

LEGISLATIVE ACTION

Senate Comm: RCS 03/28/2023 House

The Committee on Health Policy (Brodeur) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause

and insert:

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Section 1. This act may be cited as the "Prescription Drug Reform Act."

Section 2. Subsection (29) is added to section 499.005, Florida Statutes, to read:

9 499.005 Prohibited acts.-It is unlawful for a person to
10 perform or cause the performance of any of the following acts in

## 100780

11	this state:
12	(29) Failure to accurately complete and timely submit
13	reportable drug price increase forms and reports as required
14	under this part and rules adopted thereunder.
15	Section 3. Subsection (16) is added to section 499.012,
16	Florida Statutes, to read:
17	499.012 Permit application requirements
18	(16) A permit for a prescription drug manufacturer or a
19	nonresident prescription drug manufacturer is subject to the
20	requirements of s. 499.026.
21	Section 4. Section 499.026, Florida Statutes, is created to
22	read:
23	499.026 Notification of manufacturer prescription drug
24	price increases
25	(1) As used in this section, the term:
26	(a) "Course of therapy" means the recommended daily dose
27	units of a prescription drug pursuant to its prescribing label
28	for 30 days or the recommended daily dose units of a
29	prescription drug pursuant to its prescribing label for a normal
30	course of treatment which is less than 30 days.
31	(b) "Manufacturer" means a person holding a prescription
32	drug manufacturer permit or a nonresident prescription drug
33	manufacturer permit under s. 499.01.
34	(c) "Prescription drug" has the same meaning as in s.
35	499.003 and includes biological products but is limited to those
36	prescription drugs and biological products intended for human
37	use.
38	(d) "Reportable drug price increase" means, for a
39	prescription drug with a wholesale acquisition cost of at least

100780

40	\$100 for a course of therapy before the effective date of an
41	increase:
42	1. Any increase of 15 percent or more of the wholesale
43	acquisition cost during the preceding 12-month period; or
44	2. Any increase of 40 percent or more of the wholesale
45	acquisition cost during the preceding 3 calendar years.
46	(e) "Wholesale acquisition cost" means, with respect to a
47	prescription drug or biological product, the manufacturer's list
48	price for the prescription drug or biological product to
49	wholesalers or direct purchasers in the United States, not
50	including prompt pay or other discounts, rebates, or reductions
51	in price, for the most recent month for which the information is
52	available, as reported in wholesale price guides or other
53	publications of drug or biological product pricing data.
54	(2) On the effective date of a manufacturer's reportable
55	drug price increase, the manufacturer must provide notification
56	of each reportable drug price increase to the department on a
57	form prescribed by the department. The form must require the
58	manufacturer to specify all of the following:
59	(a) The proprietary and nonproprietary names of the
60	prescription drug, as applicable.
61	(b) The wholesale acquisition cost before the reportable
62	drug price increase.
63	(c) The dollar amount of the reportable drug price
64	increase.
65	(d) The percentage amount of the reportable drug price
66	increase from the wholesale acquisition cost before the
67	reportable drug price increase.
68	(e) A statement regarding whether a change or improvement

## 100780

69	in the prescription drug necessitates the reportable drug price
70	increase. If so, the manufacturer must describe the change or
71	improvement.
72	(f) The intended uses of the prescription drug.
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74	This subsection does not prohibit a manufacturer from notifying
75	other parties, such as pharmacy benefit managers, of a drug
76	price increase before the effective date of the drug price
77	increase.
78	(3) By April 1 of each year, each manufacturer shall submit
79	a report to the department on a form prescribed by the
80	department. A report is not deemed to be submitted until
81	approved by the department. The report must include all of the
82	following:
83	(a) A list of all prescription drugs affected by a
84	reportable drug price increase during the previous calendar year
85	and both the dollar amount of each reportable drug price
86	increase and the percentage increase of each reportable drug
87	price increase relative to the previous wholesale acquisition
88	cost of the prescription drug. The prescription drugs must be
89	identified using their proprietary names and nonproprietary
90	names, as applicable.
91	(b) If more than one form has been filed under this section
92	for previous reportable drug price increases, the percentage
93	increase of the prescription drug from the earliest form filed
94	to the most recent form filed.
95	(c) The intended uses of each prescription drug listed in
96	the report and whether the prescription drug manufacturer
97	benefits from market exclusivity for such drug.

100780

98	(d) The length of time the prescription drug has been
99	available for purchase.
100	(e) A complete description of the factors contributing to
101	each reportable drug price increase. The factors must be
102	provided with such specificity as to explain the need or
103	justification for each reportable drug price increase. The
104	department may request additional information from a
105	manufacturer relating to the need or justification of any
106	reportable drug price increase before approving the
107	manufacturer's report.
108	(f) Any action that the manufacturer has filed to extend a
109	patent report after the first extension has been granted.
110	(4)(a) The department shall submit all forms and reports
111	submitted by manufacturers to the Agency for Health Care
112	Administration, to be posted on the agency's website pursuant to
113	s. 408.062. The agency may not post on its website any of the
114	information provided pursuant to paragraph (2)(e), paragraph
115	(3)(e), or paragraph (3)(f) which is marked as a trade secret.
116	The agency shall compile all information on the forms and
117	reports submitted by manufacturers and make it available upon
118	request to the Governor, the President of the Senate, and the
119	Speaker of the House of Representatives.
120	(b) Except for information provided pursuant to paragraph
121	(2)(e), paragraph (3)(e), or paragraph (3)(f), a manufacturer
122	may not claim a public records exemption for a trade secret
123	under s. 119.0715 for any information required by the department
124	under this section. Department employees remain protected from
125	liability for release of forms and reports pursuant to s.
126	119.0715(4).
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100780

127 (5) The department, in consultation with the Agency for Health Care Administration, shall adopt rules to implement this 128 129 section. 130 (a) The department shall adopt necessary emergency rules 131 pursuant to s. 120.54(4) to implement this section. If an 132 emergency rule adopted under this section is held to be unconstitutional or an invalid exercise of delegated legislative 133 134 authority and becomes void, the department may adopt an 135 emergency rule pursuant to this section to replace the rule that 136 has become void. If the emergency rule adopted to replace the void emergency rule is also held to be unconstitutional or an 137 138 invalid exercise of delegated legislative authority and becomes 139 void, the department must follow the nonemergency rulemaking 140 procedures of the Administrative Procedure Act to replace the 141 rule that has become void. 142 (b) For emergency rules adopted under this section, the 143 department need not make the findings required under s. 144 120.54(4)(a). Emergency rules adopted under this section are 145 also exempt from: 146 1. Sections 120.54(3)(b) and 120.541. Challenges to 147 emergency rules adopted under this section are subject to the time schedules provided in s. 120.56(5). 148 149 2. Section 120.54(4)(c) and remain in effect until replaced 150 by rules adopted under the nonemergency rulemaking procedures of 151 the Administrative Procedure Act. Section 5. Paragraph (a) of subsection (10) of section 152 153 624.307, Florida Statutes, is amended, and paragraph (b) of that 154 subsection is republished, to read: 155 624.307 General powers; duties.-

Page 6 of 46

100780

(10) (a) The Division of Consumer Services shall perform the following functions concerning products or services regulated by the department or office:

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1. Receive inquiries and complaints from consumers.

2. Prepare and disseminate information that the department deems appropriate to inform or assist consumers.

3. Provide direct assistance to and advocacy for consumers who request such assistance or advocacy.

4. With respect to apparent or potential violations of law or applicable rules committed by a person or entity licensed by the department or office, report apparent or potential violations to the office or to the appropriate division of the department, which may take any additional action it deems appropriate.

5. Designate an employee of the division as the primary contact for consumers on issues relating to sinkholes.

6. Designate an employee of the division as the primary contact for consumers and pharmacies on issues relating to pharmacy benefit managers. The division must refer to the office any consumer complaint that alleges conduct that may constitute a violation of part VII of chapter 626 or for which a pharmacy benefit manager does not respond in accordance with paragraph (b).

(b) Any person licensed or issued a certificate of authority by the department or the office shall respond, in writing, to the division within 20 days after receipt of a written request for documents and information from the division concerning a consumer complaint. The response must address the issues and allegations raised in the complaint and include any



185 requested documents concerning the consumer complaint not 186 subject to attorney-client or work-product privilege. The division may impose an administrative penalty for failure to 187 188 comply with this paragraph of up to \$2,500 per violation upon 189 any entity licensed by the department or the office and \$250 for 190 the first violation, \$500 for the second violation, and up to 191 \$1,000 for the third or subsequent violation upon any individual 192 licensed by the department or the office.

Section 6. Subsection (1) of section 624.490, Florida Statutes, is amended to read:

624.490 Registration of pharmacy benefit managers.-

(1) As used in this section, the term "pharmacy benefit manager" <u>has the same meaning as in s. 626.88</u> means a person or entity doing business in this state which contracts to administer prescription drug benefits on behalf of a health insurer or a health maintenance organization to residents of this state.

Section 7. Subsections (1) and (5) of section 624.491, Florida Statutes, are amended to read:

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624.491 Pharmacy audits.-

205 (1) A pharmacy benefits plan or program as defined in s. 206 626.8825 health insurer or health maintenance organization 207 providing pharmacy benefits through a major medical individual or group health insurance policy or a health maintenance 2.08 209 contract, respectively, must comply with the requirements of 210 this section when the pharmacy benefits plan or program health 211 insurer or health maintenance organization or any person or 212 entity acting on behalf of the pharmacy benefits plan or program 213 health insurer or health maintenance organization, including,

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214 but not limited to, a pharmacy benefit manager as defined in <u>s.</u> 215 626.88 = 624.490(1), audits the records of a pharmacy licensed 216 under chapter 465. The person or entity conducting such audit 217 must:

(a) Except as provided in subsection (3), notify the pharmacy at least 7 calendar days before the initial onsite audit for each audit cycle.

(b) Not schedule an onsite audit during the first 3 calendar days of a month unless the pharmacist consents otherwise.

(c) Limit the duration of the audit period to 24 months after the date a claim is submitted to or adjudicated by the entity.

(d) In the case of an audit that requires clinical or professional judgment, conduct the audit in consultation with, or allow the audit to be conducted by, a pharmacist.

(e) Allow the pharmacy to use the written and verifiable records of a hospital, physician, or other authorized practitioner, which are transmitted by any means of communication, to validate the pharmacy records in accordance with state and federal law.

(f) Reimburse the pharmacy for a claim that was retroactively denied for a clerical error, typographical error, scrivener's error, or computer error if the prescription was properly and correctly dispensed, unless a pattern of such errors exists, fraudulent billing is alleged, or the error results in actual financial loss to the entity.

(g) Provide the pharmacy with a copy of the preliminaryaudit report within 120 days after the conclusion of the audit.



(h) Allow the pharmacy to produce documentation to address
a discrepancy or audit finding within 10 business days after the
preliminary audit report is delivered to the pharmacy.
(i) Provide the pharmacy with a copy of the final audit
report within 6 months after the pharmacy's receipt of the
preliminary audit report.
(i) Calculate any recomment or penalties based on actual

(j) Calculate any recoupment or penalties based on actual overpayments and not according to the accounting practice of extrapolation.

(5) A <u>pharmacy benefits plan or program</u> health insurer or health maintenance organization that, under terms of a contract, transfers to a pharmacy benefit manager the obligation to pay a pharmacy licensed under chapter 465 for any pharmacy benefit claims arising from services provided to or for the benefit of an insured or subscriber remains responsible for a violation of this section.

Section 8. Subsection (1) of section 626.88, Florida Statutes, is amended, and subsection (6) is added to that section, to read:

626.88 Definitions.-For the purposes of this part, the term:

(1) "Administrator" <u>means</u> is any person who directly or indirectly solicits or effects coverage of, collects charges or premiums from, or adjusts or settles claims on residents of this state in connection with authorized commercial self-insurance funds or with insured or self-insured programs which provide life or health insurance coverage or coverage of any other expenses described in s. 624.33(1); or any person who, through a health care risk contract as defined in s. 641.234 with an

Page 10 of 46



insurer or health maintenance organization, provides billing and collection services to health insurers and health maintenance organizations on behalf of health care providers; or a pharmacy benefit manager. The term does not include, other than any of the following persons:

(a) An employer or wholly owned direct or indirect subsidiary of an employer, on behalf of such employer's employees or the employees of one or more subsidiary or affiliated corporations of such employer.

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(b) A union on behalf of its members.

(c) An insurance company which is either authorized to transact insurance in this state or is acting as an insurer with respect to a policy lawfully issued and delivered by such company in and pursuant to the laws of a state in which the insurer was authorized to transact an insurance business.

(d) A health care services plan, health maintenance organization, professional service plan corporation, or person in the business of providing continuing care, possessing a valid certificate of authority issued by the office, and the sales representatives thereof, if the activities of such entity are limited to the activities permitted under the certificate of authority.

(e) An entity that is affiliated with an insurer and that only performs the contractual duties, between the administrator and the insurer, of an administrator for the direct and assumed insurance business of the affiliated insurer. The insurer is responsible for the acts of the administrator and is responsible for providing all of the administrator's books and records to the insurance commissioner, upon a request from the insurance



301 commissioner. For purposes of this paragraph, the term "insurer" 302 means a licensed insurance company, health maintenance 303 organization, prepaid limited health service organization, or 304 prepaid health clinic.

(f) A nonresident entity licensed in its state of domicile as an administrator if its duties in this state are limited to the administration of a group policy or plan of insurance and no more than a total of 100 lives for all plans reside in this state.

310 (g) An insurance agent licensed in this state whose 311 activities are limited exclusively to the sale of insurance.

312 (h) A person appointed as a managing general agent in this 313 state, whose activities are limited exclusively to the scope of 314 activities conveyed under such appointment.

315 (i) An adjuster licensed in this state whose activities are 316 limited to the adjustment of claims.

317 (j) A creditor on behalf of such creditor's debtors with 318 respect to insurance covering a debt between the creditor and 319 its debtors.

320 (k) A trust and its trustees, agents, and employees acting 321 pursuant to such trust established in conformity with 29 U.S.C. 322 s. 186.

(1) A trust exempt from taxation under s. 501(a) of the Internal Revenue Code, a trust satisfying the requirements of ss. 624.438 and 624.439, or any governmental trust as defined in s. 624.33(3), and the trustees and employees acting pursuant to such trust, or a custodian and its agents and employees, including individuals representing the trustees in overseeing the activities of a service company or administrator, acting

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330 pursuant to a custodial account which meets the requirements of 331 s. 401(f) of the Internal Revenue Code.

(m) A financial institution which is subject to supervision or examination by federal or state authorities or a mortgage lender licensed under chapter 494 who collects and remits premiums to licensed insurance agents or authorized insurers concurrently or in connection with mortgage loan payments.

(n) A credit card issuing company which advances for and collects premiums or charges from its credit card holders who 339 have authorized such collection if such company does not adjust 340 or settle claims.

(o) A person who adjusts or settles claims in the normal course of such person's practice or employment as an attorney at law and who does not collect charges or premiums in connection with life or health insurance coverage.

345 (p) A person approved by the department who administers 346 only self-insured workers' compensation plans.

(q) A service company or service agent and its employees, authorized in accordance with ss. 626.895-626.899, serving only a single employer plan, multiple-employer welfare arrangements, or a combination thereof.

(r) Any provider or group practice, as defined in s. 456.053, providing services under the scope of the license of the provider or the member of the group practice.

(s) Any hospital providing billing, claims, and collection 355 services solely on its own and its physicians' behalf and 356 providing services under the scope of its license.

357 (t) A corporation not for profit whose membership consists 358 entirely of local governmental units authorized to enter into



359	risk management consortiums under s. 112.08.
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361	A person who provides billing and collection services to health
362	insurers and health maintenance organizations on behalf of
363	health care providers shall comply with the provisions of ss.
364	627.6131, 641.3155, and 641.51(4).
365	(6) "Pharmacy benefit manager" means a person or an entity
366	doing business in this state which contracts to administer
367	prescription drug benefits on behalf of a pharmacy benefits plan
368	or program as defined in s. 626.8825. The term includes, but is
369	not limited to, a person or an entity that performs one or more
370	of the following services:
371	(a) Pharmacy claims processing.
372	(b) Administration or management of pharmacy discount card
373	programs.
374	(c) Managing pharmacy networks or pharmacy reimbursement.
375	(d) Paying or managing claims for pharmacist services
376	provided to covered persons.
377	(e) Developing or managing a clinical formulary, including
378	utilization management or quality assurance programs.
379	(f) Pharmacy rebate administration.
380	(g) Managing patient compliance, therapeutic intervention,
381	or generic substitution programs.
382	(h) Administration or management of a mail-order pharmacy
383	program.
384	Section 9. Present subsections (3) through (6) of section
385	626.8805, Florida Statutes, are redesignated as subsections (4)
386	through (7), respectively, a new subsection (3) and subsection
387	(8) are added to that section, and subsection (1) and present

100780

subsection (3) of that section are amended, to read: 626.8805 Certificate of authority to act as administrator.-(1) It is unlawful for any person to act as or hold himself or herself out to be an administrator in this state without a valid certificate of authority issued by the office pursuant to ss. 626.88-626.894. A pharmacy benefit manager that is registered with the office under s. 624.490 as of June 30, 2023, may continue to operate until January 1, 2024, as an administrator without a certificate of authority and is not in violation of the requirement to possess a valid certificate of authority as an administrator during that timeframe. To qualify for and hold authority to act as an administrator in this state, an administrator must otherwise be in compliance with this code and with its organizational agreement. The failure of any person, excluding a pharmacy benefit manager, to hold such a certificate while acting as an administrator shall subject such person to a fine of not less than \$5,000 or more than \$10,000 for each violation. A person who, on or after January 1, 2024, does not hold a certificate of authority to act as an administrator while operating as a pharmacy benefit manager is subject to a fine of \$10,000 per violation per day. (3) An applicant that is a pharmacy benefit manager must also submit all of the following: (a) A complete biographical statement on forms prescribed by the commission, an independent investigation report, and fingerprints obtained pursuant to chapter 624 of all of the individuals referred to in paragraph (2)(c). (b) A self-disclosure of any administrative, civil, or criminal complaints, settlements, or discipline of the

Page 15 of 46

100780

417	applicant, or any of the applicant's affiliates, which relate to
418	a violation of the insurance laws, including pharmacy benefit
419	manager laws, in any state.
420	(c) A statement attesting to compliance with the network
421	requirements in s. 626.8825 beginning January 1, 2024.
422	(4)(a) <del>(3)</del> The applicant shall make available for inspection
423	by the office copies of all contracts relating to services
424	provided by the administrator to insurers or other persons using
425	the services of the administrator.
426	(b) An applicant that is a pharmacy benefit manager shall
427	also make available for inspection by the office:
428	1. Copies of all contract templates with any pharmacy as
429	defined in s. 465.003; and
430	2. Copies of all subcontracts to support its operations.
431	(8) A pharmacy benefit manager is exempt from fees
432	associated with the initial application and the annual filing
433	<u>fees in s. 626.89.</u>
434	Section 10. Section 626.8814, Florida Statutes, is amended
435	to read:
436	626.8814 Disclosure of ownership or affiliation
437	(1) Each administrator shall identify to the office any
438	ownership interest or affiliation of any kind with any insurance
439	company responsible for providing benefits directly or through
440	reinsurance to any plan for which the administrator provides
441	administrative services.
442	(2) Pharmacy benefit managers shall also identify to the
443	office any ownership affiliation of any kind with any pharmacy
444	which, either directly or indirectly, through one or more
445	intermediaries:

100780

446	(a) Has an investment or ownership interest in a pharmacy
447	benefit manager holding a certificate of authority issued under
448	this part;
449	(b) Shares common ownership with a pharmacy benefit manager
450	holding a certificate of authority issued under this part; or
451	(c) Has an investor or a holder of an ownership interest
452	which is a pharmacy benefit manager holding a certificate of
453	authority issued under this part.
454	(3) A pharmacy benefit manager shall report any change in
455	information required by subsection (2) to the office in writing
456	within 60 days after the change occurs.
457	Section 11. Section 626.8825, Florida Statutes, is created
458	to read:
459	626.8825 Pharmacy benefit manager transparency and
460	accountability
461	(1) DEFINITIONSAs used in this section, the term:
462	(a) "Adjudication transaction fee" means a fee charged by
463	the pharmacy benefit manager to the pharmacy for electronic
464	claim submissions.
465	(b) "Affiliated pharmacy" means a pharmacy that, either
466	directly or indirectly through one or more intermediaries:
467	1. Has an investment or ownership interest in a pharmacy
468	benefit manager holding a certificate of authority issued under
469	this part;
470	2. Shares common ownership with a pharmacy benefit manager
471	holding a certificate of authority issued under this part; or
472	3. Has an investor or a holder of an ownership interest
473	which is a pharmacy benefit manager holding a certificate of
474	authority issued under this part.

Page 17 of 46

100780

475 (c) "Brand name or generic effective rate" means the 476 contractual rate set forth by a pharmacy benefit manager for the reimbursement of covered brand name or generic drugs, calculated 477 478 using the total payments in the aggregate, by drug type, during 479 the performance period. The effective rates are typically 480 calculated as a discount from industry benchmarks, such as average wholesale price or wholesale acquisition cost. 481 482 (d) "Covered person" means a person covered by, participating in, or receiving the benefit of a pharmacy 483 484 benefits plan or program. 485 (e) "Direct and indirect remuneration fees" means price 486 concessions that are paid to the pharmacy benefit manager by the 487 pharmacy retrospectively and that cannot be calculated at the 488 point of sale. The term may also include discounts, chargebacks 489 or rebates, cash discounts, free goods contingent on a purchase 490 agreement, upfront payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or 491 492 similar benefits from manufacturers, pharmacies, or similar 493 entities. 494 (f) "Dispensing fee" means a fee intended to cover 495 reasonable costs associated with providing the drug to a covered 496 person. This cost includes the pharmacist's services and the 497 overhead associated with maintaining the facility and equipment 498 necessary to operate the pharmacy. 499 (g) "Effective rate guarantee" means the minimum ingredient 500 cost reimbursement a pharmacy benefit manager guarantees it will 501 pay for pharmacist services during the applicable measurement 502 period. 503 (h) "Erroneous claims" means pharmacy claims submitted in

100780

504	error, including, but not limited to, unintended, incorrect,
505	fraudulent, or test claims.
506	(i) "Incentive payment" means a retrospective monetary
507	payment made as a reward or recognition by the pharmacy benefits
508	plan or program or pharmacy benefit manager to a pharmacy for
509	meeting or exceeding predefined pharmacy performance metrics as
510	related to quality measures, such as Healthcare Effectiveness
511	Data and Information Set measures.
512	(j) "Maximum allowable cost appeal pricing adjustment"
513	means a retrospective positive payment adjustment made to a
514	pharmacy by the pharmacy benefits plan or program or by the
515	pharmacy benefit manager pursuant to an approved maximum
516	allowable cost appeal request submitted by the same pharmacy to
517	dispute the amount reimbursed for a drug based on the pharmacy
518	benefit manager's listed maximum allowable cost price.
519	(k) "Monetary recoupments" means rescinded or recouped
520	payments from a pharmacy or provider by the pharmacy benefits
521	plan or program or by the pharmacy benefit manager.
522	(1) "Network" means a group of pharmacies that agree to
523	provide pharmacist services to covered persons on behalf of a
524	pharmacy benefits plan or program or a group of pharmacy
525	benefits plans or programs in exchange for payment for such
526	services. The term includes a pharmacy that generally dispenses
527	outpatient prescription drugs to covered persons.
528	(m) "Network reconciliation offsets" means a process during
529	annual payment reconciliation between a pharmacy benefit manager
530	and a pharmacy which allows the pharmacy benefit manager to
531	offset an amount for overperformance or underperformance of
532	contractual guarantees across guaranteed line items, channels,

Page 19 of 46



533	networks, or payors, as applicable.
534	(n) "Participation contract" means any agreement between a
535	pharmacy benefit manager and pharmacy for the provision and
536	reimbursement of pharmacist services and any exhibits,
537	attachments, amendments, or addendums to such agreement.
538	(o) "Pass-through pricing model" means a payment model used
539	by a pharmacy benefit manager in which the payments made by the
540	pharmacy benefits plan or program to the pharmacy benefit
541	manager for the covered outpatient drugs are:
542	1. Equivalent to the payments the pharmacy benefit manager
543	makes to a dispensing pharmacy or provider for such drugs,
544	including any contracted professional dispensing fee between the
545	pharmacy benefit manager and its network of pharmacies. Such
546	dispensing fee would be paid if the pharmacy benefits plan or
547	program was making the payments directly.
548	2. Passed through in their entirety by the pharmacy
549	benefits plan or program or by the pharmacy benefit manager to
550	the pharmacy or provider that dispenses the drugs, and the
551	payments are made in a manner that is not offset by any
552	reconciliation.
553	(p) "Pharmacist" has the same meaning as in s. 465.003.
554	(q) "Pharmacist services" means products, goods, and
555	services or any combination of products, goods, and services
556	provided as part of the practice of the profession of pharmacy
557	as defined in s. 465.003 or otherwise covered by a pharmacy
558	benefits plan or program.
559	(r) "Pharmacy" has the same meaning as in s. 465.003.
560	(s) "Pharmacy benefit manager" has the same meaning as in
561	<u>s. 626.88.</u>

100780

562 (t) "Pharmacy benefits plan or program" means a plan or program that pays for, reimburses, covers the cost of, or 563 564 provides access to discounts on pharmacist services provided by 565 one or more pharmacies to covered persons who reside in, are 566 employed by, or receive pharmacist services from this state. The 567 term includes, but is not limited to, health maintenance organizations, health insurers, self-insured employer health 568 569 plans, discount card programs, and government-funded health 570 plans, including the Statewide Medicaid Managed Care program 571 established pursuant to part IV of chapter 409 and the state 572 group insurance program pursuant to part I of chapter 110. 573 (u) "Rebate" means all payments that accrue to a pharmacy 574 benefit manager or its pharmacy benefits plan or program client, 575 directly or indirectly, from a pharmaceutical manufacturer, 576 including, but not limited to, discounts, administration fees, 577 credits, incentives, or penalties associated directly or indirectly in any way with claims administered on behalf of a 578 579 pharmacy benefits plan or program client. (v) "Spread pricing" is the practice in which a pharmacy 580 581 benefit manager charges a pharmacy benefits plan or program a 582 different amount for pharmacist services than the amount the 583 pharmacy benefit manager reimburses a pharmacy for such 584 pharmacist services. (w) "Usual and customary price" means the amount charged to 585 586 cash customers for a pharmacist service exclusive of sales tax 587 or other amounts claimed. 588 (2) CONTRACTS BETWEEN A PHARMACY BENEFIT MANAGER AND A 589 PHARMACY BENEFITS PLAN OR PROGRAM.-In addition to any other 590 requirements in the Florida Insurance Code, all contractual

Page 21 of 46

100780

591	arrangements executed, amended, adjusted, or renewed on or after
592	July 1, 2023, which are applicable to pharmacy benefits covered
593	on or after January 1, 2024, between a pharmacy benefit manager
594	and a pharmacy benefits plan or program must:
595	(a) Use a pass-through pricing model, remaining consistent
596	with the prohibition in paragraph (3)(c).
597	(b) Exclude terms that allow for the direct or indirect
598	engagement in the practice of spread pricing unless the pharmacy
599	benefit manager passes along the entire amount of such
600	difference to the pharmacy benefits plan or program as allowable
601	under paragraph (a).
602	(c) Ensure that funds received in relation to providing
603	services for a pharmacy benefits plan or program or a pharmacy
604	are received by the pharmacy benefit manager in trust for the
605	pharmacy benefits plan or program or pharmacy, as applicable,
606	and are used or distributed only pursuant to the pharmacy
607	benefit manager's contract with the pharmacy benefits plan or
608	program or with the pharmacy or as otherwise required by
609	applicable law.
610	(d) Require the pharmacy benefit manager to calculate a
611	covered person's defined cost-sharing obligation at the point of
612	sale based on a price that is reduced by an amount equal to at
613	least 100 percent of all rebates received, or to be received, in
614	connection with the dispensing or administration of the covered
615	prescription drug, if the contractual arrangement delegates the
616	negotiation of rebates to the pharmacy benefit manager. All
617	rebates above the defined cost-sharing obligation must be passed
618	to the pharmacy benefits plan or program for the purpose of
619	reducing premiums. This paragraph does not preclude a pharmacy

Page 22 of 46

100780

620	benefits plan or program from decreasing a covered person's
621	defined cost-sharing obligation by an amount greater than that
622	provided for under this paragraph. The commission shall adopt
623	rules to implement this paragraph.
624	(e) Include network adequacy requirements that meet or
625	exceed the Medicare Part D program standards for convenient
626	access to network pharmacies set forth in 42 C.F.R. s. 423.120,
627	and that:
628	1. Do not limit a network to solely include affiliated
629	pharmacies;
630	2. Require a pharmacy benefit manager to offer a provider
631	contract to licensed pharmacies physically located on the
632	physical site of providers that are:
633	a. Within the pharmacy benefits plan's or program's
634	geographic service area and that have been specifically
635	designated as essential providers by the Agency for Health Care
636	Administration pursuant to s. 409.975(1)(a);
637	b. Designated as a Cancer Center of Excellence under s.
638	381.925, regardless of the pharmacy benefits plan's or program's
639	geographic service area;
640	c. Organ transplant hospitals, regardless of the pharmacy
641	benefits plan's or program's geographic service area;
642	d. Hospitals licensed as specialty children's hospitals as
643	defined in s. 395.002; or
644	e. Regional perinatal intensive care centers as defined in
645	s. 383.16(2), regardless of the pharmacy benefits plan's or
646	program's geographic service area.
647	
648	Such provider contracts must be solely for the administration or
	·



649 dispensing of covered prescription drugs, including biological 650 products, that are administered through infusions, intravenously 651 injected, inhaled during a surgical procedure, or a covered 652 parenteral drug, as part of onsite outpatient care; 653 3. Do not require a covered person to receive a 654 prescription drug by United States mail, common carrier, local 655 courier, third-party company or delivery service, or pharmacy 656 direct delivery. This subparagraph does not prohibit a pharmacy 657 benefit manager from operating mail order or delivery programs 658 on an opt-in basis at the sole discretion of a covered person; 659 4. Prohibit a requirement for a covered person to receive 660 pharmacist services from an affiliated pharmacy or an affiliated 661 health care provider for the in-person administration of covered 662 prescription drugs; offering or implementing pharmacy networks 663 that require or provide a promotional item or an incentive, 664 defined as anything other than a reduced copay or premium of a 665 covered drug, to a covered person to use an affiliated pharmacy 666 or an affiliated health care provider for the in-person 667 administration of covered prescription drugs; or advertising, 668 marketing, or promoting an affiliated pharmacy to covered 669 persons. Subject to the foregoing, a pharmacy benefit manager 670 may include an affiliated pharmacy in communications to covered 671 persons regarding network pharmacies and prices, provided that 672 the pharmacy benefit manager includes information, such as links

prominence. This paragraph may not be construed to prohibit a pharmacy benefit manager from entering into an agreement with an affiliated pharmacy to provide pharmacist services to covered

and that the information provided is accurate and of equal

to all nonaffiliated network pharmacies, in such communications

Page 24 of 46

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## 100780

678	persons.
679	(f) Prohibit the ability of a pharmacy benefit manager to
680	condition participation in one pharmacy network on participation
681	in any other pharmacy network or penalize a pharmacy for
682	exercising its prerogative not to participate in a specific
683	pharmacy network.
684	(g) Prohibit a pharmacy benefit manager from instituting a
685	network that requires a pharmacy to meet accreditation standards
686	inconsistent with or more stringent than applicable federal and
687	state requirements for licensure and operation as a pharmacy in
688	this state.
689	(3) CONTRACTS BETWEEN A PHARMACY BENEFIT MANAGER AND A
690	PARTICIPATING PHARMACYIn addition to other requirements in the
691	Florida Insurance Code, a participation contract executed,
692	amended, adjusted, or renewed on or after July 1, 2023, that
693	applies to pharmacist services on or after January 1, 2024,
694	between a pharmacy benefit manager and one or more pharmacies or
695	pharmacists, must include, in substantial form, terms that
696	ensure compliance with all of the following requirements, and
697	that, except to the extent not allowed by law, shall supersede
698	any contractual terms in the participation contract to the
699	contrary:
700	(a) At the time of adjudication for electronic claims or
701	the time of reimbursement for nonelectronic claims, the pharmacy
702	benefit manager shall provide the pharmacy with a remittance,
703	including such detailed information as is necessary for the
704	pharmacy or pharmacist to identify the reimbursement schedule
705	for the specific network applicable to the claim and which is
706	the basis used by the pharmacy benefit manager to calculate the

Page 25 of 46

100780

707	amount of reimbursement paid. This information must include, but
708	is not limited to, the applicable network reimbursement ID or
709	plan ID as defined in the most current version of the National
710	Council for Prescription Drug Programs (NCPDP) Telecommunication
711	Standard Implementation Guide, or its nationally recognized
712	successor industry guide. The commission shall adopt rules to
713	implement this paragraph.
714	(b) The pharmacy benefit manager must ensure that any basis
715	of reimbursement information is communicated to a pharmacy in
716	accordance with the NCPDP Telecommunication Standard
717	Implementation Guide, or its nationally recognized successor
718	industry guide, when performing reconciliation for any effective
719	rate guarantee, and that such basis of reimbursement information
720	communicated is accurate, corresponds with the applicable
721	network rate, and may be relied upon by the pharmacy.
722	(c) A prohibition of financial clawbacks or reconciliation
723	offsets. A pharmacy benefit manager may not recoup direct or
724	indirect remuneration fees, dispensing fees, brand name or
725	generic effective rate adjustments through reconciliation, or
726	any other monetary recoupments as related to discounts, multiple
727	network reconciliation offsets, adjudication transaction fees,
728	and any other instance when a fee may be recouped from a
729	pharmacy. For purposes of this section, the terms "financial
730	clawbacks" or "reconciliation offsets" do not include:
731	1. Any incentive payments provided by the pharmacy benefit
732	manager to a network pharmacy for meeting or exceeding
733	predefined quality measures, such as Healthcare Effectiveness
734	Data and Information Set measures; recoupment due to an
735	erroneous claim, fraud, waste, or abuse; a claim adjudicated in

Page 26 of 46

100780

i de la constante de	
error; a maximum allowab	le cost appeal pricing adjustment; or an
adjustment made as part of	of a pharmacy audit pursuant to s.
624.491.	
2. Any recoupment th	nat is returned to the state for
programs in chapter 409 c	or the state group insurance program in
s. 110.123.	
(d) A pharmacy bene:	fit manager may not unilaterally change
the terms of any particip	pation contract.
(e) Unless otherwise	e prohibited by law, a pharmacy benefit
manager may not prohibit	a pharmacy or pharmacist from:
1. Offering mail or	delivery services on an opt-in basis at
the sole discretion of the	ne covered person.
2. Mailing or delive	ering a prescription drug to a covered
person upon his or her re	equest.
3. Charging a shipp:	ing or handling fee to a covered person
requesting a prescription	n drug be mailed or delivered if the
pharmacy or pharmacist d	iscloses to the covered person before
the mailing or delivery t	the amount of the fee that will be
charged and that the fee	may not be reimbursable by the covered
person's pharmacy benefit	ts plan or program.
(f) The pharmacy ber	nefit manager must provide a pharmacy,
upon its request, a list	of pharmacy benefits plans or programs
in which the pharmacy is	a part of the network. Updates to the
list must be communicated	d to the pharmacy within 7 days. The
pharmacy benefit manager	may not restrict the pharmacy or
pharmacist from disclosin	ng this information to the public.
(g) The pharmacy ber	nefit manager must ensure that the
Electronic Remittance Adv	vice contains claim level payment
adjustments in accordance	e with the American National Standards

100780

for the pharmacy to reconcile any debits or credits, including,but not limited to, pharmacy NCPDP or NPI identifier, date ofservice, prescription number, refill number, adjustment code, ifapplicable, and transaction amount.(h) The pharmacy benefit manager shall provide a reasonableadministrative appeal procedure to allow a pharmacy orpharmacist to challenge the maximum allowable cost pricinginformation and the reimbursement made under the maximumallowable cost as defined in s. 627.64741 for a specific drug asbeing below the acquisition cost available to the challengingpharmacy or pharmacist.1. The administrative appeal procedure must include atelephone number and e-mail address, or a website, for thepurpose of submitting the administrative appeal. The appeal maybe submitted by the pharmacy or an agent of the pharmacygirectly to the pharmacy benefit manager or through a pharmacistmust be given at least 30 business days after a maximumallowable cost update or after an adjudication for an electronicclaim or reimbursement for a nonelectronic claim to file theadministrative appeal.2. The pharmacy benefit manager must respond to theadministrative appeal within 30 business days after receipt ofthe appeal.3. If the appeal is upheld, the pharmacy benefit managermust:	765	Institute Accredited Standards Committee, X12 format, and
but not limited to, pharmacy NCPDP or NPI identifier, date of service, prescription number, refill number, adjustment code, if applicable, and transaction amount. (h) The pharmacy benefit manager shall provide a reasonable administrative appeal procedure to allow a pharmacy or pharmacist to challenge the maximum allowable cost pricing information and the reimbursement made under the maximum allowable cost as defined in s. 627.64741 for a specific drug as being below the acquisition cost available to the challenging pharmacy or pharmacist. 1. The administrative appeal procedure must include a telephone number and e-mail address, or a website, for the purpose of submitting the administrative appeal. The appeal may be submitted by the pharmacy or an agent of the pharmacy directly to the pharmacy benefit manager or through a pharmacy service administration organization. The pharmacy or pharmacist must be given at least 30 business days after a maximum allowable cost update or after an adjudication for an electronic claim or reimbursement for a nonelectronic claim to file the administrative appeal. 2. The pharmacy benefit manager must respond to the administrative appeal within 30 business days after receipt of the appeal. 3. If the appeal is upheld, the pharmacy benefit manager must:	766	includes or is accompanied by the appropriate level of detail
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792 <u>must:</u>	790	the appeal.
	791	3. If the appeal is upheld, the pharmacy benefit manager
793 <u>a. Update the maximum allowable cost pricing information to</u>	792	must:
	793	a. Update the maximum allowable cost pricing information to

100780

794	at least the acquisition cost available to the pharmacy;
795	b. Permit the pharmacy or pharmacist to reverse and rebill
796	the claim in question;
797	c. Provide to the pharmacy or pharmacist the national drug
798	code on which the increase or change is based; and
799	d. Make the increase or change effective for each similarly
800	situated pharmacy or pharmacist who is subject to the applicable
801	maximum allowable cost pricing information.
802	4. If the appeal is denied, the pharmacy benefit manager
803	must provide to the pharmacy or pharmacist the national drug
804	code and the name of the national or regional pharmaceutical
805	wholesalers operating in this state which have the drug
806	currently in stock at a price below the maximum allowable cost
807	pricing information.
808	5. Every 90 days, a pharmacy benefit manager shall report
809	to the office the total number of appeals received and denied in
810	the preceding 90-day period for each specific drug for which an
811	appeal was submitted pursuant to this paragraph.
812	Section 12. Section 626.8827, Florida Statutes, is created
813	to read:
814	626.8827 Pharmacy benefit manager prohibited practicesIn
815	addition to other prohibitions in this part, a pharmacy benefit
816	manager may not do any of the following:
817	(1) Prohibit, restrict, or penalize in any way a pharmacy
818	or pharmacist from disclosing to any person any information that
819	the pharmacy or pharmacist deems appropriate, including, but not
820	limited to, information regarding any of the following:
821	(a) The nature of treatment, risks, or alternatives
822	thereto.

100780

823	(b) The availability of alternate treatment, consultations,
824	or tests.
825	(c) The decision of utilization reviewers or similar
826	persons to authorize or deny pharmacist services.
827	(d) The process used to authorize or deny pharmacist
828	services or benefits.
829	(e) Information on financial incentives and structures used
830	by the pharmacy benefits plan or program.
831	(f) Information that may reduce the costs of pharmacist
832	services.
833	(g) Whether the cost-sharing obligation exceeds the retail
834	price for a covered prescription drug and the availability of a
835	more affordable alternative drug, pursuant to s. 465.0244.
836	(2) Prohibit, restrict, or penalize in any way a pharmacy
837	or pharmacist from disclosing information to the office, the
838	Agency for Health Care Administration, Department of Management
839	Services, law enforcement, or state and federal governmental
840	officials, provided that the recipient of the information
841	represents it has the authority, to the extent provided by state
842	or federal law, to maintain proprietary information as
843	confidential; and before disclosure of information designated as
844	confidential, the pharmacist or pharmacy marks as confidential
845	any document in which the information appears or requests
846	confidential treatment for any oral communication of the
847	information.
848	(3) Communicate at the point-of-sale, or otherwise require,
849	a cost-sharing obligation for the covered person in an amount
850	that exceeds the lesser of:
851	(a) The applicable cost-sharing amount under the applicable

Page 30 of 46

100780

852	pharmacy benefits plan or program; or
853	(b) The usual and customary price, as defined in s.
854	626.8825, of the pharmacist services.
855	(4) Transfer or share records relative to prescription
856	information containing patient-identifiable or prescriber-
857	identifiable data to an affiliated pharmacy for any commercial
858	purpose other than the limited purposes of facilitating pharmacy
859	reimbursement, formulary compliance, or utilization review on
860	behalf of the applicable pharmacy benefits plan or program.
861	(5) Fail to make any payment due to a pharmacy for an
862	adjudicated claim with a date of service before the effective
863	date of a pharmacy's termination from a pharmacy benefit network
864	unless payments are withheld because of actual fraud on the part
865	of the pharmacy or except as otherwise required by law.
866	(6) Terminate the contract of, penalize, or disadvantage a
867	pharmacist or pharmacy due to a pharmacist or pharmacy:
868	(a) Disclosing information about pharmacy benefit manager
869	practices in accordance with this act;
870	(b) Exercising any of its prerogatives under this part; or
871	(c) Sharing any portion, or all, of the pharmacy benefit
872	manager contract with the office pursuant to a complaint or a
873	query regarding whether the contract is in compliance with this
874	act.
875	(7) Fail to comply with the requirements in s. 626.8825 or
876	<u>s. 624.491.</u>
877	Section 13. Section 626.8828, Florida Statutes, is created
878	to read:
879	626.8828 Investigations and examinations of pharmacy
880	benefit managers; expenses; penalties

Page 31 of 46

100780

881 (1) The office may investigate administrators who are 882 pharmacy benefit managers and applicants for authorization as provided in ss. 624.307 and 624.317. The office shall review any 883 884 referral made pursuant to s. 624.307(10) and shall investigate 885 any referral that, as determined by the Commissioner of 886 Insurance Regulation or his or her designee, reasonably 887 indicates a possible violation of this part. 888 (2) (a) The office shall examine the business and affairs of 889 each pharmacy benefit manager at least biennially. The biennial 890 examination of each pharmacy benefit manager must be a 891 systematic review for the purpose of determining the pharmacy 892 benefit manager's compliance with all provisions of this part 893 and all other laws or rules applicable to pharmacy benefit 894 managers and must include a detailed review of the pharmacy 895 benefit manager's compliance with ss. 626.8825 and 626.8827. The 896 first 2-year cycle for conducting biennial reviews begins July 897 1, 2023. By January 1 of the year following a 2-year cycle, the office must deliver to the Governor, the President of the 898 899 Senate, and the Speaker of the House of Representatives a report 900 summarizing the results of the biennial examinations during the 901 most recent 2-year cycle which includes detailed descriptions of 902 any violations committed by each pharmacy benefit manager and 903 detailed reporting of actions taken by the office against each 904 pharmacy benefit manager for such violations. 905 (b) The office also may conduct additional examinations as 906 often as it deems advisable or necessary for the purpose of 907 ascertaining compliance with this part and any other laws or 908 rules applicable to pharmacy benefit managers or applicants for 909 authorization.

100780

910	(c) If a referral made pursuant to s. 624.307(10)
911	reasonably indicates a pattern or practice of violations of this
912	part by a pharmacy benefit manager, the office must begin an
913	examination of the pharmacy benefit manager or include findings
914	related to such referral within an ongoing examination.
915	(d) Based on the findings of an examination that a pharmacy
916	benefit manager or an applicant for authorization has exhibited
917	a pattern or practice of knowing and willful violations of s.
918	626.8825 or s. 626.8827, the office may, pursuant to chapter
919	120, order a pharmacy benefit manager to file all contracts
920	between the pharmacy benefit manager and pharmacies or pharmacy
921	benefits plans or programs and any policies, guidelines, rules,
922	protocols, standard operating procedures, instructions, or
923	directives that govern or guide the manner in which the pharmacy
924	benefit manager or applicant conducts business related to such
925	knowing and willful violations for review and inspection for the
926	following 36-month period. Such documents are public records and
927	are not trade secrets or otherwise exempt from s. 119.07(1). As
928	used in this section, the term:
929	1. "Contracts" means any contract to which s. 626.8825 is
930	applicable.
931	2. "Knowing and willful" means any act of commission or
932	omission which is committed intentionally, as opposed to
933	accidentally, and which is committed with knowledge of the act's
934	unlawfulness or with reckless disregard as to the unlawfulness
935	of the act.
936	(e) Examinations may be conducted by an independent
937	professional examiner under contract to the office, in which
938	case payment must be made directly to the contracted examiner by

100780

939	the pharmacy benefit manager examined in accordance with the
940	rates and terms agreed to by the office and the examiner. The
941	commission shall adopt rules providing for the types of
942	independent professional examiners who may conduct examinations
943	under this section, which types must include, but need not be
944	limited to, independent certified public accountants, actuaries,
945	investment specialists, information technology specialists, or
946	others meeting criteria specified by commission rule. The rules
947	must also require that:
948	1. The rates charged to the pharmacy benefit manager being
949	examined are consistent with rates charged by other firms in a
950	similar profession and are comparable with the rates charged for
951	comparable examinations.
952	2. The firm selected by the office to perform the
953	examination has no conflicts of interest which might affect its
954	ability to independently perform its responsibilities for the
955	examination.
956	(3) In making investigations and examinations of pharmacy
957	benefit managers and applicants for authorization, the office
958	and such pharmacy benefit manager are subject to all of the
959	following provisions:
960	(a) Section 624.318, as to the conduct of examinations.
961	(b) Section 624.319, as to examination and investigation
962	reports.
963	(c) Section 624.321, as to witnesses and evidence.
964	(d) Section 624.322, as to compelled testimony.
965	(e) Section 624.324, as to hearings.
966	(f) Section 624.34, as to fingerprinting.
967	(g) Any other provision of chapter 624 applicable to the
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Page 34 of 46

100780

968	investigation or examination of a licensee under this part.
969	(4)(a) A pharmacy benefit manager must maintain an accurate
970	record of all contracts and records with all pharmacies and
971	pharmacy benefits plans or programs for the duration of the
972	contract, and for 5 years thereafter. Such contracts must be
973	made available to the office and kept in a form accessible to
974	the office.
975	(b) The office may order any pharmacy benefit manager or
976	applicant to produce any records, books, files, contracts,
977	advertising and solicitation materials, or other information and
978	may take statements under oath to determine whether the pharmacy
979	benefit manager or applicant is in violation of the law or is
980	acting contrary to the public interest.
981	(5)(a) Notwithstanding s. 624.307(3), each pharmacy benefit
982	manager and applicant for authorization must pay to the office
983	the expenses of the examination or investigation. Such expenses
984	include actual travel expenses, a reasonable living expense
985	allowance, compensation of the examiner, investigator, or other
986	person making the examination or investigation, and necessary
987	costs of the office directly related to the examination or
988	investigation. Such travel expenses and living expense
989	allowances are limited to those expenses necessarily incurred on
990	account of the examination or investigation and shall be paid by
991	the examined pharmacy benefit manager or applicant together with
992	compensation upon presentation by the office to such pharmacy
993	benefit manager or applicant of such charges and expenses after
994	a detailed statement has been filed by the examiner and approved
995	by the office.
996	(b) All moneys collected from pharmacy benefit managers and

100780

997	applicants for authorization pursuant to this subsection shall
998	be deposited into the Insurance Regulatory Trust Fund, and the
999	office may make deposits from time to time into such fund from
1000	moneys appropriated for the operation of the office.
1001	(c) Notwithstanding s. 112.061, the office may pay to the
1002	examiner, investigator, or person making such examination or
1003	investigation out of such trust fund the actual travel expenses,
1004	reasonable living expense allowance, and compensation in
1005	accordance with the statement filed with the office by the
1006	examiner, investigator, or other person, as provided in
1007	paragraph (a).
1008	(6) In addition to any other enforcement authority
1009	available to the office, the office shall impose an
1010	administrative fine of \$5,000 for each violation of s. 626.8825
1011	or s. 626.8827. Each instance of a violation of such sections by
1012	a pharmacy benefit manager against each individual pharmacy or
1013	prescription benefits plan or program constitutes a separate
1014	violation. Notwithstanding any other provision of law, there is
1015	no limitation on aggregate fines issued pursuant to this
1016	section. The proceeds from any administrative fine shall be
1017	deposited into the General Revenue Fund.
1018	(7) Failure by a pharmacy benefit manager to pay expenses
1019	incurred or administrative fines imposed under this section is
1020	grounds for the denial, suspension, or revocation of its
1021	certificate of authority.
1022	Section 14. Section 626.89, Florida Statutes, is amended to
1023	read:
1024	626.89 Annual financial statement and filing fee; notice of
1025	change of ownership; pharmacy benefit manager filings

Page 36 of 46



(1) Each authorized administrator shall annually file with the office a full and true statement of its financial condition, transactions, and affairs within 3 months after the end of the administrator's fiscal year or within such extension of time as the office for good cause may have granted. The statement must be for the preceding fiscal year and must be in such form and contain such matters as the commission prescribes and must be verified by at least two officers of the administrator.

(2) Each authorized administrator shall also file an audited financial statement performed by an independent certified public accountant. The audited financial statement <u>must shall</u> be filed with the office within 5 months after the end of the administrator's fiscal year and be for the preceding fiscal year. An audited financial statement prepared on a consolidated basis must include a columnar consolidating or combining worksheet that must be filed with the statement and must comply with the following:

(a) Amounts shown on the consolidated audited financial statement must be shown on the worksheet;

(b) Amounts for each entity must be stated separately; and

(c) Explanations of consolidating and eliminating entries must be included.

(3) At the time of filing its annual statement, the administrator shall pay a filing fee in the amount specified in s. 624.501 for the filing of an annual statement by an insurer.

(4) In addition, the administrator shall immediately notify the office of any material change in its ownership.

(5) <u>A pharmacy benefit manager shall also notify the office</u> within 30 days after any administrative, civil, or criminal

Page 37 of 46

100780

1055	complaints, settlements, or discipline of the pharmacy benefit
1056	manager or any of its affiliates which relate to a violation of
1057	the insurance laws, including pharmacy benefit laws in any
1058	state.
1059	(6) A pharmacy benefit manager shall also annually submit
1060	to the office a statement attesting to its compliance with the
1061	network requirements of s. 626.8825.
1062	(7) The commission may by rule require all or part of the
1063	statements or filings required under this section to be
1064	submitted by electronic means in a computer-readable form
1065	compatible with the electronic data format specified by the
1066	commission.
1067	Section 15. Subsection (5) is added to section 627.42393,
1068	Florida Statutes, to read:
1069	627.42393 Step-therapy protocol
1070	(5) This section applies to a pharmacy benefit manager
1071	acting on behalf of a health insurer.
1072	Section 16. Subsections (2), (3), and (4) of section
1073	627.64741, Florida Statutes, are amended to read:
1074	627.64741 Pharmacy benefit manager contracts
1075	(2) In addition to the requirements of part VII of chapter
1076	626, a contract between a health insurer and a pharmacy benefit
1077	manager must require that the pharmacy benefit manager:
1078	(a) Update maximum allowable cost pricing information at
1079	least every 7 calendar days.
1080	(b) Maintain a process that will, in a timely manner,
1081	eliminate drugs from maximum allowable cost lists or modify drug
1082	prices to remain consistent with changes in pricing data used in
1083	formulating maximum allowable cost prices and product



1084 availability. 1085 (3) A contract between a health insurer and a pharmacy 1086 benefit manager must prohibit the pharmacy benefit manager from 1087 limiting a pharmacist's ability to disclose whether the cost-1088 sharing obligation exceeds the retail price for a covered 1089 prescription drug, and the availability of a more affordable 1090 alternative drug, pursuant to s. 465.0244. 1091 (4) A contract between a health insurer and a pharmacy 1092 benefit manager must prohibit the pharmacy benefit manager from 1093 requiring an insured to make a payment for a prescription drug 1094 at the point of sale in an amount that exceeds the lesser of: 1095 (a) The applicable cost-sharing amount; or 1096 (b) The retail price of the drug in the absence of 1097 prescription drug coverage. 1098 Section 17. Subsections (2), (3), and (4) of section 1099 627.6572, Florida Statutes, are amended to read: 1100 627.6572 Pharmacy benefit manager contracts.-1101 (2) In addition to the requirements of part VII of chapter 1102 626, a contract between a health insurer and a pharmacy benefit 1103 manager must require that the pharmacy benefit manager: 1104 (a) Update maximum allowable cost pricing information at 1105 least every 7 calendar days. 1106 (b) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug 1107 1108 prices to remain consistent with changes in pricing data used in 1109 formulating maximum allowable cost prices and product 1110 availability. (3) A contract between a health insurer and a pharmacy 1111 benefit manager must prohibit the pharmacy benefit manager from 1112

Page 39 of 46

100780

1113	limiting a pharmacist's ability to disclose whether the cost-
1114	sharing obligation exceeds the retail price for a covered
1115	prescription drug, and the availability of a more affordable
1116	alternative drug, pursuant to s. 465.0244.
1117	(4) A contract between a health insurer and a pharmacy
1118	benefit manager must prohibit the pharmacy benefit manager from
1119	requiring an insured to make a payment for a prescription drug
1120	at the point of sale in an amount that exceeds the lesser of:
1121	(a) The applicable cost-sharing amount; or
1122	(b) The retail price of the drug in the absence of
1123	prescription drug coverage.
1124	Section 18. Paragraph (e) is added to subsection (46) of
1125	section 641.31, Florida Statutes, to read:
1126	641.31 Health maintenance contracts
1127	(46)
1128	(e) This subsection applies to a pharmacy benefit manager
1129	acting on behalf of a health maintenance organization.
1130	Section 19. Subsections (2), (3), and (4) of section
1131	641.314, Florida Statutes, are amended to read:
1132	641.314 Pharmacy benefit manager contracts
1133	(2) In addition to the requirements of part VII of chapter
1134	626, a contract between a health maintenance organization and a
1135	pharmacy benefit manager must require that the pharmacy benefit
1136	manager:
1137	(a) Update maximum allowable cost pricing information at
1138	least every 7 calendar days.
1139	(b) Maintain a process that will, in a timely manner,
1140	eliminate drugs from maximum allowable cost lists or modify drug
1141	prices to remain consistent with changes in pricing data used in



1142 formulating maximum allowable cost prices and product 1143 availability. 1144 (3) A contract between a health maintenance organization 1145 and a pharmacy benefit manager must prohibit the pharmacy 1146 benefit manager from limiting a pharmacist's ability to disclose whether the cost-sharing obligation exceeds the retail price for 1147 a covered prescription drug, and the availability of a more 1148 1149 affordable alternative drug, pursuant to s. 465.0244. (4) A contract between a health maintenance organization 1150 1151 and a pharmacy benefit manager must prohibit the pharmacy benefit manager from requiring a subscriber to make a payment 1152 1153 for a prescription drug at the point of sale in an amount that 1154 exceeds the lesser of: 1155 (a) The applicable cost-sharing amount; or 1156 (b) The retail price of the drug in the absence of 1157 prescription drug coverage. 1158 Section 20. (1) This act establishes requirements for pharmacy benefit managers as defined in s. 626.88, Florida 1159 Statutes, including, without limitation, pharmacy benefit 1160 1161 managers in their performance of services for or otherwise on 1162 behalf of a pharmacy benefits plan or program as defined in s. 1163 626.8825, Florida Statutes, which includes coverage pursuant to 1164 Titles XVIII, XIX, or XXI of the Social Security Act, 42 U.S.C. 1165 ss. 1395 et seq., 1396 et seq., and 1397aa et seq., known as Medicare, Medicaid, or any other similar coverage under a state 1166 1167 or Federal Government funded health plan, including the 1168 Statewide Medicaid Managed Care program established pursuant to 1169 part IV of chapter 409, Florida Statutes, and the state group 1170 insurance program pursuant to part I of chapter 110, Florida

Page 41 of 46

## 100780

1171	Statutes.
1172	(2) This act is not intended, nor may it be construed, to
1173	conflict with existing, relevant federal law.
1174	(3) If any provision of this act or its application to any
1175	person or circumstances is held invalid, the invalidity does not
1176	affect other provisions or applications of this act which can be
1177	given effect without the invalid provision or application, and
1178	to this end the provisions of this act are severable.
1179	Section 21. The sum of \$1.5 million is hereby appropriated
1180	to the Office of Insurance Regulation to implement this act.
1181	Section 22. This act shall take effect July 1, 2023.
1182	
1183	======================================
1184	And the title is amended as follows:
1185	Delete everything before the enacting clause
1186	and insert:
1187	A bill to be entitled
1188	An act relating to prescription drugs; providing a
1189	short title; amending s. 499.005, F.S.; specifying
1190	additional prohibited acts related to the Florida Drug
1191	and Cosmetic Act; amending s. 499.012, F.S.; providing
1192	that prescription drug manufacturer and nonresident
1193	prescription drug manufacturer permitholders are
1194	subject to specified requirements; creating s.
1195	499.026, F.S.; defining terms; requiring certain drug
1196	manufacturers to notify the Department of Business and
1197	Professional Regulation of reportable drug price
1198	increases on a specified form on the effective date of
1199	such increase; providing requirements for the form;

Page 42 of 46



1200 providing construction; requiring such manufacturers 1201 to submit certain reports to the department by a 1202 specified date each year; providing requirements for 1203 the reports; authorizing the department to request certain additional information from the manufacturer 1204 1205 before approving the report; requiring the department 1206 to submit the forms and reports to the Agency for 1207 Health Care Administration to be posted on the 1208 agency's website; prohibiting the agency from posting 1209 on its website certain submitted information that is 1210 marked as a trade secret; requiring the agency to 1211 compile all information from the submitted forms and 1212 reports and make it available to the Governor and the 1213 Legislature upon request; prohibiting manufacturers 1214 from claiming a public records exemption for trade 1215 secrets for certain information provided in such forms 1216 or reports; providing that department employees remain 1217 protected from liability for releasing the forms and 1218 reports as public records; authorizing the department, 1219 in consultation with the agency, to adopt rules; 1220 providing for emergency rulemaking; amending s. 1221 624.307, F.S.; requiring the Division of Consumer 1222 Services of the Department of Financial Services to 1223 designate an employee as the primary contact for 1224 consumer complaints involving pharmacy benefit 1225 managers; requiring the division to refer certain 1226 complaints to the Office of Insurance Regulation; 1227 amending s. 624.490, F.S.; revising the definition of 1228 the term "pharmacy benefit manager"; amending s.

Page 43 of 46



1229 624.491, F.S.; revising provisions related to pharmacy 1230 audits; amending s. 626.88, F.S.; revising the 1231 definition of the term "administrator"; defining the 1232 term "pharmacy benefit manager"; amending s. 626.8805, 1233 F.S.; providing a grandfathering provision for certain 1234 pharmacy benefit managers operating as administrators; 1235 providing a penalty for certain persons who do not 1236 hold a certificate of authority to act as an 1237 administrator on or after a specified date; providing 1238 additional requirements for pharmacy benefit managers 1239 applying for a certificate of authority to act as an 1240 administrator; exempting pharmacy benefit managers 1241 from certain fees; amending s. 626.8814, F.S.; 1242 requiring pharmacy benefit managers to identify 1243 certain ownership affiliations to the office; 1244 requiring pharmacy benefit managers to report any 1245 change in such information to the office within a 1246 specified timeframe; creating s. 626.8825, F.S.; 1247 defining terms; providing requirements for certain 1248 contracts between a pharmacy benefit manager and a 1249 pharmacy benefits plan or program or a participating 1250 pharmacy; requiring the Financial Services Commission 1251 to adopt rules; specifying requirements for certain 1252 administrative appeal procedures that such contracts 1253 with participating pharmacies must include; requiring 1254 pharmacy benefit managers to submit reports on 1255 submitted appeals to the office every 90 days; 1256 creating s. 626.8827, F.S.; specifying prohibited 1257 practices for pharmacy benefit managers; creating s.



1258 626.8828, F.S.; authorizing the office to investigate 1259 administrators that are pharmacy benefit managers and 1260 certain applicants; requiring the office to review 1261 certain referrals and investigate them under certain 1262 circumstances; providing for biennial reviews of 1263 pharmacy benefit managers; authorizing the office to 1264 conduct additional examinations; requiring the office 1265 to conduct an examination under certain circumstances; 1266 providing procedures and requirements for such 1267 examinations; defining the terms "contracts" and 1268 "knowing and willful"; providing that independent 1269 professional examiners under contract with the office 1270 may conduct examinations of pharmacy benefit managers; 1271 requiring the commission to adopt specified rules; 1272 specifying provisions that apply to such 1273 investigations and examinations; providing 1274 recordkeeping requirements for pharmacy benefit 1275 managers; authorizing the office to order the 1276 production of such records and other specified 1277 information; authorizing the office to take statements 1278 under oath; requiring pharmacy benefit managers and 1279 applicants subjected to an investigation or 1280 examination to pay the associated expenses; specifying 1281 covered expenses; providing for collection of such 1282 expenses; providing for the deposit of certain moneys 1283 into the Insurance Regulatory Trust Fund; authorizing 1284 the office to pay examiners, investigators, and other 1285 persons from such fund; providing administrative 1286 penalties; providing grounds for administrative action

Page 45 of 46

COMMITTEE AMENDMENT

Florida Senate - 2023 Bill No. SB 1550



1287 against a certificate of authority; amending s. 1288 626.89, F.S.; requiring pharmacy benefit managers to 1289 notify the office of specified complaints, 1290 settlements, or discipline within a specified 1291 timeframe; requiring pharmacy benefit managers to 1292 annually submit a certain attestation statement to the 1293 office; amending s. 627.42393, F.S.; providing that 1294 certain step-therapy protocol requirements apply to a 1295 pharmacy benefit manager acting on behalf of a health 1296 insurer; amending ss. 627.64741 and 627.6572, F.S.; 1297 conforming provisions to changes made by the act; 1298 amending s. 641.31, F.S.; providing that certain step-1299 therapy protocol requirements apply to a pharmacy 1300 benefit manager acting on behalf of a health 1301 maintenance organization; amending s. 641.314, F.S.; 1302 conforming a provision to changes made by the act; 1303 providing legislative intent, construction, and 1304 severability; providing an appropriation; providing an effective date. 1305