PHARMACY BENEFIT MANAGER AMENDMENTS 1 2 2019 GENERAL SESSION 3 STATE OF UTAH **Chief Sponsor: Paul Ray** 4 5 Senate Sponsor: Evan J. Vickers 6 Cosponsors: Dan N. Johnson Angela Romero 7 Patrice M. Arent Brian S. King Douglas V. Sagers 8 Melissa G. Ballard Karen Kwan Mike Schultz 9 Stewart E. Barlow Kelly B. Miles Lawanna Shurtliff 10 Walt Brooks Carol Spackman Moss Casey Snider 11 Kay J. Christofferson Merrill F. Nelson Norman K. Thurston Christine F. Watkins 12 Brad M. Daw Lee B. Perry 13 Steve Eliason Val K. Potter Elizabeth Weight 14 Francis D. Gibson Marie H. Poulson Mark A. Wheatley 15 Mike Winder Stephen G. Handy Susan Pulsipher 16 Jon Hawkins Tim Quinn Sandra Hollins

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- 19 **General Description:**
- This bill amends and creates requirements for pharmacy benefit managers.
- 21 **Highlighted Provisions:**
- This bill:
- creates a pharmacy benefit manager license;



24 requires a person who acts as a pharmacy benefit manager in the state to be licensed 25 by the Insurance Department; and 26 reactes certain operating and reporting requirements for pharmacy benefit managers. 27 Money Appropriated in this Bill: 28 None 29 **Other Special Clauses:** 30 This bill provides a special effective date. 31 **Utah Code Sections Affected:** 32 AMENDS: 33 **31A-2-201.2**, as last amended by Laws of Utah 2018, Chapter 319 34 **ENACTS:** 35 **31A-46-101**, Utah Code Annotated 1953 36 **31A-46-102**, Utah Code Annotated 1953 37 **31A-46-201**, Utah Code Annotated 1953 38 **31A-46-202**, Utah Code Annotated 1953 39 **31A-46-301**, Utah Code Annotated 1953 40 **31A-46-304**, Utah Code Annotated 1953 41 **31A-46-401**, Utah Code Annotated 1953 42 **31A-46-402**, Utah Code Annotated 1953 43 RENUMBERS AND AMENDS: 44 31A-46-302, (Renumbered from 58-17b-626, as enacted by Laws of Utah 2018, Chapter 305) 45 31A-46-303, (Renumbered from 31A-22-640, as last amended by Laws of Utah 2015, 46 Chapter 258) 47 48 49 *Be it enacted by the Legislature of the state of Utah:* 50 Section 1. Section **31A-2-201.2** is amended to read: 51 31A-2-201.2. Evaluation of health insurance market. 52 (1) Each year the commissioner shall: 53 (a) conduct an evaluation of the state's health insurance market; 54 (b) report the findings of the evaluation to the Health and Human Services Interim

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Committee before December 1 of each year; and

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56	(c) publish the findings of the evaluation on the department website.
57	(2) The evaluation required by this section shall:
58	(a) analyze the effectiveness of the insurance regulations and statutes in promoting a
59	healthy, competitive health insurance market that meets the needs of the state, and includes an
60	analysis of:
61	(i) the availability and marketing of individual and group products;
62	(ii) rate changes;
63	(iii) coverage and demographic changes;
64	(iv) benefit trends;
65	(v) market share changes; and
66	(vi) accessibility;
67	(b) assess complaint ratios and trends within the health insurance market, which
68	assessment shall include complaint data from the Office of Consumer Health Assistance within
69	the department;
70	(c) contain recommendations for action to improve the overall effectiveness of the
71	health insurance market, administrative rules, and statutes; [and]
72	(d) include claims loss ratio data for each health insurance company doing business in
73	the state[:]; and
74	(e) include information about pharmacy benefit managers collected under Section
75	<u>31A-46-301.</u>
76	(3) When preparing the evaluation and report required by this section, the
77	commissioner may seek the input of insurers, employers, insured persons, providers, and others
78	with an interest in the health insurance market.
79	(4) The commissioner may adopt administrative rules for the purpose of collecting the
80	data required by this section, taking into account the business confidentiality of the insurers.
81	(5) Records submitted to the commissioner under this section shall be maintained by
82	the commissioner as protected records under Title 63G, Chapter 2, Government Records
83	Access and Management Act.
84	Section 2. Section 31A-46-101 is enacted to read:
85	CHAPTER 46. PHARMACY BENEFIT MANAGER LICENSING ACT

86	Part 1. General Provisions
87	31A-46-101. Title.
88	This chapter is known as the "Pharmacy Benefit Manager Licensing Act."
89	Section 3. Section 31A-46-102 is enacted to read:
90	31A-46-102. Definitions.
91	As used in this chapter:
92	(1) "Administrative fee" means any payment, other than a rebate, that a pharmaceutical
93	manufacturer makes directly or indirectly to a pharmacy benefit manager.
94	(2) "Contracting insurer" means an insurer as defined in Section 31A-22-636 with
95	whom a pharmacy benefit manager contracts to provide a pharmacy benefit management
96	service.
97	(3) "Pharmacist" means the same as that term is defined in Section 58-17b-102.
98	(4) "Pharmacy" means the same as that term is defined in Section 58-17b-102.
99	(5) "Pharmacy benefits management service" means any of the following services
100	provided to a health benefit plan, or to a participant of a health benefit plan:
101	(a) negotiating the amount to be paid by a health benefit plan for a prescription drug; or
102	(b) administering or managing a prescription drug benefit provided by the health
103	benefit plan for the benefit of a participant of the health benefit plan, including administering
104	or managing:
105	(i) a mail service pharmacy;
106	(ii) a specialty pharmacy;
107	(iii) claims processing;
108	(iv) payment of a claim;
109	(v) retail network management;
110	(vi) clinical formulary development;
111	(vii) clinical formulary management services;
112	(viii) rebate contracting;
113	(ix) rebate administration;
114	(x) a participant compliance program;
115	(xi) a therapeutic intervention program;
116	(xii) a disease management program; or

117	(xiii) a service that is similar to, or related to, a service described in Subsection (5)(a)
118	or (5)(b)(i) through (xii).
119	(6) "Pharmacy benefit manager" means a person licensed under this chapter to provide
120	a pharmacy benefit management service.
121	(7) "Pharmacy service" means a product, good, or service provided to an individual by
122	a pharmacy or pharmacist.
123	(8) (a) "Rebate" means a refund, discount, or other price concession that is paid by a
124	pharmaceutical manufacturer to a pharmacy benefit manager based on a prescription drug's
125	utilization or effectiveness.
126	(b) "Rebate" does not include an administrative fee.
127	Section 4. Section 31A-46-201 is enacted to read:
128	Part 2. Licensure
129	31A-46-201. License required.
130	(1) A person may not perform, offer to perform, or advertise any pharmacy benefits
131	management service in the state unless the person is licensed as a pharmacy benefit manager
132	under this chapter.
133	(2) A person may not utilize the services of another person as a pharmacy benefit
134	manager if the person knows or has reason to know that the other person does not have a
135	license under this chapter.
136	Section 5. Section 31A-46-202 is enacted to read:
137	31A-46-202. Application for licensure.
138	(1) To obtain or renew a license as a pharmacy benefit manager, a person shall:
139	(a) submit an application to the commissioner on forms and in a manner established by
140	the commissioner by rule made in accordance with Title 63G, Chapter 3, Utah Administrative
141	Rulemaking Act; and
142	(b) pay a licensure fee established by the department in accordance with Section
143	<u>31A-3-103.</u>
144	(2) (a) The commissioner may require an applicant to submit information or
145	documentation regarding the management and ownership of the pharmacy benefit manager in
146	the application described in Subsection (1)(a).
147	(b) Any material change in the information submitted in an application described in

148	Subsection (1)(a) shall be reported to the department within 30 days after the day on which the
149	information changes.
150	(3) The term of a license issued under this section is one year.
151	Section 6. Section 31A-46-301 is enacted to read:
152	Part 3. Operating Requirements
153	31A-46-301. Reporting requirements.
154	(1) Before April 1 of each year, a pharmacy benefit manager operating in the state shall
155	report to the department, for the previous calendar year:
156	(a) any insurer, pharmacy, or pharmacist in the state with which the pharmacy benefit
157	manager had a contract;
158	(b) the total value, in the aggregate, of all rebates and administrative fees that are
159	attributable to enrollees of a contracting insurer; and
160	(c) the percentage of aggregate rebates that the pharmacy benefit manager retained
161	under the pharmacy benefit manager's agreement to provide pharmacy benefits management
162	services to a contracting insurer.
163	(2) Records submitted to the commissioner under Subsections (1)(b) and (c) are a
164	protected record under Title 63G, Chapter 2, Government Records Access and Management
165	Act.
166	(3) (a) The department shall publish the information provided by a pharmacy benefit
167	manager under Subsection (1)(c) in the annual report described in Section 31A-2-201.2.
168	(b) The department may not publish information submitted under Subsection (1)(b) or
169	(c) in a manner that:
170	(i) makes a specific submission from a contracting insurer or pharmacy benefit
171	manager identifiable; or
172	(ii) is likely to disclose information that is a trade secret as defined in Section 13-24-2.
173	(c) At least 30 days before the day on which the department publishes the data, the
174	department shall provide a pharmacy benefit manager that submitted data under Subsection
175	(1)(b) or (c) with:
176	(i) a general description of the data that will be published by the department;
177	(ii) an opportunity to submit to the department, within a reasonable period of time and
178	in a manner established by the department by rule made in accordance with Title 63G, Chapter

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1/9	5, Otan Administrative Rulemaking Act.
180	(A) any correction of errors, with supporting evidence and comments; and
181	(B) information that demonstrates that the publication of the data will violate
182	Subsection (3)(b), with supporting evidence and comments.
183	Section 7. Section 31A-46-302, which is renumbered from Section 58-17b-626 is
184	renumbered and amended to read:
185	[58-17b-626]. <u>31A-46-302.</u> Direct or indirect remuneration by pharmacy
186	benefit managers Disclosure of customer costs Limit on customer payment for
187	prescription drugs.
188	(1) As used in this section:
189	(a) "Allowable claim amount" means the amount paid by an insurer under the
190	customer's health benefit plan.
191	[(a)] (b) "Cost share" means the amount paid by an insured customer under the
192	customer's health benefit plan.
193	[(b)] (c) "Direct or indirect remuneration" means any adjustment in the total
194	compensation:
195	(i) received by a pharmacy from a pharmacy [benefits manager or coordinator] benefit
196	manager for the sale of a drug, device, or other product or service; and
197	(ii) that is determined after the sale of the product or service.
198	[(c)] (d) "Health benefit plan" means the same as that term is defined in Section
199	31A-1-301.
200	(e) "Pharmacy reimbursement" means the amount paid to a pharmacy by a pharmacy
201	benefit manager for a dispensed prescription drug.
202	[(d)] (f) "Pharmacy services administration organization" means an entity that contracts
203	with a pharmacy to assist with third-party payer interactions and administrative services related
204	to third-party payer interactions, including:
205	(i) contracting with a pharmacy [benefits manager or coordinator] benefit manager on
206	behalf of the pharmacy; and
207	(ii) managing a pharmacy's claims payments from third-party payers.
208	[(e)] (g) "Pharmacy service entity" means:
209	(i) a pharmacy services administration organization; or

210	(11) a pharmacy [benefits manager or coordinator] benefit manager.
211	[(f)] (h) (i) "Reimbursement report" means a report on the adjustment in total
212	compensation for a claim.
213	(ii) "Reimbursement report" does not include a report on adjustments made pursuant to
214	a pharmacy audit or reprocessing.
215	[(g)] (i) "Sale" means a prescription drug claim covered by a health benefit plan.
216	(2) If a pharmacy service entity engages in direct or indirect remuneration with a
217	pharmacy, the pharmacy service entity shall make a reimbursement report available to the
218	pharmacy upon the pharmacy's request.
219	(3) For the reimbursement report described in Subsection (2), the pharmacy service
220	entity shall:
221	(a) include the adjusted compensation amount related to a claim and the reason for the
222	adjusted compensation; and
223	(b) provide the reimbursement report:
224	(i) in accordance with the contract between the pharmacy and the pharmacy service
225	entity;
226	(ii) in an electronic format that is easily accessible; and
227	(iii) within 120 days after the day on which the pharmacy [benefits manager or
228	coordinator] benefit manager receives a report of a sale of a product or service by the
229	pharmacy.
230	(4) A pharmacy service entity shall, upon a pharmacy's request, provide the pharmacy
231	with:
232	(a) the reasons for any adjustments contained in a reimbursement report; and
233	(b) an explanation of the reasons provided in Subsection (4)(a).
234	(5) (a) A pharmacy [benefits manager or coordinator] benefit manager may not prohibit
235	or penalize the disclosure by a pharmacist of:
236	(i) an insured customer's cost share for a covered prescription drug;
237	(ii) the availability of any therapeutically equivalent alternative medications; or
238	(iii) alternative methods of paying for the prescription medication, including paying the
239	cash price, that are less expensive than the cost share of the prescription drug.
240	(b) Penalties that are prohibited under Subsection (5)(a) include increased utilization

241 review, reduced payments, and other financial disincentives. 242 (6) A pharmacy [benefits manager or coordinator] benefit manager may not require an insured customer to pay, for a covered prescription drug, more than the lesser of: 243 244 (a) the applicable cost share of the prescription drug being dispensed; [or] 245 (b) the applicable allowable claim amount of the prescription drug being dispensed; 246 (c) the applicable pharmacy reimbursement of the prescription drug being dispensed; or [(b)] (d) the retail price of the drug without prescription drug coverage. 247 248 Section 8. Section 31A-46-303, which is renumbered from Section 31A-22-640 is renumbered and amended to read: 249 250 [31A-22-640]. 31A-46-303. Insurer and pharmacy benefit management 251 services -- Registration -- Maximum allowable cost -- Audit restrictions. 252 (1) [For purposes of] As used in this section: (a) "Maximum allowable cost" means: 253 254 (i) a maximum reimbursement amount for a group of pharmaceutically and 255 therapeutically equivalent drugs; or 256 (ii) any similar reimbursement amount that is used by a pharmacy benefit manager to 257 reimburse pharmacies for multiple source drugs. 258 (b) "Obsolete" means a product that may be listed in national drug pricing compendia 259 but is no longer available to be dispensed based on the expiration date of the last lot manufactured. 260 261 (c) "Pharmacy benefit manager" means a person or entity that provides pharmacy 262 benefit management services as defined in Section 49-20-502 on behalf of an insurer as defined 263 in Subsection 31A-22-636(1). 264 (2) An insurer and an insurer's pharmacy benefit manager is subject to the pharmacy 265 audit provisions of Section 58-17b-622. 266 (3) A pharmacy benefit manager shall not use maximum allowable cost as a basis for 267 reimbursement to a pharmacy unless: (a) the drug is listed as "A" or "B" rated in the most recent version of the United States 268 269 Food and Drug Administration's approved drug products with therapeutic equivalent 270 evaluations, also known as the "Orange Book," or has an "NR" or "NA" rating or similar rating 271 by a nationally recognized reference; and

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272 (b) the drug is: 273 (i) generally available for purchase in this state from a national or regional wholesaler; 274 and 275 (ii) not obsolete. 276 (4) The maximum allowable cost may be determined using comparable and current 277 data on drug prices obtained from multiple nationally recognized, comprehensive data sources, 278 including wholesalers, drug file vendors, and pharmaceutical manufacturers for drugs that are 279 available for purchase by pharmacies in the state. 280 (5) For every drug for which the pharmacy benefit manager uses maximum allowable cost to reimburse a contracted pharmacy, the pharmacy benefit manager shall: 281 282 (a) include in the contract with the pharmacy information identifying the national drug 283 pricing compendia and other data sources used to obtain the drug price data; 284 (b) review and make necessary adjustments to the maximum allowable cost, using the most recent data sources identified in Subsection (5)(a), at least once per week; 285 286 (c) provide a process for the contracted pharmacy to appeal the maximum allowable 287 cost in accordance with Subsection (6); and 288 (d) include in each contract with a contracted pharmacy a process to obtain an update 289 to the pharmacy product pricing files used to reimburse the pharmacy in a format that is readily 290 available and accessible. 291 (6) (a) The right to appeal in Subsection (5)(c) shall be: 292 (i) limited to 21 days following the initial claim adjudication; and 293 (ii) investigated and resolved by the pharmacy benefit manager within 14 business 294 days. 295 (b) If an appeal is denied, the pharmacy benefit manager shall provide the contracted 296 pharmacy with the reason for the denial and the identification of the national drug code of the 297 drug that may be purchased by the pharmacy at a price at or below the price determined by the 298 pharmacy benefit manager.

(7) The contract with each pharmacy shall contain a dispute resolution mechanism in

[(8) (a) To conduct business in the state, a pharmacy benefit manager shall register

with the Division of Corporations and Commercial Code within the Department of Commerce

the event either party breaches the terms or conditions of the contract.

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303	and annually renew the registration. To register under this section, the pharmacy benefit
304	manager shall submit an application which shall contain only the following information:
305	[(i) the name of the pharmacy benefit manager;]
306	[(ii) the name and contact information for the registered agent for the pharmacy benefit
307	manager; and]
308	[(iii) if applicable, the federal employer identification number for the pharmacy benefit
309	manager.]
310	[(b) The Department of Commerce may establish a fee in accordance with Title 63J,
311	Chapter 1, Budgetary Procedures Act, for the initial registration and the annual renewal of the
312	registration, which may not exceed \$100 per year.]
313	[(c) The following entities do not have to register as a pharmacy benefit manager under
314	Subsection (8)(a) when the entity is providing formulary services to its own patients,
315	employees, members, or beneficiaries:]
316	[(i) a health care facility licensed under Title 26, Chapter 21, Health Care Facility
317	Licensing and Inspection Act;
318	[(ii) a pharmacy licensed under Title 58, Chapter 17b, Pharmacy Practice Act;]
319	[(iii) a health care professional licensed under Title 58, Occupations and Professions;]
320	[(iv) a health insurer; and]
321	[(v) a labor union.]
322	[(9)] (8) This section does not apply to a pharmacy benefit manager when the
323	pharmacy benefit manager is providing pharmacy benefit management services on behalf of the
324	state Medicaid program.
325	Section 9. Section 31A-46-304 is enacted to read:
326	31A-46-304. Claims practices.
327	(1) A pharmacy benefit manager shall permit a pharmacy to collect the amount of a
328	customer's cost share from any source.
329	(2) A pharmacy benefit manager may not deny or reduce a reimbursement to a
330	pharmacy or a pharmacist after the adjudication of the claim, unless:
331	(a) the pharmacy or pharmacist submitted the original claim fraudulently;
332	(b) the original reimbursement was incorrect because:
333	(i) the pharmacy or pharmacist had already been paid for the pharmacy service; or

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334	(ii) an unintentional error resulted in an incorrect reimbursement; or
335	(c) the pharmacy service was not rendered by the pharmacy or pharmacist.
336	(3) Subsection (2) does not apply if:
337	(a) an investigative audit of pharmacy records for fraud, waste, abuse, or other
338	intentional misrepresentation indicates that the pharmacy or pharmacist engaged in criminal
339	wrongdoing, fraud, or other intentional misrepresentation; or
340	(b) the reimbursement is reduced as the result of the reconciliation of a reimbursement
341	amount under a performance contract if:
342	(i) the performance contract lays out clear performance standards under which the
343	reimbursement for a specific drug may be increased or decreased; and
344	(ii) the agreement between the pharmacy benefit manager and the pharmacy or
345	pharmacist explicitly states, in a separate document that is signed by the pharmacy benefit
346	manager and the pharmacy or pharmacist, that the provisions of Subsection (2) do not apply.
347	Section 10. Section 31A-46-401 is enacted to read:
348	Part 4. Miscellaneous
349	31A-46-401. Penalties.
350	A person that violates a provision of this chapter is subject to the penalties described in
351	Section 31A-2-308.
352	Section 11. Section 31A-46-402 is enacted to read:
353	31A-46-402. Severability.
354	If any provision of this chapter or the application of any provision of this chapter is
355	found invalid, the remainder of this chapter shall be given effect without the invalid provision
356	or application.
357	Section 12. Effective date.
358	This bill takes effect on July 1, 2019.