${\bf By}$  Senator Brodeur

	10-00822D-23 20231550_
1	A bill to be entitled
2	An act relating to prescription drugs; providing a
3	short title; amending s. 499.005, F.S.; specifying
4	additional prohibited acts related to the Florida Drug
5	and Cosmetic Act; amending s. 499.012, F.S.; providing
6	that prescription drug manufacturer and nonresident
7	prescription drug manufacturer permitholders are
8	subject to specified requirements; creating s.
9	499.026, F.S.; defining terms; requiring certain drug
10	manufacturers to notify the Department of Business and
11	Professional Regulation of reportable drug price
12	increases on a specified form on the effective date of
13	such increase; providing requirements for the form;
14	providing construction; requiring such manufacturers
15	to submit certain reports to the department by a
16	specified date each year; providing requirements for
17	the reports; authorizing the department to request
18	certain additional information from the manufacturer
19	before approving the report; requiring the department
20	to submit the forms and reports to the Agency for
21	Health Care Administration to be posted on the
22	agency's website; prohibiting manufacturers from
23	claiming a public records exemption for trade secrets
24	for any information provided in such notifications or
25	reports; providing that department employees remain
26	protected from liability for releasing the forms and
27	reports as public records; authorizing the department,
28	in consultation with the agency, to adopt rules;
29	providing for emergency rulemaking; amending s.

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10-00822D-23 20231550 30 624.307, F.S.; requiring the Division of Consumer 31 Services of the Department of Financial Services to 32 designate an employee as the primary contact for consumer complaints involving pharmacy benefit 33 34 managers; requiring the division to refer certain 35 complaints to the Office of Insurance Regulation; 36 amending s. 624.490, F.S.; revising the definition of 37 the term "pharmacy benefit manager"; amending s. 626.88, F.S.; revising the definition of the term 38 39 "administrator"; defining the term "pharmacy benefit 40 manager"; amending s. 626.8805, F.S.; providing a grandfathering provision for certain pharmacy benefit 41 42 managers operating as administrators; providing a penalty for certain persons who do not hold a 43 44 certificate of authority to act as an administrator on or after a specified date; providing additional 45 46 requirements for pharmacy benefit managers applying 47 for a certificate of authority to act as an administrator; exempting pharmacy benefit managers for 48 49 certain fees; amending s. 626.8814, F.S.; requiring 50 pharmacy benefit managers to identify certain 51 ownership affiliations to the office; requiring pharmacy benefit managers to report any change in such 52 53 information to the office within a specified 54 timeframe; creating s. 626.8825, F.S.; defining terms; providing requirements for certain contracts between a 55 56 pharmacy benefit manager and a pharmacy benefits plan 57 or program or a participating pharmacy; specifying 58 requirements for certain administrative appeal

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59 procedures that such contracts with participating 60 pharmacies must include; requiring pharmacy benefit 61 managers to submit reports on submitted appeals to the 62 office every 90 days; creating s. 626.8827, F.S.; 63 specifying prohibited practices for pharmacy benefit managers; creating s. 626.8828, F.S.; authorizing the 64 65 office to investigate administrators that are pharmacy benefit managers and certain applicants; requiring the 66 office to review certain referrals and investigate 67 68 them under certain circumstances; providing for 69 biennial reviews of pharmacy benefit managers; 70 authorizing the office to conduct additional 71 examinations; requiring the office to conduct an 72 examination under certain circumstances; providing 73 procedures and requirements for such examinations; 74 defining the terms "contracts" and "knowing and 75 willful"; specifying provisions that apply to such 76 investigations and examinations; providing 77 recordkeeping requirements for pharmacy benefit 78 managers; authorizing the office to order the production of such records and other specified 79 80 information; authorizing the office to take statements 81 under oath; requiring pharmacy benefit managers and 82 applicants subjected to an investigation or 83 examination to pay the associated expenses; specifying covered expenses; providing for collection of such 84 85 expenses; providing for the deposit of certain moneys 86 into the Insurance Regulatory Trust Fund; authorizing

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the office to pay examiners, investigators, and other

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88	persons from such fund; providing administrative
89	penalties; providing grounds for administrative action
90	against a certificate of authority; amending s.
91	626.89, F.S.; requiring pharmacy benefit managers to
92	notify the office of specified complaints,
93	settlements, or discipline within a specified
94	timeframe; requiring pharmacy benefit managers to
95	annually submit a certain attestation statement to the
96	office; amending s. 627.42393, F.S.; providing that
97	certain step-therapy protocol requirements apply to a
98	pharmacy benefit manager acting on behalf of a health
99	insurer; amending ss. 627.64741 and 627.6572, F.S.;
100	conforming provisions to changes made by the act;
101	amending s. 641.31, F.S.; providing that certain step-
102	therapy protocol requirements apply to a pharmacy
103	benefit manager acting on behalf of a health
104	maintenance organization; amending s. 641.314, F.S.;
105	conforming a provision to changes made by the act;
106	amending s. 624.491, F.S.; conforming a cross-
107	reference; providing legislative intent, construction,
108	and severability; providing an appropriation;
109	providing an effective date.
110	
111	Be It Enacted by the Legislature of the State of Florida:
112	
113	Section 1. This act may be cited as the "Prescription Drug
114	Reform Act."
115	Section 2. Subsection (29) is added to section 499.005,
116	Florida Statutes, to read:
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117	499.005 Prohibited actsIt is unlawful for a person to
118	perform or cause the performance of any of the following acts in
119	this state:
120	(29) Failure to accurately complete and timely submit
121	reportable drug price increase forms and reports as required
122	under this part and rules adopted thereunder.
123	Section 3. Subsection (16) is added to section 499.012,
124	Florida Statutes, to read:
125	499.012 Permit application requirements
126	(16) A permit for a prescription drug manufacturer or a
127	nonresident prescription drug manufacturer is subject to the
128	requirements of s. 499.026.
129	Section 4. Section 499.026, Florida Statutes, is created to
130	read:
131	499.026 Notification of manufacturer prescription drug
132	price increases.—
133	(1) As used in this section, the term:
134	(a) "Course of therapy" means the recommended daily dose
135	units of a prescription drug pursuant to its prescribing label
136	for 30 days or the recommended daily dose units of a
137	prescription drug pursuant to its prescribing label for a normal
138	course of treatment which is less than 30 days.
139	(b) "Manufacturer" means a person holding a prescription
140	drug manufacturer permit or a nonresident prescription drug
141	manufacturer permit under s. 499.01.
142	(c) "Prescription drug" has the same meaning as in s.
143	499.003 and includes biological products but is limited to those
144	prescription drugs and biological products intended for human
145	use.

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146	(d) "Reportable drug price increase" means, for a
147	prescription drug with a wholesale acquisition cost of at least
148	\$100 for a course of therapy before the effective date of an
149	increase:
150	1. Any increase of 15 percent or more of the wholesale
151	acquisition cost during the preceding 12-month period; or
152	2. Any increase of 40 percent or more of the wholesale
153	acquisition cost during the preceding 3 calendar years.
154	(e) "Wholesale acquisition cost" means, with respect to a
155	prescription drug or biological product, the manufacturer's list
156	price for the prescription drug or biological product to
157	wholesalers or direct purchasers in the United States, not
158	including prompt pay or other discounts, rebates, or reductions
159	in price, for the most recent month for which the information is
160	available, as reported in wholesale price guides or other
161	publications of drug or biological product pricing data.
162	(2) On the effective date of a manufacturer's reportable
163	drug price increase, the manufacturer must provide notification
164	of each reportable drug price increase to the department on a
165	form prescribed by the department. The form must require the
166	manufacturer to specify all of the following:
167	(a) The proprietary and nonproprietary names of the
168	prescription drug, as applicable.
169	(b) The wholesale acquisition cost before the reportable
170	drug price increase.
171	(c) The dollar amount of the reportable drug price
172	increase.
173	(d) The percentage amount of the reportable drug price
174	increase from the wholesale acquisition cost before the
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187 a report to the department on a form prescribed by the 188 department. A report is not deemed to be submitted until 189 approved by the department. At a minimum, the report must 190 include all of the following: 191 (a) A list of all prescription drugs affected by a 192 reportable drug price increase during the previous calendar year 193 and both the dollar amount of each reportable drug price 194 increase and the percentage increase of each reportable drug 195 price increase relative to the previous wholesale acquisition 196 cost of the prescription drug. The prescription drugs shall be 197 identified using their proprietary names and nonproprietary 198 names, as applicable.		10-00822D-23 20231550
in the prescription drug necessitates the reportable drug price         increase. If so, the manufacturer must describe the change or         improvement.         (f) The intended uses of the prescription drug.         (f) The intended uses of the prescription drug         (f) The intended uses of the prescription drug affected by a         (f) Experiment. A report is not deemed to be submitted until         (f) approved by the department. At a minimum, the report must         (g) (a) A list of all prescription drugs affected by a         (g) and both the dollar amount of each reportable drug price         (g) increase and the percentage increase of each reportable drug         (f) price increase relative to the previous wholesale acquisition         (f) cost of the prescription drug. The presc	175	reportable drug price increase.
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improvement.179improvement.180(f) The intended uses of the prescription drug.181182This subsection does not prohibit a manufacturer from notifying183other parties, such as pharmacy benefit managers, of a drug184price increase before the effective date of the drug price185increase.186(3) By April 1 of each year, each manufacturer shall submit187a report to the department on a form prescribed by the188department. A report is not deemed to be submitted until189approved by the department. At a minimum, the report must190(a) A list of all prescription drugs affected by a192reportable drug price increase during the previous calendar year193and both the dollar amount of each reportable drug price194increase relative to the previous wholesale acquisition195price increase relative to the previous wholesale acquisition196cost of the prescription drug. The prescription drugs shall be197identified using their proprietary names and nonproprietary198names, as applicable.	177	in the prescription drug necessitates the reportable drug price
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181         This subsection does not prohibit a manufacturer from notifying         0 other parties, such as pharmacy benefit managers, of a drug         price increase before the effective date of the drug price         185         increase.         186         (3) By April 1 of each year, each manufacturer shall submit         a report to the department on a form prescribed by the         188         department. A report is not deemed to be submitted until         approved by the department. At a minimum, the report must         include all of the following:         (a) A list of all prescription drugs affected by a         reportable drug price increase during the previous calendar year         and both the dollar amount of each reportable drug price         increase and the percentage increase of each reportable drug         price increase relative to the previous wholesale acquisition         cost of the prescription drug. The prescription drugs shall be         identified using their proprietary names and nonproprietary         names, as applicable.	179	improvement.
182This subsection does not prohibit a manufacturer from notifying other parties, such as pharmacy benefit managers, of a drug price increase before the effective date of the drug price increase.184price increase before the effective date of the drug price increase.185increase.186(3) By April 1 of each year, each manufacturer shall submit a report to the department on a form prescribed by the department. A report is not deemed to be submitted until approved by the department. At a minimum, the report must include all of the following:191(a) A list of all prescription drugs affected by a reportable drug price increase during the previous calendar year and both the dollar amount of each reportable drug price increase and the percentage increase of each reportable drug price increase relative to the previous wholesale acquisition cost of the prescription drug. The prescription drugs shall be identified using their proprietary names and nonproprietary names, as applicable.	180	(f) The intended uses of the prescription drug.
183other parties, such as pharmacy benefit managers, of a drug184price increase before the effective date of the drug price185increase.186(3) By April 1 of each year, each manufacturer shall submit187a report to the department on a form prescribed by the188department. A report is not deemed to be submitted until189approved by the department. At a minimum, the report must190include all of the following:191(a) A list of all prescription drugs affected by a192reportable drug price increase during the previous calendar year193and both the dollar amount of each reportable drug price194increase relative to the previous wholesale acquisition195price increase relative to the previous wholesale acquisition196cost of the prescription drug. The prescription drugs shall be197identified using their proprietary names and nonproprietary198names, as applicable.	181	
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190 <u>include all of the following:</u> (a) A list of all prescription drugs affected by a 192 <u>reportable drug price increase during the previous calendar year</u> 193 <u>and both the dollar amount of each reportable drug price</u> 194 <u>increase and the percentage increase of each reportable drug</u> 195 <u>price increase relative to the previous wholesale acquisition</u> 196 <u>cost of the prescription drug. The prescription drugs shall be</u> 197 <u>identified using their proprietary names and nonproprietary</u> 198 <u>names, as applicable.</u>	188	department. A report is not deemed to be submitted until
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<pre>196 cost of the prescription drug. The prescription drugs shall be 197 identified using their proprietary names and nonproprietary 198 names, as applicable.</pre>	194	increase and the percentage increase of each reportable drug
<pre>197 identified using their proprietary names and nonproprietary 198 names, as applicable.</pre>	195	price increase relative to the previous wholesale acquisition
198 names, as applicable.	196	cost of the prescription drug. The prescription drugs shall be
	197	identified using their proprietary names and nonproprietary
(b) If more than one form has been filed under this section	198	names, as applicable.
	199	(b) If more than one form has been filed under this section
200 for previous reportable drug price increases, the percentage	200	for previous reportable drug price increases, the percentage
201 increase of the prescription drug from the earliest form filed	201	increase of the prescription drug from the earliest form filed
202 to the most recent form filed.	202	to the most recent form filed.
203 (c) The intended uses of each prescription drug listed in	203	(c) The intended uses of each prescription drug listed in

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204	the report and whether the prescription drug manufacturer
205	benefits from market exclusivity for such drug.
206	(d) The length of time the prescription drug has been
207	available for purchase.
208	(e) A complete description of the factors contributing to
209	each reportable drug price increase. The factors must be
210	provided with such specificity as to explain the need or
211	justification for each reportable drug price increase. The
212	department may request additional information from a
213	manufacturer relating to the need or justification of any
214	reportable drug price increase before approving the
215	manufacturer's report.
216	(f) Any action that the manufacturer has filed to extend a
217	patent report after the first extension has been granted.
218	(4)(a) The department shall submit all forms and reports
219	submitted by manufacturers to the Agency for Health Care
220	Administration, to be posted on the agency's website pursuant to
221	<u>s. 408.062.</u>
222	(b) A manufacturer may not claim a public records exemption
223	for a trade secret under s. 119.0715 for any information
224	required by the department under this section. Department
225	employees remain protected from liability for release of forms
226	and reports pursuant to s. 119.0715(4).
227	(5) The department, in consultation with the Agency for
228	Health Care Administration, shall adopt rules to implement this
229	section.
230	(a) The department shall adopt necessary emergency rules
231	pursuant to s. 120.54(4) to implement this section. If an
232	emergency rule adopted under this section is held to be

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233	unconstitutional or an invalid exercise of delegated legislative
234	authority and becomes void, the department may adopt an
235	emergency rule pursuant to this section to replace the rule that
236	has become void. If the emergency rule adopted to replace the
237	void emergency rule is also held to be unconstitutional or an
238	invalid exercise of delegated legislative authority and becomes
239	void, the department shall follow the nonemergency rulemaking
240	procedures of the Administrative Procedure Act to replace the
241	rule that has become void.
242	(b) For emergency rules adopted under this section, the
243	department need not make the findings required under s.
244	120.54(4)(a). Emergency rules adopted under this section are
245	also exempt from:
246	1. Sections 120.54(3)(b) and 120.541. Challenges to
247	emergency rules adopted under this section are subject to the
248	time schedules provided in s. 120.56(5).
249	2. Section 120.54(4)(c), and remain in effect until
250	replaced by rules adopted under the nonemergency rulemaking
251	procedures of the Administrative Procedure Act.
252	Section 5. Paragraph (a) of subsection (10) of section
253	624.307, Florida Statutes, is amended, and paragraph (b) of that
254	subsection is republished, to read:
255	624.307 General powers; duties
256	(10)(a) The Division of Consumer Services shall perform the
257	following functions concerning products or services regulated by
258	the department or office:
259	1. Receive inquiries and complaints from consumers.
260	2. Prepare and disseminate information that the department
261	deems appropriate to inform or assist consumers.
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262
          3. Provide direct assistance to and advocacy for consumers
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     who request such assistance or advocacy.
264
          4. With respect to apparent or potential violations of law
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     or applicable rules committed by a person or entity licensed by
266
     the department or office, report apparent or potential
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     violations to the office or to the appropriate division of the
268
     department, which may take any additional action it deems
269
     appropriate.
270
          5. Designate an employee of the division as the primary
271
     contact for consumers on issues relating to sinkholes.
272
          6. Designate an employee of the division as the primary
273
     contact for consumers on issues relating to pharmacy benefit
274
     managers. The division must refer to the office any consumer
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     complaint that alleges conduct that may constitute a violation
276
     of part VII of chapter 626 or for which a pharmacy benefit
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     manager does not respond in accordance with paragraph (b).
278
           (b) Any person licensed or issued a certificate of
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     authority by the department or the office shall respond, in
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     writing, to the division within 20 days after receipt of a
281
     written request for documents and information from the division
282
     concerning a consumer complaint. The response must address the
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     issues and allegations raised in the complaint and include any
284
     requested documents concerning the consumer complaint not
285
     subject to attorney-client or work-product privilege. The
     division may impose an administrative penalty for failure to
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     comply with this paragraph of up to $2,500 per violation upon
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     any entity licensed by the department or the office and $250 for
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     the first violation, $500 for the second violation, and up to
     $1,000 for the third or subsequent violation upon any individual
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291	licensed by the department or the office.
292	Section 6. Subsection (1) of section 624.490, Florida
293	Statutes, is amended to read:
294	624.490 Registration of pharmacy benefit managers
295	(1) As used in this section, the term "pharmacy benefit
296	manager" <u>has the same meaning as in s. 626.88</u> <del>means a person or</del>
297	entity doing business in this state which contracts to
298	administer prescription drug benefits on behalf of a health
299	insurer or a health maintenance organization to residents of
300	this state.
301	Section 7. Subsection (1) of section 626.88, Florida
302	Statutes, is amended, and subsection (6) is added to that
303	section, to read:
304	626.88 DefinitionsFor the purposes of this part, the
305	term:
306	(1) "Administrator" <u>means</u> <del>is</del> any person who directly or
307	indirectly solicits or effects coverage of, collects charges or
308	premiums from, or adjusts or settles claims on residents of this
309	state in connection with authorized commercial self-insurance
310	funds or with insured or self-insured programs which provide
311	life or health insurance coverage or coverage of any other
312	expenses described in s. 624.33(1) <u>;</u>
313	health care risk contract as defined in s. 641.234 with an
314	insurer or health maintenance organization, provides billing and
315	collection services to health insurers and health maintenance
316	organizations on behalf of health care providers; or a pharmacy
317	benefit manager. The term does not include, other than any of
318	the following <del>persons</del> :
319	(a) An employer or wholly owned direct or indirect

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10-00822D-23 20231550 320 subsidiary of an employer, on behalf of such employer's 321 employees or the employees of one or more subsidiary or 322 affiliated corporations of such employer. 323 (b) A union on behalf of its members. 324 (c) An insurance company which is either authorized to 325 transact insurance in this state or is acting as an insurer with 326 respect to a policy lawfully issued and delivered by such 327 company in and pursuant to the laws of a state in which the 328 insurer was authorized to transact an insurance business. 329 (d) A health care services plan, health maintenance 330 organization, professional service plan corporation, or person 331 in the business of providing continuing care, possessing a valid 332 certificate of authority issued by the office, and the sales 333 representatives thereof, if the activities of such entity are 334 limited to the activities permitted under the certificate of 335 authority. 336 (e) An entity that is affiliated with an insurer and that 337 only performs the contractual duties, between the administrator 338 and the insurer, of an administrator for the direct and assumed 339 insurance business of the affiliated insurer. The insurer is 340 responsible for the acts of the administrator and is responsible 341 for providing all of the administrator's books and records to 342 the insurance commissioner, upon a request from the insurance 343 commissioner. For purposes of this paragraph, the term "insurer"

345 organization, prepaid limited health service organization, or 346 prepaid health clinic.

means a licensed insurance company, health maintenance

347 (f) A nonresident entity licensed in its state of domicile348 as an administrator if its duties in this state are limited to

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     the administration of a group policy or plan of insurance and no
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     more than a total of 100 lives for all plans reside in this
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     state.
352
           (q) An insurance agent licensed in this state whose
353
     activities are limited exclusively to the sale of insurance.
354
           (h) A person appointed as a managing general agent in this
355
     state, whose activities are limited exclusively to the scope of
356
     activities conveyed under such appointment.
357
           (i) An adjuster licensed in this state whose activities are
358
     limited to the adjustment of claims.
359
          (j) A creditor on behalf of such creditor's debtors with
360
     respect to insurance covering a debt between the creditor and
361
     its debtors.
362
           (k) A trust and its trustees, agents, and employees acting
363
     pursuant to such trust established in conformity with 29 U.S.C.
364
     s. 186.
365
           (1) A trust exempt from taxation under s. 501(a) of the
366
     Internal Revenue Code, a trust satisfying the requirements of
367
     ss. 624.438 and 624.439, or any governmental trust as defined in
368
     s. 624.33(3), and the trustees and employees acting pursuant to
369
     such trust, or a custodian and its agents and employees,
370
     including individuals representing the trustees in overseeing
371
     the activities of a service company or administrator, acting
372
     pursuant to a custodial account which meets the requirements of
373
     s. 401(f) of the Internal Revenue Code.
374
           (m) A financial institution which is subject to supervision
375
     or examination by federal or state authorities or a mortgage
376
     lender licensed under chapter 494 who collects and remits
377
     premiums to licensed insurance agents or authorized insurers
```

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378	concurrently or in connection with mortgage loan payments.
379	(n) A credit card issuing company which advances for and
380	collects premiums or charges from its credit card holders who
381	have authorized such collection if such company does not adjust
382	or settle claims.
383	(o) A person who adjusts or settles claims in the normal
384	course of such person's practice or employment as an attorney at
385	law and who does not collect charges or premiums in connection
386	with life or health insurance coverage.
387	(p) A person approved by the department who administers
388	only self-insured workers' compensation plans.
389	(q) A service company or service agent and its employees,
390	authorized in accordance with ss. 626.895-626.899, serving only
391	a single employer plan, multiple-employer welfare arrangements,
392	or a combination thereof.
393	(r) Any provider or group practice, as defined in s.
394	456.053, providing services under the scope of the license of
395	the provider or the member of the group practice.
396	(s) Any hospital providing billing, claims, and collection
397	services solely on its own and its physicians' behalf and
398	providing services under the scope of its license.
399	(t) A corporation not for profit whose membership consists
400	entirely of local governmental units authorized to enter into
401	risk management consortiums under s. 112.08.
402	
403	A person who provides billing and collection services to health
404	insurers and health maintenance organizations on behalf of
405	health care providers shall comply with the provisions of ss.
406	627.6131, 641.3155, and 641.51(4).
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407	(6) "Pharmacy benefit manager" means a person or entity
408	doing business in this state which contracts to administer
409	prescription drug benefits on behalf of a pharmacy benefits plan
410	or program as defined in s. 626.8825. The term includes, but is
411	not limited to, a person or entity that performs one or more of
412	the following services:
413	(a) Pharmacy claims processing.
414	(b) Administration or management of pharmacy discount card
415	programs.
416	(c) Managing pharmacy networks or pharmacy reimbursement.
417	(d) Paying or managing claims for pharmacist services
418	provided to covered persons.
419	(e) Developing or managing a clinical formulary, including
420	utilization management or quality assurance programs.
421	(f) Pharmacy rebate administration.
422	(g) Managing patient compliance, therapeutic intervention,
423	or generic substitution programs.
424	Section 8. Present subsections (3) through (6) of section
425	626.8805, Florida Statutes, are redesignated as subsection (4)
426	through (7), respectively, a new subsection (3) and subsection
427	(8) are added to that section, and subsection (1) and present
428	subsection (3) of that section are amended, to read:
429	626.8805 Certificate of authority to act as administrator
430	(1) It is unlawful for any person to act as or hold himself
431	or herself out to be an administrator in this state without a
432	valid certificate of authority issued by the office pursuant to
433	ss. 626.88-626.894. A pharmacy benefit manager that is
434	registered with the office under s. 624.490 as of June 30, 2023,
435	may continue to operate until January 1, 2024, as an
I	

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10-00822D-23 20231550 436 administrator without a certificate of authority and is not in 437 violation of the requirement to possess a valid certificate of 438 authority as an administrator during that timeframe. To qualify 439 for and hold authority to act as an administrator in this state, 440 an administrator must otherwise be in compliance with this code 441 and with its organizational agreement. The failure of any 442 person, excluding a pharmacy benefit manager, to hold such a 443 certificate while acting as an administrator shall subject such 444 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, 445 446 does not hold a certificate of authority to act as an 447 administrator while operating as a pharmacy benefit manager is subject to a fine of \$10,000 per violation per day. 448 449 (3) An applicant that is a pharmacy benefit manager must 450 also submit all of the following: 451 (a) A complete biographical statement on forms prescribed by the commission, an independent investigation report, and 452 453 fingerprints obtained pursuant to chapter 624, of all of the 454 individuals referred to in paragraph (2)(c). 455 (b) A self-disclosure of any administrative, civil, or 456 criminal complaints, settlements, or discipline of the 457 applicant, or any of the applicant's affiliates, which relate to 458 a violation of the insurance laws, including pharmacy benefit 459 manager laws, in any state. 460 (c) A statement attesting to compliance with the network 461 requirements in s. 626.8825 beginning January 1, 2024. 462 (4) (a) The applicant shall make available for inspection by 463 the office copies of all contracts relating to services provided 464 by the administrator to insurers or other persons using the

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465	services of the administrator.
466	(b) An applicant that is a pharmacy benefit manager shall
467	also make available for inspection by the office:
468	1. Copies of all contract templates with any pharmacy as
469	defined in s. 465.003; and
470	2. Copies of all subcontracts to support its operations.
471	(8) A pharmacy benefit manager is exempt from fees
472	associated with the initial application and the annual filing
473	<u>fees in s. 626.89.</u>
474	Section 9. Section 626.8814, Florida Statutes, is amended
475	to read:
476	626.8814 Disclosure of ownership or affiliation
477	(1) Each administrator shall identify to the office any
478	ownership interest or affiliation of any kind with any insurance
479	company responsible for providing benefits directly or through
480	reinsurance to any plan for which the administrator provides
481	administrative services.
482	(2) Pharmacy benefit managers shall also identify to the
483	office any ownership affiliation of any kind with any pharmacy
484	which, either directly or indirectly, through one or more
485	intermediaries:
486	(a) Has an investment or ownership interest in a pharmacy
487	benefit manager holding a certificate of authority issued under
488	this part;
489	(b) Shares common ownership with a pharmacy benefit manager
490	holding a certificate of authority issued under this part; or
491	(c) Has an investor or a holder of an ownership interest
492	which is a pharmacy benefit manager holding a certificate of
493	authority issued under this part.
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494	(3) A pharmacy benefit manager shall report any change in
495	information required by subsection (2) to the office in writing
496	within 60 days after the change occurs.
497	Section 10. Section 626.8825, Florida Statutes, is created
498	to read:
499	626.8825 Pharmacy benefit manager transparency and
500	accountability
501	(1) DEFINITIONSAs used in this section, the term:
502	(a) "Adjudication transaction fee" means a fee charged by
503	the pharmacy benefit manager to the pharmacy for electronic
504	claim submissions.
505	(b) "Affiliated pharmacy" means a pharmacy that, either
506	directly or indirectly through one or more intermediaries:
507	1. Has an investment or ownership interest in a pharmacy
508	benefit manager holding a certificate of authority issued under
509	this part;
510	2. Shares common ownership with a pharmacy benefit manager
511	holding a certificate of authority issued under this part; or
512	3. Has an investor or a holder of an ownership interest
513	which is a pharmacy benefit manager holding a certificate of
514	authority issued under this part.
515	(c) "Brand name or generic effective rate" means the
516	contractual rate set forth by a pharmacy benefit manager for the
517	reimbursement of covered brand name or generic drugs, calculated
518	using the total payments in the aggregate, by drug type, during
519	the performance period. The effective rates are typically
520	calculated as a discount from industry benchmarks, such as
521	average wholesale price or wholesale acquisition cost.
522	(d) "Covered person" means a person covered by,

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523	participating in, or receiving the benefit of a pharmacy
524	benefits plan or program.
525	(e) "Direct and indirect remuneration fees" means price
526	concessions that are paid to the pharmacy benefit manager by the
527	pharmacy retrospectively and that cannot be calculated at the
528	point of sale. The term may also include discounts, chargebacks
529	or rebates, cash discounts, free goods contingent on a purchase
530	agreement, upfront payments, coupons, goods in kind, free or
531	reduced-price services, grants, or other price concessions or
532	similar benefits from manufacturers, pharmacies, or similar
533	entities.
534	(f) "Dispensing fee" means a fee intended to cover
535	reasonable costs associated with providing the drug to a covered
536	person. This cost includes the pharmacist's services and the
537	overhead associated with maintaining the facility and equipment
538	necessary to operate the pharmacy.
539	(g) "Effective rate guarantee" means the minimum ingredient
540	cost reimbursement a pharmacy benefit manager guarantees it will
541	pay for pharmacist services during the applicable measurement
542	period.
543	(h) "Erroneous claims" means pharmacy claims submitted in
544	error, including, but not limited to, unintended, incorrect,
545	fraudulent, or test claims.
546	(i) "Incentive payment" means a retrospective monetary
547	payment made as a reward or recognition by the pharmacy benefits
548	plan or program or pharmacy benefit manager to a pharmacy for
549	meeting or exceeding predefined pharmacy performance metrics as
550	related to quality measure, such as Healthcare Effectiveness
551	Data and Information Set measures.

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552	(j) "Maximum allowable cost appeal pricing adjustment"
553	means a retrospective positive payment adjustment made to a
554	pharmacy by the pharmacy benefits plan or program or by the
555	pharmacy benefit manager pursuant to an approved maximum
556	allowable cost appeal request submitted by the same pharmacy to
557	dispute the amount reimbursed for a drug based on the pharmacy
558	benefit manager's listed maximum allowable cost price.
559	(k) "Monetary recoupments" means rescinded or recouped
560	payments from a pharmacy or provider by the pharmacy benefits
561	plan or program or by the pharmacy benefit manager.
562	(1) "Network" means a pharmacy or group of pharmacies that
563	agree to provide pharmacist services to covered persons on
564	behalf of a pharmacy benefits plan or program or a group of
565	pharmacy benefits plans or programs in exchange for payment for
566	such services. The term includes a pharmacy that generally
567	dispenses outpatient prescription drugs to covered persons or
568	dispenses particular types of prescription drugs, provides
569	pharmacist services to particular types of covered persons, or
570	dispenses prescriptions in particular health care settings,
571	including networks of specialty, institutional, or long-term
572	care facilities.
573	(m) "Network reconciliation offsets" means a process during
574	annual payment reconciliation between a pharmacy benefit manager
575	and a pharmacy which allows the pharmacy benefit manager to
576	offset an amount for overperformance or underperformance of
577	contractual guarantees across guaranteed line items, channels,
578	networks, or payers, as applicable.
579	(n) "Participation contract" means any agreement between a
580	pharmacy benefit manager and pharmacy for the provision and
I	

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581	reimbursement of pharmacist services and any exhibits,
582	attachments, amendments, or addendums to such agreement.
583	(o) "Pass-through pricing model" means a payment model used
584	by a pharmacy benefit manager in which the payments made by the
585	pharmacy benefits plan or program to the pharmacy benefit
586	manager for the covered outpatient drugs are:
587	1. Equivalent to the payments the pharmacy benefit manager
588	makes to a dispensing pharmacy or provider for such drugs,
589	including any contracted professional dispensing fee between the
590	pharmacy benefit manager and its network of pharmacies. Such
591	dispensing fee would be paid if the pharmacy benefits plan or
592	program was making the payments directly.
593	2. Passed through in their entirety by the pharmacy
594	benefits plan or program or by the pharmacy benefit manager to
595	the pharmacy or provider that dispenses the drugs, and the
596	payments are made in a manner that is not offset by any
597	reconciliation.
598	(p) "Pharmacist" means a pharmacist as defined in s.
599	465.003.
600	(q) "Pharmacist services" means products, goods, and
601	services or any combination of products, goods, and services
602	provided as part of the practice of the profession of pharmacy
603	as defined in s. 465.003 or otherwise covered by a pharmacy
604	benefits plan or program.
605	(r) "Pharmacy" means a pharmacy as defined in s. 465.003.
606	(s) "Pharmacy benefit manager" has the same meaning as in
607	<u>s. 626.88.</u>
608	(t) "Pharmacy benefits plan or program" means a plan or
609	program that pays for, reimburses, covers the cost of, or
I	

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610	provides access to discounts on pharmacist services provided by
611	one or more pharmacies to covered persons who reside in, are
612	employed by, or receive pharmacist services from this state. The
613	term includes, but is not limited to, health maintenance
614	organizations, health insurers, self-insured employer health
615	plans, discount card programs, and government-funded health
616	plans, including the Statewide Medicaid Managed Care program
617	established pursuant to part IV of chapter 409 and the state
618	group insurance program pursuant to part I of chapter 110.
619	(u) "Rebate" means all payments that accrue to a pharmacy
620	benefit manager or its pharmacy benefits plan or program client,
621	directly or indirectly, from a pharmaceutical manufacturer,
622	including, but not limited to, discounts, administration fees,
623	credits, incentives, or penalties associated directly or
624	indirectly in any way with claims administered on behalf of a
625	pharmacy benefits plan or program client.
626	(v) "Spread pricing" is the practice in which a pharmacy
627	benefit manager charges a pharmacy benefits plan or program a
628	different amount for pharmacist services than the amount the
629	pharmacy benefit manager reimburses a pharmacy for such
630	pharmacist services.
631	(w) "Usual and customary price" means the amount charged to
632	cash customers for a pharmacist service exclusive of sales tax
633	or other amounts claimed.
634	(2) CONTRACTS BETWEEN A PHARMACY BENEFIT MANAGER AND A
635	PHARMACY BENEFITS PLAN OR PROGRAMIn addition to any other
636	requirements in the Florida Insurance Code, all contractual
637	arrangements executed, amended, adjusted, or renewed on or after
638	July 1, 2023, which are applicable to pharmacy benefits covered

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639	on or after January 1, 2024, between a pharmacy benefit manager
640	and a pharmacy benefits plan or program must:
641	(a) Use a pass-through pricing model, remaining consistent
642	with the prohibition in paragraph (3)(c).
643	(b) Exclude terms that allow for the direct or indirect
644	engagement in the practice of spread pricing unless the pharmacy
645	benefit manager passes along the entire amount of such
646	difference to the pharmacy benefits plan or program as allowable
647	under paragraph (a).
648	(c) Ensure that funds received in relation to providing
649	services for a pharmacy benefits plan or program or a pharmacy
650	are received by the pharmacy benefit manager in trust for the
651	pharmacy benefits plan or program or pharmacy, as applicable,
652	and are used or distributed only pursuant to the pharmacy
653	benefit manager's contract with the pharmacy benefits plan or
654	program or with the pharmacy or as otherwise required by
655	applicable law.
656	(d) Include network adequacy requirements that meet or
657	exceed the Medicare Part D program standards for convenient
658	access to network pharmacies set forth in 42 C.F.R. s. 423.120,
659	and that:
660	1. Do not limit a network to solely include affiliated
661	pharmacies;
662	2. Require a pharmacy benefit manager to offer a provider
663	contract to licensed pharmacies physically located on the
664	physical site of providers within the pharmacy benefits plan's
665	or program's geographic service area which have been
666	specifically designated as essential providers by the Agency for
667	Health Care Administration pursuant to s. 409.975(1)(a), and

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668	Florida cancer hospitals that meet the criteria in s.
669	409.975(1)(b), regardless of the pharmacy benefits plan's or
670	program's geographic service area, solely for the administration
671	or dispensing of covered prescription drugs, including
672	biological products, that are administered through infusions,
673	intravenously injected, inhaled during a surgical procedure, or
674	a covered parenteral drug, as part of onsite outpatient care;
675	3. Do not require a covered person to receive a
676	prescription drug by United States mail, common carrier, local
677	courier, third-party company or delivery service, or pharmacy
678	direct delivery. This subparagraph does not prohibit a pharmacy
679	benefit manager from operating mail order or delivery programs
680	on an opt-in basis at the sole discretion of a covered person;
681	4. Prohibit a requirement for a covered person to receive
682	pharmacist services from an affiliated pharmacy or an affiliated
683	health care provider for the in-person administration of covered
684	prescription drugs; offering or implementing pharmacy networks
685	that require or incentivize a covered person to use an
686	affiliated pharmacy or an affiliated health care provider for
687	the in-person administration of covered prescription drugs; or
688	advertising, marketing, or promoting an affiliated pharmacy to
689	covered persons. Subject to the foregoing, a pharmacy benefit
690	manager may include an affiliated pharmacy in communications to
691	covered persons regarding network pharmacies and prices,
692	provided that the pharmacy benefit manager includes information,
693	such as links to all nonaffiliated network pharmacies, in such
694	communications and that the information provided is accurate and
695	of equal prominence. This paragraph may not be construed to
696	prohibit a pharmacy benefit manager from entering into an

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697	agreement with an affiliated pharmacy to provide pharmacist
698	services to covered persons.
699	(e) Prohibit the ability of a pharmacy benefit manager to
700	condition participation in one pharmacy network on participation
701	in any other pharmacy network or penalize a pharmacy for
702	exercising its prerogative not to participate in a specific
703	pharmacy network.
704	(f) Prohibit a pharmacy benefit manager from instituting a
705	network that requires a pharmacy to meet accreditation standards
706	inconsistent with or more stringent than applicable federal and
707	state requirements for licensure and operation as a pharmacy in
708	this state.
709	(3) CONTRACTS BETWEEN A PHARMACY BENEFIT MANAGER AND A
710	PARTICIPATING PHARMACYIn addition to other requirements in the
711	Florida Insurance Code, a participation contract executed,
712	amended, adjusted, or renewed on or after July 1, 2023, that
713	applies to pharmacist services on or after January 1, 2024,
714	between a pharmacy benefit manager and one or more pharmacies or
715	pharmacists, must include, in substantial form, terms that
716	ensure compliance with all of the following requirements, and
717	which, except to the extent not allowed by law, shall supersede
718	any contractual terms in the participation contract to the
719	contrary:
720	(a) At the time of adjudication for electronic claims or
721	the time of reimbursement for non-electronic claims, the
722	pharmacy benefit manager shall provide the pharmacy with a
723	remittance, including such detailed information as is necessary
724	for the pharmacy or pharmacist to identify the reimbursement
725	schedule for the specific network applicable to the claim and
1	

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726	which is the basis used by the pharmacy benefit manager to
727	calculate the amount of reimbursement paid. This information
728	must include, but is not limited to, the applicable network
729	reimbursement ID or plan ID as defined in the most current
730	version of the National Council for Prescription Drug Programs
731	(NCPDP) Telecommunication Standard Implementation Guide, or its
732	nationally recognized successor industry guide. The office shall
733	adopt rules to implement this paragraph.
734	(b) The pharmacy benefit manager must ensure that any basis
735	of reimbursement information is communicated to a pharmacy in
736	accordance with the NCPDP Telecommunication Standard
737	Implementation Guide, or its nationally recognized successor
738	industry guide, when performing reconciliation for any effective
739	rate guarantee, and that such basis of reimbursement information
740	communicated is accurate, corresponds with the applicable
741	network rate, and may be relied upon by the pharmacy.
742	(c) A prohibition of financial clawbacks or reconciliation
743	offsets. A pharmacy benefit manager may not recoup direct or
744	indirect remuneration fees, dispensing fees, brand name or
745	generic effective rate adjustments through reconciliation, or
746	any other monetary recoupments as related to discounts, multiple
747	network reconciliation offsets, adjudication transaction fees,
748	and any other instance when a fee may be recouped from a
749	pharmacy. For purposes of this section, the terms "financial
750	clawbacks" or "reconciliation offsets" do not include:
751	1. Any incentive payments provided by the pharmacy benefit
752	manager to a network pharmacy for meeting or exceeding
753	predefined quality measures, such as Healthcare Effectiveness
754	Data and Information Set measures; recoupment due to an

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755	erroneous claim, fraud, waste, or abuse; a claim adjudicated in
756	error; a maximum allowable cost appeal pricing adjustment; or an
757	adjustment made as part of a pharmacy audit pursuant to s.
758	<u>624.491.</u>
759	2. Any recoupment that is returned to the state for
760	programs in chapter 409 or the state group insurance program in
761	<u>s. 110.123.</u>
762	(d) A pharmacy benefit manager may not unilaterally change
763	the terms of any participation contract.
764	(e) The pharmacy benefit manager must provide a pharmacy,
765	upon its request, a list of pharmacy benefits plans or programs
766	in which the pharmacy is a part of the network. Updates to the
767	list must be communicated to the pharmacy within 7 days. The
768	pharmacy benefit manager may not restrict the pharmacy or
769	pharmacist from disclosing this information to the public.
770	(f) The pharmacy benefit manager must ensure that the
771	Electronic Remittance Advice contains claim level payment
772	adjustments in accordance with American National Standards
773	Institute Accredited Standard Committee, X12 format, and must
774	include or be accompanied by the appropriate level of detail for
775	the pharmacy to reconcile any debits or credits, including, but
776	not limited to, pharmacy NCPDP or NPI identifier, date of
777	service, prescription number, refill number, adjustment code, if
778	applicable, and transaction amount.
779	(g) The pharmacy benefit manager shall provide a reasonable
780	administrative appeal procedure to allow a pharmacy or
781	pharmacist to challenge the maximum allowable cost pricing
782	information and the reimbursement made under the maximum
783	allowable cost for a specific drug as being below the

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CODING: Words stricken are deletions; words underlined are additions.

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784	acquisition cost available to the challenging pharmacy or
785	pharmacist.
786	1. The administrative appeal procedure must include a
787	telephone number and e-mail address, or a website, for the
788	purpose of submitting the administrative appeal. The appeal may
789	be submitted directly to the pharmacy benefit manager or through
790	a pharmacy service administration organization. The pharmacy or
791	pharmacist must be given at least 30 business days after a
792	maximum allowable cost update or after an adjudication for an
793	electronic claim or reimbursement for a non-electronic claim to
794	file the administrative appeal.
795	2. The pharmacy benefit manager must respond to the
796	administrative appeal within 30 business days after receipt of
797	the appeal.
798	3. If the appeal is upheld, the pharmacy benefit manager
799	must:
800	a. Update the maximum allowable cost pricing information to
801	at least the acquisition cost available to the pharmacy;
802	b. Permit the pharmacy or pharmacist to reverse and rebill
803	the claim in question;
804	c. Provide to the pharmacy or pharmacist the national drug
805	code on which the increase or change is based; and
806	d. Make the increase or change effective for each similarly
807	situated pharmacy or pharmacist who is subject to the applicable
808	maximum allowable cost pricing information.
809	4. If the appeal is denied, the pharmacy benefit manager
810	must provide to the pharmacy or pharmacist the national drug
811	code and the name of the national or regional pharmaceutical
812	wholesalers operating in this state which have the drug

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813	currently in stock at a price below the maximum allowable cost
814	pricing information.
815	5. If the drug with the national drug code provided by the
816	pharmacy benefit manager is not available below the acquisition
817	cost to the pharmacy or pharmacist from the pharmaceutical
818	wholesaler from whom the pharmacy or pharmacist purchases the
819	majority of drugs for resale, the pharmacy benefits manager must
820	adjust the maximum allowable cost pricing information above the
821	acquisition cost to the pharmacy or pharmacist and permit the
822	pharmacy or pharmacist to reverse and rebill each claim affected
823	by the pharmacy's or pharmacist's inability to procure the drug
824	at a cost that is equal to or less than the previously
825	challenged maximum allowable cost.
826	6. Every 90 days, a pharmacy benefit manager shall report
827	to the office the total number of appeals received and denied in
828	the preceding 90-day period for each specific drug for which an
829	appeal was submitted pursuant to this paragraph.
830	Section 11. Section 626.8827, Florida Statutes, is created
831	to read:
832	626.8827 Pharmacy benefit manager prohibited practicesIn
833	addition to other prohibitions in this part, a pharmacy benefit
834	manager may not do any of the following:
835	(1) Prohibit, restrict, or penalize in any way a pharmacy
836	or pharmacist from disclosing to any person any information that
837	the pharmacy or pharmacist deems appropriate, including, but not
838	limited to, information regarding any of the following:
839	(a) The nature of treatment, risks, or alternatives
840	thereto.
841	(b) The availability of alternate treatment, consultations,
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1	10-00822D-23 20231550
842	<u>or tests.</u>
843	(c) The decision of utilization reviewers or similar
844	persons to authorize or deny pharmacist services.
845	(d) The process used to authorize or deny pharmacist
846	services or benefits.
847	(e) Information on financial incentives and structures used
848	by the pharmacy benefits plan or program.
849	(f) Information that may reduce the costs of pharmacist
850	services.
851	(g) Whether the cost-sharing obligation exceeds the retail
852	price for a covered prescription drug and the availability of a
853	more affordable alternative drug, pursuant to s. 465.0244.
854	(2) Prohibit, restrict, or penalize in any way a pharmacy
855	or pharmacist from disclosing information to the office, the
856	Agency for Health Care Administration, Department of Management
857	Services, law enforcement, or state and federal governmental
858	officials, provided that the recipient of the information
859	represents it has the authority, to the extent provided by state
860	or federal law, to maintain proprietary information as
861	confidential; and before disclosure of information designated as
862	confidential, the pharmacist or pharmacy marks as confidential
863	any document in which the information appears or requests
864	confidential treatment for any oral communication of the
865	information.
866	(3) Communicate at the point-of-sale, or otherwise require,
867	a cost-sharing obligation for the covered person in an amount
868	that exceeds the lesser of:
869	(a) The applicable cost-sharing amount under the applicable
870	pharmacy benefits plan or program; or

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871	(b) The usual and customary price, as defined in s.
872	626.8825, of the pharmacist services.
873	(4) Transfer or share records relative to prescription
874	information containing patient-identifiable or prescriber-
875	identifiable data to an affiliated pharmacy for any commercial
876	purpose other than the limited purposes of facilitating pharmacy
877	reimbursement, formulary compliance, or utilization review on
878	behalf of the applicable pharmacy benefits plan or program.
879	(5) Fail to make any payment due to a pharmacy for an
880	adjudicated claim with a date of service before the effective
881	date of a pharmacy's termination from a pharmacy benefit network
882	unless payments are withheld because of actual fraud on the part
883	of the pharmacy or except as otherwise required by law.
884	(6) Terminate the contract of, penalize, or disadvantage a
885	pharmacist or pharmacy due to a pharmacist or pharmacy:
886	(a) Disclosing information about pharmacy benefit manager
887	practices in accordance with this act;
888	(b) Exercising any of its prerogatives under this part; or
889	(c) Sharing any portion, or all, of the pharmacy benefit
890	manager contract with the office pursuant to a complaint or a
891	query regarding whether the contract is in compliance with this
892	act.
893	(7) Fail to comply with the requirements in s. 626.8825.
894	Section 12. Section 626.8828, Florida Statutes, is created
895	to read:
896	626.8828 Investigations and examinations of pharmacy
897	benefit managers; expenses; penalties
898	(1) The office may investigate administrators who are
899	pharmacy benefit managers and applicants for authorization as
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900	provided in ss. 624.307 and 624.317. The office must review any
901	referral made pursuant to s. 624.307(10) and must investigate
902	any referral that, as determined by the Commissioner of
903	Insurance Regulation or his or her designee, reasonably
904	indicates a possible violation of this part.
905	(2)(a) The office shall examine the business and affairs of
906	each pharmacy benefit manager at least biennially. The biennial
907	examination of each pharmacy benefit manager must be a
908	systematic review for the purpose of determining the pharmacy
909	benefit manager's compliance with all provisions of this part
910	and all other laws or rules applicable to pharmacy benefit
911	managers and must include a detailed review of the pharmacy
912	benefit manager's compliance with ss. 626.8825 and 626.8827. The
913	first 2-year cycle for conducting biennial reviews begins July
914	1, 2023. By January 1 of the year following a 2-year cycle, the
915	office must deliver to the Governor, the President of the
916	Senate, and the Speaker of the House of Representatives a report
917	summarizing the results of the biennial examinations during the
918	most recent 2-year cycle which includes detailed descriptions of
919	any violations committed by each pharmacy benefit manager and
920	detailed reporting of actions taken by the office against each
921	pharmacy benefit manager for such violations.
922	(b) The office also may conduct additional examinations as
923	often as it deems advisable or necessary for the purpose of
924	ascertaining compliance with this part and any other laws or
925	rules applicable to pharmacy benefit managers or applicants for
926	authorization.
927	(c) If a referral made pursuant to s. 624.307(10)
928	reasonably indicates a pattern or practice of violations of this

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929	part by a pharmacy benefit manager, the office must begin an
930	examination of the pharmacy benefit manager or include findings
931	related to such referral within an ongoing examination.
932	(d) Based on the findings of an examination that a pharmacy
933	benefit manager or an applicant for authorization has exhibited
934	a pattern or practice of knowing and willful violations of s.
935	626.8825 or s. 626.8827, the office may, pursuant to chapter
936	120, order a pharmacy benefit manager to file all contracts
937	between the pharmacy benefit manager and pharmacies or pharmacy
938	benefits plans or programs and any policies, guidelines, rules,
939	protocols, standard operating procedures, instructions, or
940	directives that govern or guide the manner in which the pharmacy
941	benefit manager or applicant conducts business related to such
942	knowing and willful violations for review and inspection for the
943	following 36-month period. Such documents are public records and
944	are not trade secrets or otherwise exempt from s. 119.07(1). As
945	used in this section, the term:
946	1. "Contracts" means any contract to which s. 626.8825 is
947	applicable.
948	2. "Knowing and willful" means any act of commission or
949	omission which is committed intentionally, as opposed to
950	accidentally, and which is committed with knowledge of the act's
951	unlawfulness or with reckless disregard as to the unlawfulness
952	of the act.
953	(e) Examinations may be conducted by an independent
954	professional examiner under contract to the office, in which
955	case payment must be made directly to the contracted examiner by
956	the pharmacy benefit manager examined in accordance with the
957	rates and terms agreed to by the office and the examiner.

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958(3) In making investigations and examinations of pharmacy959benefit managers and applicants for authorization, the office960and such pharmacy benefit manager is subject to all of the961following provisions:962(a) Section 624.318, as to the conduct of examinations.963(b) Section 624.319, as to examination and investigation964reports.965(c) Section 624.321, as to witnesses and evidence.966(d) Section 624.322, as to compelled testimony.967(e) Section 624.324, as to hearings.968(f) Section 624.34, as to fingerprinting.969(g) Any other provision of chapter 624 applicable to the970investigation or examination of a licensee under this part.	
960 and such pharmacy benefit manager is subject to all of the 961 following provisions: 962 (a) Section 624.318, as to the conduct of examinations. 963 (b) Section 624.319, as to examination and investigation 964 reports. 965 (c) Section 624.321, as to witnesses and evidence. 966 (d) Section 624.322, as to compelled testimony. 967 (e) Section 624.324, as to hearings. 968 (f) Section 624.34, as to fingerprinting. 969 (g) Any other provision of chapter 624 applicable to the	
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969 (g) Any other provision of chapter 624 applicable to the	
970 investigation or examination of a licensee under this part.	
971 (4) (a) A pharmacy benefit manager must maintain an accuration	е
972 record of all contracts and records with all pharmacies and	
973 pharmacy benefits plans or programs for the duration of the	
974 contract, and for 5 years thereafter. Such contracts must be	
975 <u>made available to the office and kept in a form accessible to</u>	
976 the office.	
977 (b) The office may order any pharmacy benefit manager or	
978 applicant to produce any records, books, files, contracts,	
979 advertising and solicitation materials, or other information and	d
980 may take statements under oath to determine whether the pharmad	<u>Y</u>
981 benefit manager or applicant is in violation of the law or is	
982 acting contrary to the public interest.	
983 (5) (a) Notwithstanding s. 624.307(3), each pharmacy benef:	t
984 manager and applicant for authorization must pay to the office	
985 the expenses of the examination or investigation. Such expenses	
986 <u>include actual travel expenses</u> , reasonable living expense	

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987	allowance, compensation of the examiner, investigator, or other
988	person making the examination or investigation, and necessary
989	costs of the office directly related to the examination or
990	investigation. Such travel expense and living expense allowances
991	are limited to those expenses necessarily incurred on account of
992	the examination or investigation and shall be paid by the
993	examined pharmacy benefit manager or applicant together with
994	compensation upon presentation by the office to such pharmacy
995	benefit manager or applicant of such charges and expenses after
996	a detailed statement has been filed by the examiner and approved
997	by the office.
998	(b) All moneys collected from pharmacy benefit managers and
999	applicants for authorization pursuant to this subsection shall
1000	be deposited into the Insurance Regulatory Trust Fund, and the
1001	office may make deposits from time to time into such fund from
1002	moneys appropriated for the operation of the office.
1003	(c) Notwithstanding s. 112.061, the office may pay to the
1004	examiner, investigator, or person making such examination or
1005	investigation out of such trust fund the actual travel expenses,
1006	reasonable living expense allowance, and compensation in
1007	accordance with the statement filed with the office by the
1008	examiner, investigator, or other person, as provided in
1009	paragraph (a).
1010	(6) In addition to any other enforcement authority
1011	available to the office, the office shall impose an
1012	administrative fine of \$5,000 for each violation of s. 626.8825
1013	or s. 626.8827. Each instance of a violation of such sections by
1014	a pharmacy benefit manager against each individual pharmacy or
1015	prescription benefits plan or program constitutes a separate

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1016	violation. Notwithstanding any other provision of law, there is
1017	no limitation on aggregate fines issued pursuant to this
1018	section. The proceeds from any administrative fine shall be
1019	deposited into the General Revenue Fund.
1020	(7) Failure by a pharmacy benefit manager to pay expenses
1021	incurred or administrative fines imposed under this section is
1022	grounds for the denial, suspension, or revocation of its
1023	certificate of authority.
1024	Section 13. Section 626.89, Florida Statutes, is amended,
1025	to read:
1026	626.89 Annual financial statement and filing fee; notice of
1027	change of ownership; pharmacy benefit manager filings
1028	(1) Each authorized administrator shall annually file with
1029	the office a full and true statement of its financial condition,
1030	transactions, and affairs within 3 months after the end of the
1031	administrator's fiscal year or within such extension of time as
1032	the office for good cause may have granted. The statement must
1033	be for the preceding fiscal year and must be in such form and
1034	contain such matters as the commission prescribes and must be
1035	verified by at least two officers of the administrator.
1036	(2) Each authorized administrator shall also file an
1037	audited financial statement performed by an independent
1038	certified public accountant. The audited financial statement
1039	must shall be filed with the office within 5 months after the
1040	end of the administrator's fiscal year and be for the preceding
1041	fiscal year. An audited financial statement prepared on a
1042	consolidated basis must include a columnar consolidating or
1043	combining worksheet that must be filed with the statement and
1044	must comply with the following:
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1045	(a) Amounts shown on the consolidated audited financial
1046	statement must be shown on the worksheet;
1047	(b) Amounts for each entity must be stated separately; and
1048	(c) Explanations of consolidating and eliminating entries
1049	must be included.
1050	(3) At the time of filing its annual statement, the
1051	administrator shall pay a filing fee in the amount specified in
1052	s. 624.501 for the filing of an annual statement by an insurer.
1053	(4) In addition, the administrator shall immediately notify
1054	the office of any material change in its ownership.
1055	(5) A pharmacy benefit manager shall also notify the office
1056	within 15 days after any administrative, civil, or criminal
1057	complaints, settlements, or discipline of the pharmacy benefit
1058	manager or any of its affiliates which relate to a violation of
1059	the insurance laws, including pharmacy benefit laws in any
1060	state.
1061	(6) A pharmacy benefit manager shall also annually submit
1062	to the office a statement attesting to its compliance with the
1063	network requirements of s. 626.8825.
1064	(7) The commission may by rule require all or part of the
1065	statements or filings required under this section to be
1066	submitted by electronic means in a computer-readable form
1067	compatible with the electronic data format specified by the
1068	commission.
1069	Section 14. Subsection (5) is added to section 627.42393,
1070	Florida Statutes, to read:
1071	627.42393 Step-therapy protocol
1072	(5) This section applies to a pharmacy benefit manager
1073	acting on behalf of a health insurer.
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1074	Section 15. Subsections (2), (3), and (4) of section
1075	627.64741, Florida Statutes, are amended to read:
1076	627.64741 Pharmacy benefit manager contracts
1077	(2) In addition to the requirements of part VII of chapter
1078	<u>626,</u> a contract between a health insurer and a pharmacy benefit
1079	manager must require that the pharmacy benefit manager:
1080	(a) Update maximum allowable cost pricing information at
1081	least every 7 calendar days.
1082	(b) Maintain a process that will, in a timely manner,
1083	eliminate drugs from maximum allowable cost lists or modify drug
1084	prices to remain consistent with changes in pricing data used in
1085	formulating maximum allowable cost prices and product
1086	availability.
1087	(3) A contract between a health insurer and a pharmacy
1088	benefit manager must prohibit the pharmacy benefit manager from
1089	limiting a pharmacist's ability to disclose whether the cost-
1090	sharing obligation exceeds the retail price for a covered
1091	prescription drug, and the availability of a more affordable
1092	alternative drug, pursuant to s. 465.0244.
1093	(4) A contract between a health insurer and a pharmacy
1094	benefit manager must prohibit the pharmacy benefit manager from
1095	requiring an insured to make a payment for a prescription drug
1096	at the point of sale in an amount that exceeds the lesser of:
1097	(a) The applicable cost-sharing amount; or
1098	(b) The retail price of the drug in the absence of
1099	prescription drug coverage.
1100	Section 16. Subsections (2), (3), and (4), of section
1101	627.6572, Florida Statutes, are amended to read:
1102	627.6572 Pharmacy benefit manager contracts
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1103	(2) In addition to the requirements of part VII of chapter
1104	<u>626,</u> a contract between a health insurer and a pharmacy benefit
1105	manager must require that the pharmacy benefit manager:
1106	(a) Update maximum allowable cost pricing information at
1107	least every 7 calendar days.
1108	(b) Maintain a process that will, in a timely manner,
1109	eliminate drugs from maximum allowable cost lists or modify drug
1110	prices to remain consistent with changes in pricing data used in
1111	formulating maximum allowable cost prices and product
1112	availability.
1113	(3) A contract between a health insurer and a pharmacy
1114	benefit manager must prohibit the pharmacy benefit manager from
1115	limiting a pharmacist's ability to disclose whether the cost-
1116	sharing obligation exceeds the retail price for a covered
1117	prescription drug, and the availability of a more affordable
1118	alternative drug, pursuant to s. 465.0244.
1119	(4) A contract between a health insurer and a pharmacy
1120	benefit manager must prohibit the pharmacy benefit manager from
1121	requiring an insured to make a payment for a prescription drug
1122	at the point of sale in an amount that exceeds the lesser of:
1123	(a) The applicable cost-sharing amount; or
1124	(b) The retail price of the drug in the absence of
1125	prescription drug coverage.
1126	Section 17. Paragraph (e) is added to subsection (46) of
1127	section 641.31, Florida Statutes, to read:
1128	641.31 Health maintenance contracts
1129	(46)
1130	(e) This subsection applies to a pharmacy benefit manager
1131	acting on behalf of a health maintenance organization.

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1132	Section 18. Subsections (2), (3), and (4) of section
1133	641.314, Florida Statutes, are amended to read:
1134	641.314 Pharmacy benefit manager contracts
1135	(2) In addition to the requirements of part VII of chapter
1136	<u>626,</u> a contract between a health maintenance organization and a
1137	pharmacy benefit manager must require that the pharmacy benefit
1138	manager:
1139	(a) Update maximum allowable cost pricing information at
1140	least every 7 calendar days.
1141	(b) Maintain a process that will, in a timely manner,
1142	eliminate drugs from maximum allowable cost lists or modify drug
1143	prices to remain consistent with changes in pricing data used in
1144	formulating maximum allowable cost prices and product
1145	availability.
1146	(3) A contract between a health maintenance organization
1147	and a pharmacy benefit manager must prohibit the pharmacy
1148	benefit manager from limiting a pharmacist's ability to disclose
1149	whether the cost-sharing obligation exceeds the retail price for
1150	a covered prescription drug, and the availability of a more
1151	affordable alternative drug, pursuant to s. 465.0244.
1152	(4) A contract between a health maintenance organization
1153	and a pharmacy benefit manager must prohibit the pharmacy
1154	benefit manager from requiring a subscriber to make a payment
1155	for a prescription drug at the point of sale in an amount that
1156	exceeds the lesser of:
1157	(a) The applicable cost-sharing amount; or
1158	(b) The retail price of the drug in the absence of
1159	prescription drug coverage.
1160	Section 19. Subsection (1) of section 624.491, Florida

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1161	Statutes, is amended to read:
1162	624.491 Pharmacy audits
1163	(1) A health insurer or health maintenance organization
1164	providing pharmacy benefits through a major medical individual
1165	or group health insurance policy or a health maintenance
1166	contract, respectively, must comply with the requirements of
1167	this section when the health insurer or health maintenance
1168	organization or any person or entity acting on behalf of the
1169	health insurer or health maintenance organization, including,
1170	but not limited to, a pharmacy benefit manager as defined in $\underline{s.}$
1171	626.88 <del>s. 624.490(1)</del> , audits the records of a pharmacy licensed
1172	under chapter 465. The person or entity conducting such audit
1173	must:
1174	(a) Except as provided in subsection (3), notify the
1175	pharmacy at least 7 calendar days before the initial onsite
1176	audit for each audit cycle.
1177	(b) Not schedule an onsite audit during the first 3
1178	calendar days of a month unless the pharmacist consents
1179	otherwise.
1180	(c) Limit the duration of the audit period to 24 months
1181	after the date a claim is submitted to or adjudicated by the
1182	entity.
1183	(d) In the case of an audit that requires clinical or
1184	professional judgment, conduct the audit in consultation with,
1185	or allow the audit to be conducted by, a pharmacist.
1186	(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 

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1190	with state and federal law.
1191	(f) Reimburse the pharmacy for a claim that was
1192	retroactively denied for a clerical error, typographical error,
1193	scrivener's error, or computer error if the prescription was
1194	properly and correctly dispensed, unless a pattern of such
1195	errors exists, fraudulent billing is alleged, or the error
1196	results in actual financial loss to the entity.
1197	(g) Provide the pharmacy with a copy of the preliminary
1198	audit report within 120 days after the conclusion of the audit.
1199	(h) Allow the pharmacy to produce documentation to address
1200	a discrepancy or audit finding within 10 business days after the
1201	preliminary audit report is delivered to the pharmacy.
1202	(i) Provide the pharmacy with a copy of the final audit
1203	report within 6 months after the pharmacy's receipt of the
1204	preliminary audit report.
1205	(j) Calculate any recoupment or penalties based on actual
1206	overpayments and not according to the accounting practice of
1207	extrapolation.
1208	Section 20. (1) This act establishes requirements for
1209	pharmacy benefit managers as defined in s. 624.490, Florida
1210	Statutes, including, without limitation, pharmacy benefit
1211	managers in their performance of services for or otherwise on
1212	behalf of a pharmacy benefits plan or program providing coverage
1213	pursuant to Titles XVIII, XIX, or XXI of the Social Security
1214	Act, 42 U.S.C. ss. 1395 et seq., 1396 et seq., and 1397aa et
1215	seq., known as Medicare, Medicaid, or any other similar coverage
1216	under a state or Federal Government funded health plan,
1217	including the Statewide Medicaid Managed Care program
1218	established pursuant to part IV of chapter 409, Florida

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1219	Statutes, and the state group insurance program pursuant to part
1220	I of chapter 110, Florida Statutes.
1221	(2) This act is not intended, nor may it be construed, to
1222	conflict with existing, relevant federal law.
1223	(3) If any provision of this act or its application to any
1224	person or circumstances is held invalid, the invalidity does not
1225	affect other provisions or applications of this act which can be
1226	given effect without the invalid provision or application, and
1227	to this end the provisions of this act are severable.
1228	Section 21. The sum of \$1.5 million is hereby appropriated
1229	to the Office of Insurance Regulation to implement this act.
1230	Section 22. This act shall take effect July 1, 2023.