1 A bill to be entitled 2 An act relating to prescription drug price 3 transparency; amending s. 110.12315, F.S.; requiring the Department of Management Services to contract for 4 5 an annual audit of any pharmacy benefit vendor 6 contracted under the state employees' prescription 7 drug program; providing requirements for such audit; 8 amending s. 499.012, F.S.; providing that permits for 9 prescription drug manufacturers and nonresident prescription drug manufacturers are subject to 10 11 specified requirements; creating s. 499.026, F.S.; 12 providing definitions; requiring prescription drug manufacturers to provide notification of drug price 13 14 increases to insurers; providing requirements for such notification; requiring prescription drug 15 manufacturers to provide an annual report on drug 16 17 price increases to the Department of Business and Professional Regulation and the Office of Insurance 18 19 Regulation; providing reporting requirements; creating s. 624.491, F.S.; providing timelines and 20 21 documentation requirements for pharmacy audits 22 conducted by certain health insurers, health 23 maintenance organizations, or their agents; providing 24 that such requirements do not apply to audits in which 25 certain conditions are met; creating s. 627.42394,

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26 F.S.; requiring certain health insurers to establish a 27 single point of contact for manufacturers to report 28 drug price increases; requiring the Office of 29 Insurance Regulation to maintain and publish a list of 30 such contacts; requiring certain health insurers to 31 provide written notice to insureds in advance of 32 formulary changes resulting from manufacturer drug 33 price increases; providing applicability; amending s. 627.64741, F.S.; providing definitions; requiring 34 35 reporting requirements in contracts between health 36 insurers and pharmacy benefit managers; requiring 37 health insurers to submit an annual report to the office; requiring the office to publish such reports 38 39 and analyses of specified information; revising applicability; amending s. 627.6572, F.S.; providing 40 definitions; requiring reporting requirements in 41 42 contracts between health insurers and pharmacy benefit 43 managers; requiring health insurers to submit an annual report to the office; requiring the office to 44 publish such reports and analyses of specified 45 information; revising applicability; creating s. 46 47 641.3131, F.S.; requiring certain health maintenance 48 organizations to establish a single point of contact for manufacturers to report drug price increases; 49 50 requiring the office to maintain and publish a list of

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51 such contacts; requiring certain health maintenance 52 organizations to provide written notice to subscribers 53 in advance of formulary changes resulting from 54 manufacturer drug price increases; providing 55 applicability; amending s. 641.314, F.S.; providing 56 definitions; requiring reporting requirements in 57 contracts between health maintenance organizations and 58 pharmacy benefit managers; requiring health 59 maintenance organizations to submit an annual report 60 to the office; requiring the office to publish such reports and analyses of specified information; 61 62 revising applicability; requiring the Agency for Health Care Administration to contract for an 63 64 independent analysis of pharmacy benefit management practices under the Statewide Medicaid Managed Care 65 program; providing requirements for such audit; 66 67 providing definitions; requiring the agency to submit 68 the analysis to the Governor and the Legislature; 69 requiring the agency to conduct an analysis and 70 analyze the composition of managed care plan pharmacy 71 networks under the program; providing requirements for 72 such analysis; providing definitions; requiring the 73 agency to submit the analysis to the Governor and the 74 Legislature; providing an effective date.

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76	Be It Enacted by the Legislature of the State of Florida:
77	
78	Section 1. Subsection (11) is added to section 110.12315,
79	Florida Statutes, to read:
80	110.12315 Prescription drug programThe state employees'
81	prescription drug program is established. This program shall be
82	administered by the Department of Management Services, according
83	to the terms and conditions of the plan as established by the
84	relevant provisions of the annual General Appropriations Act and
85	implementing legislation, subject to the following conditions:
86	(11) The department shall contract for an annual audit of
87	any pharmacy benefit vendor contracted under the program. At a
88	minimum, the audit shall determine whether state funds are
89	expended in accordance with the terms of the vendor contract and
90	shall include an assessment of compliance with contract terms.
91	The audit shall identify any noncompliance and make
92	recommendations for corrective action by a pharmacy benefit
93	vendor. Specifically, the audit shall examine whether a pharmacy
94	benefit vendor is compliant with contract provisions related to
95	pass-through of pharmaceutical rebates and spread pricing, as
96	set forth in a contract between the department and such a
97	vendor.
98	Section 2. Subsection (16) is added to section 499.012,
99	Florida Statutes, to read:
100	499.012 Permit application requirements

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101	(16) A permit for a prescription drug manufacturer or a
102	nonresident prescription drug manufacturer is subject to the
103	requirements of s. 499.026.
104	Section 3. Section 499.026, Florida Statutes, is created
105	to read:
106	499.026 Prescription drug price increases
107	(1) As used in this section, the term:
108	(a) "Drug price increase" means a manufacturer price
109	increase equal to or greater than 15 percent of the price of a
110	drug for a brand-name prescription drug with a wholesale
111	acquisition cost of \$50 or more, or a manufacturer price
112	increase equal to or greater than 25 percent of the price of a
113	drug for a generic prescription drug or a biosimilar drug with a
114	wholesale acquisition cost of \$25 or more, for a 30-day supply.
115	(b) "Health insurer" means a health insurer issuing major
116	medical coverage through an individual or group policy or a
117	health maintenance organization issuing major medical coverage
118	through an individual or group contract, regulated under chapter
119	627 or chapter 641.
120	(c) "Manufacturer" means any person holding a prescription
121	drug manufacturer permit or a nonresident prescription drug
122	manufacturer permit under s. 499.01.
123	(d) "Wholesale acquisition cost" has the same meaning as
124	<u>defined in 42 U.S.C. s. 1395w-3a.</u>
125	(2) At least 60 days before the effective date of any drug
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126	price increase, a manufacturer must provide notification of the
127	upcoming drug price increase and the amount of the drug price
128	increase to every health insurer that covers the drug. A
129	manufacturer must make the notification using the contact list
130	published by the Office of Insurance Regulation pursuant to ss.
131	627.42394 and 641.3131. Notification shall be presumed to occur
132	on the date that a manufacturer attempts to communicate with the
133	applicable point of contact published by the Office of Insurance
134	Regulation.
135	(3) By April 1 of each year, a manufacturer must submit a
136	report to the department and the Office of Insurance Regulation
137	on each drug price increase made during the previous calendar
138	year. At a minimum, the report shall include:
139	(a) A list of all drugs affected by the drug price
140	increase and both the dollar amount of each drug price increase
141	and the percentage increase of each drug price increase,
142	relative to the previous price of the drug.
143	(b) A complete description of the factors contributing to
144	the drug price increase.
145	Section 4. Section 624.491, Florida Statutes, is created
146	to read:
147	624.491 Pharmacy audits
148	(1) A health insurer or health maintenance organization
149	providing pharmacy benefits through a major medical individual
150	or group health policy or health maintenance contract,
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151	respectively, shall comply with the requirements of this section
152	when the insurer or health maintenance organization or any
153	entity acting on behalf of the insurer or health maintenance
154	organization, including, but not limited to, a pharmacy benefit
155	manager, audits the records of a pharmacy licensed under chapter
156	465. This section does not apply to audits in which suspected
157	fraudulent activity or other intentional or willful
158	misrepresentation is evidenced by a physical review, review of
159	claims data or statements, or other investigative methods;
160	audits of claims paid for by federally funded programs; or
161	concurrent reviews or desk audits that occur within 3 business
162	days of transmission of a claim and where no chargeback or
163	recoupment is demanded. An entity that audits a pharmacy located
164	within a Health Care Fraud Prevention and Enforcement Action
165	Team (HEAT) Task Force area designated by the United States
166	Department of Health and Human Services and the United States
167	Department of Justice may dispense with the notice requirements
168	of subsection (2) if such pharmacy has been a member of a
169	credentialed provider network for less than 12 months.
170	(2) An entity conducting a pharmacy audit shall:
171	(a) Notify the pharmacy at least 7 calendar days before
172	the initial onsite audit for each audit cycle.
173	(b) Ensure the audit is not initiated during the first 3
174	calendar days of a month unless the pharmacist consents
175	otherwise.

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176	(c) Limit the audit period to 24 months after the date a
177	claim is submitted to or adjudicated by the entity.
178	(d) Provide a preliminary audit report to the pharmacy
179	within 120 days after the conclusion of the audit.
180	(e) Provide a final audit report to the pharmacy within 6
181	months after having providing the preliminary audit report.
182	Section 5. Section 627.42394, Florida Statutes, is created
183	to read:
184	627.42394 Formulary changes resulting from drug price
185	increases
186	(1) A health insurer issuing a major medical individual or
187	group policy shall submit, and update as necessary, contact
188	information for a single point of contact for use by
189	prescription drug manufacturers to comply with s. 499.026. The
190	office shall maintain and publish a list of such points of
191	contact.
192	(2) A health insurer issuing a major medical individual or
193	group policy must provide written notice to affected insureds at
194	least 30 days in advance of making a drug formulary change
195	resulting from a drug price increase reported pursuant to s.
196	499.026.
197	(3) This section applies to policies entered into or
198	renewed on or after January 1, 2021.
199	Section 6. Section 627.64741, Florida Statutes, is amended
200	to read:

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201

202

627.64741 Pharmacy benefit manager contracts.-

(1) As used in this section, the term:

203 (a) "Administrative fee" means a fee or payment under a 204 contract between a health insurer and a pharmacy benefit manager 205 associated with the pharmacy benefit manager's administration of 206 the insurer's prescription drug benefit programs that is paid by 207 the insurer to the pharmacy benefit manager.

208 (b) (a) "Maximum allowable cost" means the per-unit amount 209 that a pharmacy benefit manager reimburses a pharmacist for a 210 prescription drug, excluding dispensing fees, prior to the 211 application of copayments, coinsurance, and other cost-sharing 212 charges, if any.

213 <u>(c) (b)</u> "Pharmacy benefit manager" means a person or entity 214 doing business in this state which contracts to administer or 215 manage prescription drug benefits on behalf of a health insurer 216 to residents of this state.

(d) "Rebate" means all discounts and other negotiated price concessions based on utilization of a prescription drug and paid by the pharmaceutical manufacturer or other entity, other than an insured, to the pharmacy benefit manager after the claim has been adjudicated at the pharmacy.

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

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226 pharmacy that filled the prescription or provided the pharmacy 227 service.

(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:

247

(a) The applicable cost-sharing amount; or

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

250

(5) A contract between a health insurer and a pharmacy

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251 benefit manager must require the pharmacy benefit manager to 252 report annually the following to the insurer: 253 The aggregate amount of rebates the pharmacy benefit (a) 254 manager received in association with claims administered on 255 behalf of the insurer and the aggregate amount of such rebates 256 the pharmacy benefit manager received that were not passed 257 through to the insurer. (b) 258 The aggregate amount of administrative fees paid to 259 the pharmacy benefit manager by the insurer for the 260 administration of the insurer's prescription drug benefit 261 programs. 262 (c) The types and aggregate amounts of any fees or 263 remittances paid to the pharmacy benefit manager by pharmacies. 264 The pharmacy benefit manager shall distinguish between fees paid 265 by covered entities, as defined in 42 U.S.C. s. 256b, and fees 266 paid by pharmacies that are not covered entities. 267 The aggregate amount of revenue generated by the (d) 268 pharmacy benefit manager through the use of spread pricing in 269 association with the administration of the insurer's pharmacy 270 benefit programs. 271 The type and aggregate amount of any other fees (e) 272 collected by the pharmacy benefit manager in association with 273 claims administered on behalf of the insurer. 274 Not later than June 30, 2021, and annually thereafter, (6) 275 a health insurer shall submit a report to the office that

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276	includes the information provided by its contracted pharmacy
277	benefit managers under subsection (5). The office shall publish
278	on its website an analysis of the reported information required
279	to be provided to the insurer under subsection (5) in an
280	aggregated amount for each pharmacy benefit manager.
281	(7) <del>(5)</del> This section applies to contracts entered into or
282	renewed on or after July 1, <u>2020</u> <del>2018</del> .
283	Section 7. Section 627.6572, Florida Statutes, is amended
284	to read:
285	627.6572 Pharmacy benefit manager contracts
286	(1) As used in this section, the term:
287	(a) "Administrative fee" means a fee or payment under a
288	contract between a health insurer and a pharmacy benefit manager
289	associated with the pharmacy benefit manager's administration of
290	the insurer's prescription drug benefit programs that is paid by
291	the insurer to the pharmacy benefit manager.
292	(b) <del>(a)</del> "Maximum allowable cost" means the per-unit amount
293	that a pharmacy benefit manager reimburses a pharmacist for a
294	prescription drug, excluding dispensing fees, prior to the
295	application of copayments, coinsurance, and other cost-sharing
296	charges, if any.
297	<u>(c)</u> "Pharmacy benefit manager" means a person or entity
298	doing business in this state which contracts to administer or
299	manage prescription drug benefits on behalf of a health insurer
300	to residents of this state.
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301 (d) "Rebate" means all discounts and other negotiated 302 price concessions based on utilization of a prescription drug 303 and paid by the pharmaceutical manufacturer or other entity, 304 other than an insured, to the pharmacy benefit manager after the 305 claim has been adjudicated at the pharmacy.

306 (e) "Spread pricing" means any amount a pharmacy benefit 307 manager charges or receives from a health insurer for payment of 308 a prescription drug or pharmacy service that is greater than the 309 amount the pharmacy benefit manager paid to the pharmacist or 310 pharmacy that filled the prescription or provided the pharmacy 311 service.

- 312 (2) A contract between a health insurer and a pharmacy313 benefit manager must require that the pharmacy benefit manager:
- 314 (a) Update maximum allowable cost pricing information at315 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.

321 (3) A contract between a health insurer and a pharmacy 322 benefit manager must prohibit the pharmacy benefit manager from 323 limiting a pharmacist's ability to disclose whether the cost-324 sharing obligation exceeds the retail price for a covered 325 prescription drug, and the availability of a more affordable

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326	alternative drug, pursuant to s. 465.0244.
327	(4) A contract between a health insurer and a pharmacy
328	benefit manager must prohibit the pharmacy benefit manager from
329	requiring an insured to make a payment for a prescription drug
330	at the point of sale in an amount that exceeds the lesser of:
331	(a) The applicable cost-sharing amount; or
332	(b) The retail price of the drug in the absence of
333	prescription drug coverage.
334	(5) A contract between a health insurer and a pharmacy
335	benefit manager must require the pharmacy benefit manager to
336	report annually the following to the insurer:
337	(a) The aggregate amount of rebates the pharmacy benefit
338	manager received in association with claims administered on
339	behalf of the insurer and the aggregate amount of such rebates
340	the pharmacy benefit manager received that were not passed
341	through to the insurer.
342	(b) The aggregate amount of administrative fees paid to
343	the pharmacy benefit manager by the insurer for the
344	administration of the insurer's prescription drug benefit
345	programs.
346	(c) The types and aggregate amounts of any fees or
347	remittances paid to the pharmacy benefit manager by pharmacies.
348	The pharmacy benefit manager shall distinguish between fees paid
349	by covered entities, as defined in 42 U.S.C. s. 256b, and fees
350	paid by pharmacies that are not covered entities.

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351 The aggregate amount of revenue generated by the (d) 352 pharmacy benefit manager through the use of spread pricing in 353 association with the administration of the insurer's pharmacy 354 benefit programs. 355 The type and aggregate amount of any other fees (e) 356 collected by the pharmacy benefit manager in association with 357 claims administered on behalf of the insurer. 358 (6) Not later than June 30, 2021, and annually thereafter, 359 a health insurer shall submit a report to the office that 360 includes the information provided by its contracted pharmacy 361 benefit managers under subsection (5). The office shall publish 362 on its website an analysis of the reported information required 363 to be provided under subsection (5) in an aggregated amount for 364 each pharmacy benefit manager. 365 (7) (7) (5) This section applies to contracts entered into or 366 renewed on or after July 1, 2020 2018. 367 Section 8. Section 641.3131, Florida Statutes, is created 368 to read: 369 641.3131 Formulary changes resulting from drug price 370 increases.-371 (1) A health maintenance organization issuing a major medical or other comprehensive coverage contract shall submit, 372 373 and update as necessary, contact information for a single point 374 of contact for use by prescription drug manufacturers to comply 375 with s. 499.026. The office shall maintain and publish a list of

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376	such points of contact.
377	(2) A health maintenance organization issuing a major
378	medical or other comprehensive coverage contract must provide
379	written notice to affected subscribers at least 30 days in
380	advance of making a drug formulary change resulting from a drug
381	price increase reported pursuant to s. 499.026.
382	(3) This section applies to contracts entered into or
383	renewed on or after January 1, 2021.
384	Section 9. Section 641.314, Florida Statutes, is amended
385	to read:
386	641.314 Pharmacy benefit manager contracts
387	(1) As used in this section, the term:
388	(a) "Administrative fee" means a fee or payment under a
389	contract between a health maintenance organization and a
390	pharmacy benefit manager associated with the pharmacy benefit
391	manager's administration of the health maintenance
392	organization's prescription drug benefit programs that is paid
393	by the health maintenance organization to the pharmacy benefit
394	manager.
395	<u>(b)</u> "Maximum allowable cost" means the per-unit amount
396	that a pharmacy benefit manager reimburses a pharmacist for a
397	prescription drug, excluding dispensing fees, prior to the
398	application of copayments, coinsurance, and other cost-sharing
399	charges, if any.
400	(c) (b) "Pharmacy benefit manager" means a person or entity

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401 doing business in this state which contracts to administer or 402 manage prescription drug benefits on behalf of a health 403 maintenance organization to residents of this state. 404 "Rebate" means all discounts and other negotiated (d) 405 price concessions based on utilization of a prescription drug 406 and paid by the pharmaceutical manufacturer or other entity, 407 other than a subscriber, to the pharmacy benefit manager after 408 the claim has been adjudicated at the pharmacy. (e) 409 "Spread pricing" means any amount a pharmacy benefit 410 manager charges or receives from a health maintenance 411 organization for payment of a prescription drug or pharmacy 412 service that is greater than the amount the pharmacy benefit 413 manager paid to the pharmacist or pharmacy that filled the 414 prescription or provided the pharmacy service. 415 A contract between a health maintenance organization (2)416 and a pharmacy benefit manager must require that the pharmacy 417 benefit manager: 418 Update maximum allowable cost pricing information at (a) 419 least every 7 calendar days. 420 Maintain a process that will, in a timely manner, (b) 421 eliminate drugs from maximum allowable cost lists or modify drug 422 prices to remain consistent with changes in pricing data used in 423 formulating maximum allowable cost prices and product 424 availability. 425 (3) A contract between a health maintenance organization Page 17 of 22

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426 and a pharmacy benefit manager must prohibit the pharmacy 427 benefit manager from limiting a pharmacist's ability to disclose 428 whether the cost-sharing obligation exceeds the retail price for 429 a covered prescription drug, and the availability of a more 430 affordable alternative drug, pursuant to s. 465.0244. 431 (4) A contract between a health maintenance organization 432 and a pharmacy benefit manager must prohibit the pharmacy 433 benefit manager from requiring a subscriber to make a payment 434 for a prescription drug at the point of sale in an amount that 435 exceeds the lesser of: The applicable cost-sharing amount; or 436 (a) 437 (b) The retail price of the drug in the absence of 438 prescription drug coverage. 439 (5) A contract between a health maintenance organization 440 and a pharmacy benefit manager must require the pharmacy benefit 441 manager to report annually the following to the health 442 maintenance organization: 443 The aggregate amount of rebates the pharmacy benefit (a) 444 manager received in association with claims administered on 445 behalf of the health maintenance organization and the aggregate 446 amount of such rebates the pharmacy benefit manager received 447 that were not passed through to the health maintenance 448 organization. The aggregate amount of administrative fees paid to 449 (b) 450 the pharmacy benefit manager by the health maintenance

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451	organization for the administration of the health maintenance
452	organization's prescription drug benefit programs.
453	(c) The types and aggregate amounts of any fees or
454	remittances paid to the pharmacy benefit manager by pharmacies.
455	The pharmacy benefit manager shall distinguish between fees paid
456	by covered entities, as defined in 42 U.S.C. s. 256b, and fees
457	paid by pharmacies that are not covered entities.
458	(d) The aggregate amount of revenue generated by the
459	pharmacy benefit manager through the use of spread pricing in
460	association with the administration of the health maintenance
461	organization's pharmacy benefit programs.
462	(e) The type and aggregate amount of any other fees
463	collected by the pharmacy benefit manager in association with
464	claims administered on behalf of the health maintenance
465	organization.
466	(6) Not later than June 30, 2021, and annually thereafter,
467	a health maintenance organization shall submit a report to the
468	office that includes the information provided by its contracted
469	pharmacy benefit managers under subsection (5). The office shall
470	publish on its website an analysis of the reported information
471	required to be provided to the health maintenance organization
472	under subsection (5) in an aggregated amount for each pharmacy
473	benefit manager.
474	<u>(7)<del>(5)</del> This section applies to contracts entered into or</u>
475	renewed on or after July 1, <u>2020</u> <del>2018</del> .
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476	Section 10. (1) The Agency for Health Care Administration
477	shall contract for an independent analysis of pharmacy benefit
478	management practices under the Statewide Medicaid Managed Care
479	program. The analysis shall outline the types of pharmacy
480	benefit pricing contracts in place between managed care plans
481	and contracted pharmacy benefit managers and between managed
482	care plans or pharmacy benefit managers and pharmacies. At a
483	minimum, the analysis shall include:
484	(a) An examination of the fees paid to each contracted
485	pharmacy benefit manager by each managed care plan.
486	(b) An examination of the fees charged to pharmacies by
487	each managed care plan or contracted pharmacy benefit manager.
488	(c) A determination of spread pricing revenues retained by
489	each managed care plan or contracted pharmacy benefit manager.
490	(2) For purposes of this section, the term "pharmacy
491	benefit manager" means a person or entity doing business in this
492	state which contracts to administer or manage prescription drug
493	benefits on behalf of a managed care plan.
494	(3) For purposes of this section, the term "spread
495	pricing" refers to any amount a managed care plan or pharmacy
496	benefit manager received from the Medicaid program for payment
497	of a prescription drug that is greater than that paid to the
498	pharmacist or pharmacy that filled a prescription for that
499	prescription drug.
500	(4) The agency shall submit the completed analysis to the
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501	Governor, the President of the Senate, and the Speaker of the
502	House of Representatives by June 30, 2020.
503	Section 11. (1) The Agency for Health Care Administration
504	shall conduct an analysis of managed care plan pharmacy networks
505	under the Statewide Medicaid Managed Care program to ensure that
506	enrollees have sufficient choice of pharmacies within
507	established geographic parameters. The agency must also analyze
508	the composition of each managed care plan pharmacy network to
509	determine the market share of large chain pharmacies, small
510	chain pharmacies, and independent pharmacies, respectively. The
511	analysis shall include:
512	(a) An examination of the pharmacy contracting patterns by
513	each managed care plan or contracted pharmacy benefit manager.
514	(b) An examination of any financial relationship between a
515	managed care provider or contracted pharmacy benefit manager and
516	its contracted pharmacies. The analysis shall examine whether a
517	managed care plan or pharmacy benefit manager establishes a
518	network that favors pharmacies in which the managed care plan or
519	pharmacy benefit manager owns a controlling or substantial
520	financial interest.
521	(2) For purposes of this section, the term "pharmacy
522	benefit manager" means a person or entity doing business in this
523	state which contracts to administer or manage prescription drug
524	benefits on behalf of a managed care plan.
525	(3) The agency shall submit the completed analysis to the

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