Bill No. HB 7045 (2020)

Committee/Subcommittee hearing bill: Health & Human Services
Committee

Representative Andrade offered the following:

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Amendment (with title amendment)

Remove everything after the enacting clause and insert: Section 1. Subsection (16) is added to section 499.012, Florida Statutes, to read:

499.012 Permit application requirements.-

(16) A permit for a prescription drug manufacturer or a nonresident prescription drug manufacturer is subject to the requirements of s. 499.026.

Section 2. Section 499.026, Florida Statutes, is created to read:

499.026 Prescription drug price increases.-

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

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(a) "Drug Price Increase" means a manufacturer price	
increase equal to or greater than 15 percent of the price of a	
drug for a brand-name prescription drug with a wholesale	
acquisition cost of \$50 or more, or a manufacturer price	
increase equal to or greater than 25 percent of the price of a	
drug for a generic prescription drug or a biosimilar drug with	a
wholesale acquisition cost of \$25 or more, for a 30-day supply.	<u>. </u>

- (b) "Health insurer" means a health insurer issuing major medical coverage through an individual or group policy or a health maintenance organization issuing major medical coverage through an individual or group contract, regulated under chapter 627 or chapter 641.
- (c) "Manufacturer" means any person holding a prescription drug manufacturer permit or a nonresident prescription drug manufacturer permit under s. 499.01.
- (d) "Wholesale acquisition cost" means that term as defined in 42 U.S.C. § 1395w-3a.
- (2) At least 60 days before the effective date of any drug price increase, a manufacturer must provide notification of the upcoming drug price increase and the amount of the drug price increase to every health insurer that covers the drug. A manufacturer must make the notification using the contact list published by the Office of Insurance Regulation pursuant to ss. 627.42394 and 641.3131. Notification shall be presumed to occur on the date that a manufacturer attempts to communicate with the

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applicable point of contact published by the Office of Insurance Regulation.

- (3) By April 1 of each year, a manufacturer must submit a report to the department and the Office of Insurance Regulation on each drug price increase made during the previous calendar year. At a minimum, the report shall include:
- (a) A list of all drugs affected by the drug price increase and both the dollar amount of each drug price increase and the percentage increase of each drug price increase, relative to the previous price of the drug.
- (b) A complete description of the factors contributing to the drug price increase.

Section 3. Section 624.491, Florida Statutes, is created to read:

624.491 Pharmacy audits.-

(1) A health insurer or health maintenance organization providing pharmacy benefits through a major medical individual or group health policy or health maintenance contract, respectively, shall comply with the requirements of this section when the insurer or health maintenance organization or any entity acting on behalf of the insurer or health maintenance organization, including, but not limited to, a pharmacy benefit manager, audits the records of a pharmacy licensed under chapter 465. This section does not apply to audits in which suspected fraudulent activity or other intentional or willful

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misrepresentation is evidenced by a physical review, review of
claims data or statements, or other investigative methods;
audits of claims paid for by federally funded programs; or
concurrent reviews or desk audits that occur within 3 business
days of transmission of a claim and where no chargeback or
recoupment is demanded. An entity that audits a pharmacy located
within a Health Care Fraud Prevention and Enforcement Action
Team (HEAT) Task Force area designated by the United States
Department of Health and Human Services and the United States
Department of Justice may dispense with the notice requirements
if such pharmacy has been a member of a credentialed provider
network for less than 12 months.

- (2) An entity conducting a pharmacy audit shall:
- (a) Notify the pharmacy at least 7 calendar days before the initial onsite audit for each audit cycle.
- (b) Ensure the audit is not initiated during the first 3 calendar days of a month unless the pharmacist consents otherwise.
- (c) Limit the audit period to 24 months after the date a claim is submitted to or adjudicated by the entity.
- (d) Provide a preliminary audit report to the pharmacy within 120 days after the conclusion of the audit.
- (e) Provide a final audit report to the pharmacy within 6 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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the	insurer	's	pres	cription	drug	bene	efit	programs	that	is	paid	by
the	insurer	to	the	pharmacy	bene	efit	mana	ager.				_

- (b) (a) "Maximum allowable cost" means the per-unit amount that a pharmacy benefit manager reimburses a pharmacist for a prescription drug, excluding dispensing fees, prior to the application of copayments, coinsurance, and other cost-sharing charges, if any.
- (c) (b) "Pharmacy benefit manager" means a person or entity doing business in this state which contracts to administer or manage prescription drug benefits on behalf of a health insurer 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 pharmacy that filled the prescription or provided the pharmacy service.
- (2) A contract between a health insurer and a pharmacy benefit manager must require that the pharmacy benefit manager:

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139	(a)	Update maximu	m allowable	cost	pricing	information	at
140	least eve:	ry 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 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.
- (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:
 - (a) The applicable cost-sharing amount; or
- (b) The retail price of the drug in the absence of prescription drug coverage.
- (5) A contract between a health insurer and a pharmacy benefit manager must require the pharmacy benefit manager to report annually the following to the insurer:
- (a) The aggregate amount of rebates the pharmacy benefit manager 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.

- (b) The aggregate amount of administrative fees paid to the pharmacy benefit manager by the insurer for the administration of the insurer's prescription drug benefit programs.
- (c) The types and aggregate amounts of any fees or remittances paid to the pharmacy benefit manager by pharmacies. The pharmacy benefit manager shall distinguish between fees paid by covered entities, as defined in 42 U.S.C. § 256b, and fees paid by pharmacies which are not covered entities.
- (d) The aggregate amount of revenue generated by the pharmacy benefit manager through the use of spread pricing in association with the administration of the insurer's pharmacy benefit programs.
- (6) Not later than June 30, 2021, and annually thereafter, a health insurer shall submit a report to the office that includes the information provided by its contracted pharmacy benefit managers under subsection (5). The office shall publish on its website an analysis of the reported information required to be provided to the insurer under subsection (5) in an aggregated amount for each pharmacy benefit manager.
- (7) (5) This section applies to contracts entered into or renewed on or after July 1, 20202018.

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189	Section	6.	Section	627.6572,	Florida	Statutes,	is	amended
190	to read:							

- 627.6572 Pharmacy benefit manager contracts.-
- (1) As used in this section, the term:
- (a) "Administrative fee" means a fee or payment under a contract between a health insurer and a pharmacy benefit manager associated with the pharmacy benefit manager's administration of the insurer's prescription drug benefit programs that is paid by the insurer to the pharmacy benefit manager.
- (b) (a) "Maximum allowable cost" means the per-unit amount that a pharmacy benefit manager reimburses a pharmacist for a prescription drug, excluding dispensing fees, prior to the application of copayments, coinsurance, and other cost-sharing charges, if any.
- (c) (b) "Pharmacy benefit manager" means a person or entity doing business in this state which contracts to administer or manage prescription drug benefits on behalf of a health insurer 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

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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.

- (2) A contract between a health insurer and a pharmacy benefit manager must require that the pharmacy benefit manager:
- (a) Update maximum allowable cost pricing information at 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 insurer 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.
- (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:
 - (a) The applicable cost-sharing amount; or

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238	(b)	The	retail	price	of	the	drug	in	the	absence	of
239	prescript	ion d	drug co	verage							

- (5) A contract between a health insurer and a pharmacy benefit manager must require the pharmacy benefit manager to report annually the following to the insurer:
- (a) The aggregate amount of rebates the pharmacy benefit manager received in association with claims administered on behalf of the insurer and the aggregate amount of such rebates the pharmacy benefit manager received that were not passed through to the insurer.
- (b) The aggregate amount of administrative fees paid to the pharmacy benefit manager by the insurer for the administration of the insurer's prescription drug benefit programs.
- (c) The types and aggregate amounts of any fees or remittances paid to the pharmacy benefit manager by pharmacies.

 The pharmacy benefit manager shall distinguish between fees paid by covered entities, as defined in 42 U.S.C. § 256b, and fees paid by pharmacies which are not covered entities.
- (d) The aggregate amount of revenue generated by the pharmacy benefit manager through the use of spread pricing in association with the administration of the insurer's pharmacy benefit programs.
- (6) Not later than June 30, 2021, and annually thereafter, a health insurer shall submit a report to the office that

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includes the information provided by its contracted pharmacy	
benefit managers under subsection (5). The office shall publi	sh
on its website an analysis of the reported information requir	ed
to be provided under subsection (5) in an aggregated amount f	or
each pharmacy benefit manager.	

(7) (5) This section applies to contracts entered into or renewed on or after July 1, 20202018.

Section 7. Section 641.3131, Florida Statutes, is created to read:

641.3131 Formulary changes resulting from drug price increases.—

- (1) A health maintenance organization issuing a major medical or other comprehensive coverage contract shall submit, and update as necessary, contact information for a single point-of-contact for use by prescription drug manufacturers to comply with s. 499.026. The Office shall maintain and publish a list of such points of contact.
- (2) A health maintenance organization issuing a major medical or other comprehensive coverage contract must provide written notice to affected subscribers at least 30 days in advance of making a drug formulary change resulting from a drug price increase reported pursuant to s. 499.026.
- (3) This section applies to contracts entered into or renewed on or after January 1, 2021.

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287		Section	8.	Section	641.314,	Florida	Statutes,	is	amended
288	to	read:							

- 641.314 Pharmacy benefit manager contracts.-
- (1) As used in this section, the term:
- (a) "Administrative fee" means a fee or payment under a contract between a health maintenance organization and a pharmacy benefit manager associated with the pharmacy benefit manager's administration of the health maintenance organization's prescription drug benefit programs that is paid by the health maintenance organization to the pharmacy benefit manager.
- (b) (a) "Maximum allowable cost" means the per-unit amount that a pharmacy benefit manager reimburses a pharmacist for a prescription drug, excluding dispensing fees, prior to the application of copayments, coinsurance, and other cost-sharing charges, if any.
- (c) (b) "Pharmacy benefit manager" means a person or entity doing business in this state which contracts to administer or manage prescription drug benefits on behalf of a health maintenance organization 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 a subscriber, to the pharmacy benefit manager after the claim has been adjudicated at the pharmacy.

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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.

- (2) A contract between a health maintenance organization and a pharmacy benefit manager must require that the pharmacy benefit manager:
- (a) Update maximum allowable cost pricing information at 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.
- (4) A contract between a health maintenance organization and a pharmacy benefit manager must prohibit the pharmacy benefit manager from requiring a subscriber to make a payment

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for a prescription drug at the point of sale in an amount that exceeds the lesser of:

- (a) The applicable cost-sharing amount; or
- (b) The retail price of the drug in the absence of prescription drug coverage.
- (5) A contract between a health maintenance organization and a pharmacy benefit manager must require the pharmacy benefit manager to report annually the following to the health maintenance organization:
- (a) The aggregate amount of rebates the pharmacy benefit manager received in association with claims administered on behalf of the health maintenance organization and the aggregate amount of such rebates the pharmacy benefit manager received that were not passed through to the health maintenance organization.
- (b) The aggregate amount of administrative fees paid to the pharmacy benefit manager by the health maintenance organization for the administration of the health maintenance organization's prescription drug benefit programs.
- (c) The types and aggregate amounts of any fees or remittances paid to the pharmacy benefit manager by pharmacies.

 The pharmacy benefit manager shall distinguish between fees paid by covered entities, as defined in 42 U.S.C. § 256b, and fees paid by pharmacies which are not covered entities.

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<u>(d)</u>	The	aggre	egate	amount	of r	ever	nue g	generate	ed by	the	
pharmacy	benet	fit ma	nagei	throu	gh th	e us	se of	spread	d prid	cing	in
associati	ion w	ith th	ne adr	ninistr	ation	of	the	health	maint	tenar	ıce
organization's pharmacy benefit programs.											

- (6) Not later than June 30, 2021, and annually thereafter, a health maintenance organization shall submit a report to the office that includes the information provided by its contracted pharmacy benefit managers under subsection (5). The office shall publish on its website an analysis of the reported information required to be provided to the health maintenance organization under subsection (5) in an aggregated amount for each pharmacy benefit manager.
- (7) (5) This section applies to contracts entered into or renewed on or after July 1, 20202018.
- Section 9. (1) The Agency for Health Care Administration shall contract for an independent analysis of pharmacy benefit management practices under the Statewide Medicaid Managed Care program. The analysis shall outline the types of pharmacy benefit pricing contracts in place between managed care plans and contracted pharmacy benefit managers and between managed care plans or pharmacy benefit managers and pharmacies. At a minimum, the analysis shall include:
- (a) An examination of the fees paid to each contracted pharmacy benefit manager by each managed care plan.

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	(b) An exa		examination		of the fees		charged to		pharmacies		by
each	manage	d care	plan	or	contra	acted	pharmacy	, be	enefit	manag	ger.

- (c) A determination of spread pricing revenues retained by each managed care plan or contracted pharmacy benefit manager.
- (2) For purposes of this section, the term "pharmacy benefit manager" means a person or entity doing business in this state which contracts to administer or manage prescription drug benefits on behalf of a managed care plan.
- (3) For purposes of this section, the term "spread pricing" refers to any amount a managed care plan or pharmacy benefit manager received from the Medicaid program for payment of a prescription drug that is greater than that paid to the pharmacist or pharmacy that filled a prescription for that prescription drug.
- (4) The agency shall submit the completed analysis to the Governor, the President of the Senate, and the Speaker of the House of Representatives by June 30, 2020.
- Section 10. The Agency for Health Care Administration shall conduct an analysis of managed care plan pharmacy networks under the Statewide Medicaid Managed Care program to ensure that enrollees have sufficient choice of pharmacies within established geographic parameters. The agency must also analyze the composition of each managed care plan pharmacy network to 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.
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431	TITLE AMENDMENT
432	Remove everything before the enacting clause and insert:

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COMMITTEE/SUBCOMMITTEE AMENDMENT Bill No. HB 7045 (2020)

Amendment No. 1

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

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COMMITTEE/SUBCOMMITTEE AMENDMENT Bill No. HB 7045 (2020)

Amendment No. 1

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

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COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 7045 (2020)

Amendment No. 1

183	under	the	Statewi	Lde	Medicaid	Managed	Care	<pre>program;</pre>	defining
184	terms;	: pro	oviding	an	effective	e date.			

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