Bill No. HB 7045 (2020)

Amendment No. 1

	COMMITTEE/SUBCOMMITTEE ACTION
	ADOPTED (Y/N)
	ADOPTED AS AMENDED (Y/N)
	ADOPTED W/O OBJECTION (Y/N)
	FAILED TO ADOPT (Y/N)
	WITHDRAWN (Y/N)
	OTHER
1	Committee/Subcommittee hearing bill: Health & Human Services
2	Committee
3	Representative Andrade offered the following:
4	
5	Amendment (with title amendment)
6	Remove everything after the enacting clause and insert:
7	Section 1. Subsection (16) is added to section 499.012,
8	Florida Statutes, to read:
9	499.012 Permit application requirements
10	(16) A permit for a prescription drug manufacturer or a
11	nonresident prescription drug manufacturer is subject to the
12	requirements of s. 499.026.
13	Section 2. Section 499.026, Florida Statutes, is created
14	to read:
15	499.026 Prescription drug price increases
16	(1) As used in this section, the term:
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17	(a) "Drug Price Increase" means a manufacturer price
18	increase equal to or greater than 15 percent of the price of a
19	drug for a brand-name prescription drug with a wholesale
20	acquisition cost of \$50 or more, or a manufacturer price
21	increase equal to or greater than 25 percent of the price of a
22	drug for a generic prescription drug or a biosimilar drug with a
23	wholesale acquisition cost of \$25 or more, for a 30-day supply.
24	(b) "Health insurer" means a health insurer issuing major
25	medical coverage through an individual or group policy or a
26	health maintenance organization issuing major medical coverage
27	through an individual or group contract, regulated under chapter
28	627 or chapter 641.
29	(c) "Manufacturer" means any person holding a prescription
30	drug manufacturer permit or a nonresident prescription drug
31	manufacturer permit under s. 499.01.
32	(d) "Wholesale acquisition cost" means that term as
33	defined in 42 U.S.C. § 1395w-3a.
34	(2) At least 60 days before the effective date of any drug
35	price increase, a manufacturer must provide notification of the
36	upcoming drug price increase and the amount of the drug price
37	increase to every health insurer that covers the drug. A
38	manufacturer must make the notification using the contact list
39	published by the Office of Insurance Regulation pursuant to ss.
40	627.42394 and 641.3131. Notification shall be presumed to occur
41	on the date that a manufacturer attempts to communicate with the
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42	applicable point of contact published by the Office of Insurance
43	Regulation.
44	(3) By April 1 of each year, a manufacturer must submit a
45	report to the department and the Office of Insurance Regulation
46	on each drug price increase made during the previous calendar
47	year. At a minimum, the report shall include:
48	(a) A list of all drugs affected by the drug price
49	increase and both the dollar amount of each drug price increase
50	and the percentage increase of each drug price increase,
51	relative to the previous price of the drug.
52	(b) A complete description of the factors contributing to
53	the drug price increase.
54	Section 3. Section 624.491, Florida Statutes, is created
55	to read:
56	624.491 Pharmacy audits
57	(1) A health insurer or health maintenance organization
58	providing pharmacy benefits through a major medical individual
59	or group health policy or health maintenance contract,
60	respectively, shall comply with the requirements of this section
61	when the insurer or health maintenance organization or any
62	entity acting on behalf of the insurer or health maintenance
63	organization, including, but not limited to, a pharmacy benefit
64	manager, audits the records of a pharmacy licensed under chapter
65	465. This section does not apply to audits in which suspected
66	fraudulent activity or other intentional or willful
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67	misrepresentation is evidenced by a physical review, review of
68	claims data or statements, or other investigative methods;
69	audits of claims paid for by federally funded programs; or
70	concurrent reviews or desk audits that occur within 3 business
71	days of transmission of a claim and where no chargeback or
72	recoupment is demanded. An entity that audits a pharmacy located
73	within a Health Care Fraud Prevention and Enforcement Action
74	Team (HEAT) Task Force area designated by the United States
75	Department of Health and Human Services and the United States
76	Department of Justice may dispense with the notice requirements
77	if such pharmacy has been a member of a credentialed provider
78	network for less than 12 months.
79	(2) An entity conducting a pharmacy audit shall:
80	(a) Notify the pharmacy at least 7 calendar days before
81	the initial onsite audit for each audit cycle.
82	(b) Ensure the audit is not initiated during the first 3
83	calendar days of a month unless the pharmacist consents
84	otherwise.
85	(c) Limit the audit period to 24 months after the date a
86	claim is submitted to or adjudicated by the entity.
87	(d) Provide a preliminary audit report to the pharmacy
88	within 120 days after the conclusion of the audit.
89	(e) Provide a final audit report to the pharmacy within 6
90	months after having providing the preliminary audit report.
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91	Section 4. Section 627.42394, Florida Statutes, is created
92	to read:
93	627.42394 Formulary changes resulting from drug price
94	increases
95	(1) A health insurer issuing a major medical individual or
96	group policy shall submit, and update as necessary, contact
97	information for a single point-of-contact for use by
98	prescription drug manufacturers to comply with s. 499.026. The
99	Office shall maintain and publish a list of such points of
100	contact.
101	(2) A health insurer issuing a major medical individual or
102	group policy must provide written notice to affected insureds at
103	least 30 days in advance of making a drug formulary change
104	resulting from a drug price increase reported pursuant to s.
105	499.026.
106	(3) This section applies to policies entered into or
107	renewed on or after January 1, 2021.
108	Section 5. Section 627.64741, Florida Statutes, is amended
109	to read:
110	627.64741 Pharmacy benefit manager contracts
111	(1) As used in this section, the term:
112	(a) "Administrative fee" means a fee or payment under a
113	contract between a health insurer and a pharmacy benefit manager
114	associated with the pharmacy benefit manager's administration of
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115	the insurer's prescription drug benefit programs that is paid by
116	the insurer to the pharmacy benefit manager.
117	(b) (a) "Maximum allowable cost" means the per-unit amount
118	that a pharmacy benefit manager reimburses a pharmacist for a
119	prescription drug, excluding dispensing fees, prior to the
120	application of copayments, coinsurance, and other cost-sharing
121	charges, if any.
122	(c) (b) "Pharmacy benefit manager" means a person or entity
123	doing business in this state which contracts to administer or
124	manage prescription drug benefits on behalf of a health insurer
125	to residents of this state.
126	(d) "Rebate" means all discounts and other negotiated
127	price concessions based on utilization of a prescription drug
128	and paid by the pharmaceutical manufacturer or other entity,
129	other than an insured, to the pharmacy benefit manager after the
130	claim has been adjudicated at the pharmacy.
131	(e) "Spread pricing" means any amount a pharmacy benefit
132	manager charges or receives from a health insurer for payment of
133	a prescription drug or pharmacy service that is greater than the
134	amount the pharmacy benefit manager paid to the pharmacist or
135	pharmacy that filled the prescription or provided the pharmacy
136	service.
137	(2) A contract between a health insurer and a pharmacy
138	benefit manager must require that the pharmacy benefit manager:

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(a) Update maximum allowable cost pricing information atleast every 7 calendar days.

(b) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.

(3) A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from limiting a pharmacist's ability to disclose whether the costsharing obligation exceeds the retail price for a covered prescription drug, and the availability of a more affordable alternative drug, pursuant to s. 465.0244.

(4) A contract between a health insurer and a pharmacy
benefit manager must prohibit the pharmacy benefit manager from
requiring an insured to make a payment for a prescription drug
at the point of sale in an amount that exceeds the lesser of:

156

(a) The applicable cost-sharing amount; or

(b) The retail price of the drug in the absence ofprescription drug coverage.

159 (5) A contract between a health insurer and a pharmacy
 160 benefit manager must require the pharmacy benefit manager to
 161 report annually the following to the insurer:

162(a) The aggregate amount of rebates the pharmacy benefit163manager received in association with claims administered on

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164	behalf of the insurer and the aggregate amount of such rebates
165	the pharmacy benefit manager received that were not passed
166	through to the insurer.
167	(b) The aggregate amount of administrative fees paid to
168	the pharmacy benefit manager by the insurer for the
169	administration of the insurer's prescription drug benefit
170	programs.
171	(c) The types and aggregate amounts of any fees or
172	remittances paid to the pharmacy benefit manager by pharmacies.
173	The pharmacy benefit manager shall distinguish between fees paid
174	by covered entities, as defined in 42 U.S.C. § 256b, and fees
175	paid by pharmacies which are not covered entities.
176	(d) The aggregate amount of revenue generated by the
177	pharmacy benefit manager through the use of spread pricing in
178	association with the administration of the insurer's pharmacy
179	benefit programs.
180	(6) Not later than June 30, 2021, and annually thereafter,
181	a health insurer shall submit a report to the office that
182	includes the information provided by its contracted pharmacy
183	benefit managers under subsection (5). The office shall publish
184	on its website an analysis of the reported information required
185	to be provided to the insurer under subsection (5) in an
186	aggregated amount for each pharmacy benefit manager.
187	(7) (5) This section applies to contracts entered into or
188	renewed on or after July 1, <u>2020</u> 2018 .
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189 Section 6. Section 627.6572, Florida Statutes, is amended 190 to read: 191 627.6572 Pharmacy benefit manager contracts.-(1) As used in this section, the term: 192 193 (a) "Administrative fee" means a fee or payment under a 194 contract between a health insurer and a pharmacy benefit manager 195 associated with the pharmacy benefit manager's administration of 196 the insurer's prescription drug benefit programs that is paid by 197 the insurer to the pharmacy benefit manager. (b) (a) "Maximum allowable cost" means the per-unit amount 198 199 that a pharmacy benefit manager reimburses a pharmacist for a 200 prescription drug, excluding dispensing fees, prior to the 201 application of copayments, coinsurance, and other cost-sharing 202 charges, if any. 203 (c) (b) "Pharmacy benefit manager" means a person or entity 204 doing business in this state which contracts to administer or 205 manage prescription drug benefits on behalf of a health insurer 206 to residents of this state. (d) "Rebate" means all discounts and other negotiated 207 208 price concessions based on utilization of a prescription drug 209 and paid by the pharmaceutical manufacturer or other entity, 210 other than an insured, to the pharmacy benefit manager after the 211 claim has been adjudicated at the pharmacy. 212 "Spread pricing" means any amount a pharmacy benefit (e) manager charges or receives from a health insurer for payment of 213 917373 - h7045-strike.docx Published On: 2/17/2020 8:04:04 PM

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214 <u>a prescription drug or pharmacy service that is greater than the</u> 215 <u>amount the pharmacy benefit manager paid to the pharmacist or</u> 216 <u>pharmacy that filled the prescription or provided the pharmacy</u> 217 <u>service.</u>

(2) A contract between a health insurer and a pharmacybenefit manager must require that the pharmacy benefit manager:

(a) Update maximum allowable cost pricing information atleast every 7 calendar days.

(b) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.

(3) A contract between a health insurer and a pharmacy benefit manager must prohibit the pharmacy benefit manager from limiting a pharmacist's ability to disclose whether the costsharing obligation exceeds the retail price for a covered prescription drug, and the availability of a more affordable alternative drug, pursuant to s. 465.0244.

(4) A contract between a health insurer and a pharmacy
benefit manager must prohibit the pharmacy benefit manager from
requiring an insured to make a payment for a prescription drug
at the point of sale in an amount that exceeds the lesser of:

237

(a) The applicable cost-sharing amount; or

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238 The retail price of the drug in the absence of (b) 239 prescription drug coverage. 240 (5) A contract between a health insurer and a pharmacy 241 benefit manager must require the pharmacy benefit manager to 242 report annually the following to the insurer: 243 The aggregate amount of rebates the pharmacy benefit (a) manager received in association with claims administered on 244 245 behalf of the insurer and the aggregate amount of such rebates 246 the pharmacy benefit manager received that were not passed 247 through to the insurer. 248 (b) The aggregate amount of administrative fees paid to 249 the pharmacy benefit manager by the insurer for the 250 administration of the insurer's prescription drug benefit 251 programs. 252 (c) The types and aggregate amounts of any fees or 253 remittances paid to the pharmacy benefit manager by pharmacies. 254 The pharmacy benefit manager shall distinguish between fees paid 255 by covered entities, as defined in 42 U.S.C. § 256b, and fees 256 paid by pharmacies which are not covered entities. 257 (d) The aggregate amount of revenue generated by the 258 pharmacy benefit manager through the use of spread pricing in 259 association with the administration of the insurer's pharmacy 260 benefit programs. (6) Not later than June 30, 2021, and annually thereafter, 261 262 a health insurer shall submit a report to the office that 917373 - h7045-strike.docx Published On: 2/17/2020 8:04:04 PM

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263	includes the information provided by its contracted pharmacy
264	benefit managers under subsection (5). The office shall publish
265	on its website an analysis of the reported information required
266	to be provided under subsection (5) in an aggregated amount for
267	each pharmacy benefit manager.
268	(7) (5) This section applies to contracts entered into or
269	renewed on or after July 1, <u>20202018.</u>
270	Section 7. Section 641.3131, Florida Statutes, is created
271	to read:
272	641.3131 Formulary changes resulting from drug price
273	increases
274	(1) A health maintenance organization issuing a major
275	medical or other comprehensive coverage contract shall submit,
276	and update as necessary, contact information for a single point-
277	of-contact for use by prescription drug manufacturers to comply
278	with s. 499.026. The Office shall maintain and publish a list of
279	such points of contact.
280	(2) A health maintenance organization issuing a major
281	medical or other comprehensive coverage contract must provide
282	written notice to affected subscribers at least 30 days in
283	advance of making a drug formulary change resulting from a drug
284	price increase reported pursuant to s. 499.026.
285	(3) This section applies to contracts entered into or
286	renewed on or after January 1, 2021.
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287 Section 8. Section 641.314, Florida Statutes, is amended 288 to read: 289 641.314 Pharmacy benefit manager contracts.-290 (1) As used in this section, the term: 291 (a) "Administrative fee" means a fee or payment under a 292 contract between a health maintenance organization and a 293 pharmacy benefit manager associated with the pharmacy benefit manager's administration of the health maintenance 294 295 organization's prescription drug benefit programs that is paid 296 by the health maintenance organization to the pharmacy benefit 297 manager. 298 (b) (a) "Maximum allowable cost" means the per-unit amount 299 that a pharmacy benefit manager reimburses a pharmacist for a 300 prescription drug, excluding dispensing fees, prior to the 301 application of copayments, coinsurance, and other cost-sharing 302 charges, if any. 303 (c) (b) "Pharmacy benefit manager" means a person or entity 304 doing business in this state which contracts to administer or 305 manage prescription drug benefits on behalf of a health 306 maintenance organization to residents of this state. 307 (d) "Rebate" means all discounts and other negotiated 308 price concessions based on utilization of a prescription drug and paid by the pharmaceutical manufacturer or other entity, 309 310 other than a subscriber, to the pharmacy benefit manager after 311 the claim has been adjudicated at the pharmacy. 917373 - h7045-strike.docx Published On: 2/17/2020 8:04:04 PM Page 13 of 21

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(e) "Spread pricing" means any amount a pharmacy benefit manager charges or receives from a health maintenance organization for payment of a prescription drug or pharmacy service that is greater than the amount the pharmacy benefit manager paid to the pharmacist or pharmacy that filled the prescription or provided the pharmacy service.

318 (2) A contract between a health maintenance organization
319 and a pharmacy benefit manager must require that the pharmacy
320 benefit manager:

321 (a) Update maximum allowable cost pricing information at322 least every 7 calendar days.

(b) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.

(3) A contract between a health maintenance organization and a pharmacy benefit manager must prohibit the pharmacy benefit manager from limiting a pharmacist's ability to disclose whether the cost-sharing obligation exceeds the retail price for a covered prescription drug, and the availability of a more affordable alternative drug, pursuant to s. 465.0244.

334 (4) A contract between a health maintenance organization
335 and a pharmacy benefit manager must prohibit the pharmacy
336 benefit manager from requiring a subscriber to make a payment

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337	for a prescription drug at the point of sale in an amount that
338	exceeds the lesser of:
339	(a) The applicable cost-sharing amount; or
340	(b) The retail price of the drug in the absence of
341	prescription drug coverage.
342	(5) A contract between a health maintenance organization
343	and a pharmacy benefit manager must require the pharmacy benefit
344	manager to report annually the following to the health
345	maintenance organization:
346	(a) The aggregate amount of rebates the pharmacy benefit
347	manager received in association with claims administered on
348	behalf of the health maintenance organization and the aggregate
349	amount of such rebates the pharmacy benefit manager received
350	that were not passed through to the health maintenance
351	organization.
352	(b) The aggregate amount of administrative fees paid to
353	the pharmacy benefit manager by the health maintenance
354	organization for the administration of the health maintenance
355	organization's prescription drug benefit programs.
356	(c) The types and aggregate amounts of any fees or
357	remittances paid to the pharmacy benefit manager by pharmacies.
358	The pharmacy benefit manager shall distinguish between fees paid
359	by covered entities, as defined in 42 U.S.C. § 256b, and fees
360	paid by pharmacies which are not covered entities.

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361 (d) The aggregate amount of revenue generated by the 362 pharmacy benefit manager through the use of spread pricing in 363 association with the administration of the health maintenance 364 organization's pharmacy benefit programs.

365 (6) Not later than June 30, 2021, and annually thereafter, 366 a health maintenance organization shall submit a report to the 367 office that includes the information provided by its contracted pharmacy benefit managers under subsection (5). The office shall 368 369 publish on its website an analysis of the reported information 370 required to be provided to the health maintenance organization 371 under subsection (5) in an aggregated amount for each pharmacy 372 benefit manager.

373 <u>(7)-(5)</u> This section applies to contracts entered into or 374 renewed on or after July 1, <u>20202018</u>.

375 Section 9. (1) The Agency for Health Care Administration 376 shall contract for an independent analysis of pharmacy benefit 377 management practices under the Statewide Medicaid Managed Care 378 program. The analysis shall outline the types of pharmacy 379 benefit pricing contracts in place between managed care plans 380 and contracted pharmacy benefit managers and between managed care plans or pharmacy benefit managers and pharmacies. At a 381 382 minimum, the analysis shall include:

383 (a) An examination of the fees paid to each contracted
 384 pharmacy benefit manager by each managed care plan.

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385	(b) An examination of the fees charged to pharmacies by
386	each managed care plan or contracted pharmacy benefit manager.
387	(c) A determination of spread pricing revenues retained by
388	each managed care plan or contracted pharmacy benefit manager.
389	(2) For purposes of this section, the term "pharmacy
390	benefit manager" means a person or entity doing business in this
391	state which contracts to administer or manage prescription drug
392	benefits on behalf of a managed care plan.
393	(3) For purposes of this section, the term "spread
394	pricing" refers to any amount a managed care plan or pharmacy
395	benefit manager received from the Medicaid program for payment
396	of a prescription drug that is greater than that paid to the
397	pharmacist or pharmacy that filled a prescription for that
398	prescription drug.
399	(4) The agency shall submit the completed analysis to the
400	Governor, the President of the Senate, and the Speaker of the
401	House of Representatives by June 30, 2020.
402	Section 10. The Agency for Health Care Administration
403	shall conduct an analysis of managed care plan pharmacy networks
404	under the Statewide Medicaid Managed Care program to ensure that
405	enrollees have sufficient choice of pharmacies within
406	established geographic parameters. The agency must also analyze
407	the composition of each managed care plan pharmacy network to
408	determine the market share of large chain pharmacies, small

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409	chain pharmacies, and independent pharmacies, respectively. The
410	analysis shall include:
411	(a) An examination of the pharmacy contracting patterns by
412	each managed care plan or contracted pharmacy benefit manager.
413	(b) An examination of any financial relationship between a
414	managed care provider or contracted pharmacy benefit manager and
415	its contracted pharmacies. The analysis shall examine whether a
416	managed care plan or pharmacy benefit manager establishes a
417	network which favors pharmacies in which the managed care plan
418	or pharmacy benefit manager owns a controlling or substantial
419	financial interest.
420	(2) For purposes of this section, the term "pharmacy
421	benefit manager" means a person or entity doing business in this
422	state which contracts to administer or manage prescription drug
423	benefits on behalf of a managed care plan.
424	(3) The agency shall submit the completed analysis to the
425	Governor, the President of the Senate, and the Speaker of the
426	House of Representatives by June 30, 2020.
427	Section 11. This act shall take effect upon becoming law.
428	
429	
430	
431	TITLE AMENDMENT
432	Remove everything before the enacting clause and insert:
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433 An act relating to prescription drug price transparency; amending s. 499.012, F.S.; providing that permits for 434 435 prescription drug manufacturers and nonresident prescription 436 drug manufacturers are subject to specified requirements; creating s. 499.026, F.S.; providing definitions; requiring 437 438 prescription drug manufacturers to provide notice of drug price 439 increases to insurers; requiring prescription drug manufacturers to provide an annual report on drug price increases to the 440 Department of Business and Professional Regulation and the 441 442 Office of Insurance Regulation; providing reporting 443 requirements; creating s. 624.491, F.S.; providing timelines and 444 documentation requirements for pharmacy audits conducted by certain health insurers, health maintenance organizations, or 445 446 their agents; providing that such requirements do not apply to 447 audits in which certain conditions are met; creating s. 448 627.42394. F.S.; requiring insurers to establish a single point 449 of contact for manufacturer reporting of drug price increases; 450 requiring the Office of Insurance Regulation to publish and 451 maintain a list of such contacts; requiring insurers to provide 452 written notice to insureds in advance of formulary changes resulting from manufacturer drug price increases; providing 453 454 applicability; amending s. 627.64741, F.S.; providing definitions; requiring reporting requirements in contracts 455 456 between health insurers and pharmacy benefit managers; requiring health insurers to submit an annual report to the office; 457 917373 - h7045-strike.docx

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458 requiring the office to publish such reports and analyses of 459 specified information; revising applicability; amending s. 460 627.6572, F.S.; providing definitions; requiring reporting 461 requirements in contracts between health insurers and pharmacy 462 benefit managers; requiring health insurers to submit an annual 463 report to the office; requiring the office to publish such reports and analyses of specified information; revising 464 465 applicability; creating s. 641.3131, F.S.; requiring health maintenance organizations to establish a single point of contact 466 467 for manufacturer reporting of drug price increases; requiring 468 the Office of Insurance Regulation to publish and maintain a 469 list of such contacts; requiring health maintenance 470 organizations to provide written notice to subscribers in 471 advance of formulary changes resulting from manufacturer drug 472 price increases; providing applicability; amending s. 641.314, 473 F.S.; providing definitions; requiring reporting requirements in 474 contracts between health maintenance organizations and pharmacy benefit managers; requiring health maintenance organizations to 475 submit an annual report to the office; requiring the office to 476 477 publish such reports and analyses of specified information; 478 revising applicability; requiring the Agency for Health Care 479 Administration to contract for an independent analysis of pharmacy benefit practices under the Statewide Medicaid Managed 480 Care program; defining terms; requiring the Agency for Health 481 Care Administration to conduct an analysis of pharmacy networks 482 917373 - h7045-strike.docx

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483 under the Statewide Medicaid Managed Care program; defining 484 terms; providing an effective date.

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