **31A-44-402. General duties of a pharmacy benefit manager.**

505 A pharmacy benefit manager shall:

506 (1) have a written agreement with each health benefit plan to which the pharmacy
507 benefit manager provides a pharmacy benefit management service; and

508 (2) comply with the audit provisions of Section 58-17b-622.

509 Section 14. Section **31A-44-403** is enacted to read:

510 **31A-44-403. Fees -- Dedicated credit.**

511 The commissioner shall establish and impose a fee on a pharmacy benefit manager to
512 pay the costs of administering this chapter. The fee imposed under this section shall be a
513 dedicated credit, as defined in Section 51-5-3, to the department to pay for the cost of
514 administering this chapter.

515 Section 15. Section **31A-44-404** is enacted to read:

516 **31A-44-404. Penalties imposed by commissioner -- Dedicated credit.**

517 (1) A pharmacy benefit manager that is found by the commissioner, after a hearing
518 conducted in accordance with Title 63G, Chapter 4, Administrative Procedures Act, to be in
519 violation of any provisions of this title, shall:

520 (a) for each separate violation, pay a civil penalty in an amount designated by the
521 commissioner by rule; and

522 (b) be subject to revocation or suspension of the pharmacy benefit manager's license.

523 (2) The penalties imposed under this section shall be a dedicated credit, as defined in

524 Section 51-5-3, to the department to pay for the cost of administering this chapter and the cost
525 of market conduct reviews conducted by the department.

526 (3) Nothing in this section affects the right of the commissioner to impose any other
527 penalties provided in this title.

528 Section 16. Section **31A-44-405** is enacted to read:

529 **31A-44-405. Administrative Rules.**

530 The commissioner may adopt administrative rules in accordance with Title 63G,
531 Chapter 3, Utah Administrative Rulemaking Act, to enforce the provisions of this chapter.

532 Section 17. **Effective date.**

533 This bill takes effect on July 1, 2014.

Legislative Review Note
as of 2-5-14 4:00 PM

Office of Legislative Research and General Counsel

R156-17b-102. Definitions.

(6) "Centralized Prescription Processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug utilization review (DUR), claims adjudication, refill authorizations, ~~and~~ therapeutic interventions, and order entry or verification.

R156-17b-614f. Operating Standards - Class A, B, and E - Central Prescription Processing and Filling.

In accordance with Subsection 58-17b-601(1), the following operating standards apply to Class A, Class B, and Class E pharmacies that engage in central prescription processing or central prescription filling. The operating standards include:

(1) A pharmacy may perform centralized prescription processing or centralized prescription filling services for a dispensing pharmacy if the parties:

(a) have common ownership or common administrative control; or

(b) have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations; and

(c) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a prescription drug order.

(2) The parties performing or contacting for centralized prescription processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the Division upon inspection and that includes the following:

(a) a description of how the parties will comply with federal and state laws and regulations;

(b) the maintenance of appropriate records to identify the responsible pharmacists and the dispensing and counseling process;

(c) the maintenance mechanism for tracking the prescription drug order during each step in the dispensing process;

(d) the provision of adequate security to protect the integrity and prevent the illegal use or disclosure of protected health information;

(e) the maintenance of a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

Arizona Shared Services Rules

R4-23-621. Shared Services

- A. Before participating in shared services, a pharmacy shall have either a current resident or non-resident pharmacy permit issued by the Board.
- B. A pharmacy may provide or utilize shared services functions only if the pharmacies involved:
 - 1. Have the same owner; or
 - 2. Have a written contract or agreement that outlines the services provided and the shared responsibilities of each party in complying with federal and state pharmacy statutes and rules; and
 - 3. Share a common electronic file or technology that allows access to information necessary or required to perform shared services in conformance with the pharmacy act and the Board's rules.
- C. Notifications to patients.
 - 1. Before using shared services provided by another pharmacy, a pharmacy permittee shall:
 - a. Notify patients that their orders may be processed or filled by another pharmacy; and
 - b. Provide the name of that pharmacy or, if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may process or fill the order, notify the patient of this fact. The notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy.
 - 2. If an order is delivered directly to the patient by a filling pharmacy and not returned to the requesting pharmacy, the filling pharmacy permittee shall ensure that the following is placed on the prescription container or on a separate sheet delivered with the prescription container:
 - a. The local, and if applicable, the toll-free telephone number of the filling pharmacy; and
 - b. A statement that conveys to the patient or patient's care-giver the following information: "Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at (insert the filling pharmacy's local and toll-free telephone numbers)."
 - 3. The provisions of subsection (C) do not apply to orders delivered to patients in facilities where a licensed health care professional is responsible for administering the prescription medication to the patient.
- D. A pharmacy permittee engaged in shared services shall:
 - 1. Maintain manual or electronic records that identify, individually for each order processed, the name, initials, or identification code of each pharmacist, graduate intern, pharmacy intern, pharmacy technician, and pharmacy technician trainee who took part in the order interpretation, order entry verification, drug utilization review, drug compatibility and drug allergy review, final order verification, therapeutic intervention, or refill authorization functions performed at that pharmacy;
 - 2. Maintain manual or electronic records that identify, individually for each order filled or dispensed, the name, initials, or identification code of each pharmacist, graduate intern,

- pharmacy intern, pharmacy technician, and pharmacy technician trainee who took part in the filling, dispensing, and counseling functions performed at that pharmacy;
3. Report to the Board as soon as practical the results of any disciplinary action taken by another state's pharmacy regulatory agency involving shared services;
 4. Maintain a mechanism for tracking the order during each step of the processing and filling procedures performed at the pharmacy;
 5. Provide for adequate security to protect the confidentiality and integrity of patient information; and
 6. Provide for inspection of any required record or information within 72 hours of any request by the Board or its designee.
- E. Each pharmacy permittee provides or utilizes shared services shall develop, implement, review, revise, and comply with joint policies and procedures for shared services in the manner described in R4-23-610(A)(2). Each pharmacy permittee is required to maintain only those portions of the joint policies and procedures that relate to that pharmacy's operations. The policies and procedures shall:
1. Outline the responsibilities of each of the pharmacies;
 2. Include a list of the name, address, telephone numbers, and all license and permit numbers of the pharmacies involved in shared services; and
 3. Include policies and procedures for:
 - a. Notifying patients that their orders may be processed or filled by another pharmacy and providing the name of that pharmacy;
 - b. Protecting the confidentiality and integrity of patient information;
 - c. Dispensing orders when the filled order is not received or the patient comes in before the order is received;
 - d. Maintaining required manual or electronic records to identify the name, initials, or identification code and specific activity or activities of each pharmacist, graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee who performed any shared services;
 - e. Complying with federal and state laws; and
 - f. Operating a continuous quality improvement program for shared services, designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.
- F. Nothing in this Section shall prohibit an individual pharmacist licensed in Arizona, who is an employee of or under contract with a pharmacy, or an Arizona-licensed graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee, working under the supervision of the pharmacist, from accessing that pharmacy's electronic database from inside or outside the pharmacy and performing the order processing functions permitted by the pharmacy act, if both of the following conditions are met:
1. The pharmacy establishes controls to protect the confidentiality and integrity of patient information; and
 2. None of the database is duplicated, downloaded, or removed from the pharmacy's electronic database.

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R156-17b-612. Operating Standards - Prescriptions.

In accordance with Subsection 58-17b-601(1), the following shall apply to prescriptions:

(1) Prescription orders for controlled substances (including prescription transfers) shall be handled according to the rules of the Federal Drug Enforcement Administration.

(2) A prescription issued by an authorized licensed practitioner, if verbally communicated by an agent of that practitioner upon that practitioner's specific instruction and authorization, may be accepted by a pharmacist or pharmacy intern.

(3) A prescription issued by a licensed prescribing practitioner, if electronically communicated by an agent of that practitioner, upon that practitioner's specific instruction and authorization, may be accepted by a pharmacist, pharmacy intern and pharmacy technician.

(4) In accordance with Sections 58-17b-609 and 58-17b-611, prescription files, including refill information, shall be maintained for a minimum of five years and shall be immediately retrievable in written or electronic format.

(5) Prescriptions for legend drugs having a remaining authorization for refill may be transferred by the pharmacist or pharmacy intern at the pharmacy holding the prescription to a pharmacist or pharmacy intern at another pharmacy upon the authorization of the patient to whom the prescription was issued or electronically as authorized under Subsection R156-17b-613(9). The transferring pharmacist or pharmacy intern and receiving pharmacist or pharmacy intern shall act diligently to ensure that the total number of authorized refills is not exceeded. The following additional terms apply to such a transfer:

(a) the transfer shall be communicated directly between pharmacists or pharmacy interns or as authorized under Subsection R156-17b-613(9);

(b) both the original and the transferred prescription drug orders shall be maintained for a period of five years from the date of the last refill;

(c) the pharmacist or pharmacy intern transferring the prescription drug order shall void the prescription electronically or write void/transfer on the face of the invalidated prescription manually;

(d) the pharmacist or pharmacy intern receiving the transferred prescription drug order shall:

(i) indicate on the prescription record that the prescription was transferred electronically or manually; and

(ii) record on the transferred prescription drug order the following information:

(A) original date of issuance and date of dispensing or receipt, if different from date of issuance;

(B) original prescription number and the number of refills authorized on the original prescription drug order;

(C) number of valid refills remaining and the date of last refill, if applicable;

(D) the name and address of the pharmacy and the name of the pharmacist or pharmacy intern to which such prescription is transferred; and

(E) the name of the pharmacist or pharmacy intern transferring the prescription drug order information;

(e) the data processing system shall have a mechanism to prohibit the transfer or refilling of legend drugs or controlled substance prescription drug orders which have

been previously transferred; and

(f) a pharmacist or pharmacy intern may not refuse to transfer original prescription information to another pharmacist or pharmacy intern who is acting on behalf of a patient and who is making a request for this information as specified in Subsection (12) of this section.

(6) Prescriptions for terminal patients in licensed hospices, home health agencies or nursing homes may be partially filled if the patient has a medical diagnosis documenting a terminal illness and may not need the full prescription amount.

(7) Refills may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order;

(8) If there are no refill instructions on the original prescription drug order, or if all refills authorized on the original prescription drug order have been dispensed, authorization from the prescribing practitioner shall be obtained prior to dispensing any refills.

(9) Refills of prescription drug orders for legend drugs may not be refilled after one year from the date of issuance of the original prescription drug order without obtaining authorization from the prescribing practitioner prior to dispensing any additional quantities of the drug.

(10) Refills of prescription drug orders for controlled substances shall be done in accordance with Subsection 58-37-6(7)(f).

(11) A pharmacist may exercise his professional judgment in refilling a prescription drug order for a drug, other than a controlled substance listed in Schedule II, without the authorization of the prescribing practitioner, provided:

(a) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(b) either:

(i) a natural or manmade disaster has occurred which prohibits the pharmacist from being able to contact the practitioner; or

(ii) the pharmacist is unable to contact the practitioner after a reasonable effort, the effort should be documented and said documentation should be available to the Division;

(c) the quantity of prescription drug dispensed does not exceed a 72-hour supply, unless the packaging is in a greater quantity;

(d) the pharmacist informs the patient or the patient's agent at the time of dispensing that the refill is being provided without such authorization and that authorization of the practitioner is required for future refills;

(e) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable time;

(f) the pharmacist maintains a record of the emergency refill containing the information required to be maintained on a prescription as specified in this subsection; and

(g) the pharmacist affixes a label to the dispensing container as specified in Section 58-17b-602.

(12) If the prescription was originally filled at another pharmacy, the pharmacist may exercise his professional judgment in refilling the prescription provided:

(a) the patient has the prescription container label, receipt or other documentation

from the other pharmacy which contains the essential information;

(b) after a reasonable effort, the pharmacist is unable to contact the other pharmacy to transfer the remaining prescription refills or there are no refills remaining on the prescription;

(c) the pharmacist, in his professional judgment, determines that such a request for an emergency refill is appropriate and meets the requirements of (a) and (b) of this subsection; and

(d) the pharmacist complies with the requirements of Subsections (11)(c) through (g) of this section.

(13) The address specified in Subsection 58-17b-602(1)(b) shall be a physical address, not a post office box.

(14) In accordance with Subsection 58-37-6(7)(e), a prescription may not be written, issued, filled, or dispensed for a Schedule I controlled substance unless:

(a) the person who writes the prescription is licensed to prescribe Schedule I controlled substances; and

(b) the prescribed controlled substance is to be used in research.

(15) Effective November 30, 2014, prescription container labels shall comply with standards established in USP-NF Chapter 17.

(16) Discharge prescriptions shall be dispensed and labeled in accordance with standards established in this section except that medications packaged in unit-of-dose containers, such as metered-dose inhalers, insulin pens, topical creams or ointments, or ophthalmic or otic preparation that are administered to the patient during the time patient was a patient in the hospital, may be provided to the patient upon discharge provided the pharmacy receives a discharge order or prescription containing the following information:

(a) patient name;

(b) medication name and strength;

(c) directions for use;

(d) duration of therapy, if applicable; and

(e) pharmacy name and phone number.