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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
04/13/2023	.	
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The Committee on Fiscal Policy (Brodeur) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

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:

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



281818

11 this state:

12 (29) Failure to accurately complete and timely submit
13 reportable drug price increase forms, reports, and documents as
14 required by s. 499.026 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



281818

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 cumulative increase of 30 percent or more of the
45 wholesale acquisition cost during the preceding 3 calendar
46 years. In calculating the 30 percent threshold, the manufacturer
47 must base the calculation on the wholesale acquisition cost in
48 effect at the end of the 3-year period as compared to the
49 wholesale acquisition cost in effect at the beginning of the
50 same 3-year period.

51 (e) "Wholesale acquisition cost" means, with respect to a
52 prescription drug or biological product, the manufacturer's list
53 price for the prescription drug or biological product to
54 wholesalers or direct purchasers in the United States, not
55 including prompt pay or other discounts, rebates, or reductions
56 in price, for the most recent month for which the information is
57 available, as reported in wholesale price guides or other
58 publications of drug or biological product pricing data.

59 (2) On the effective date of a manufacturer's reportable
60 drug price increase, the manufacturer must provide notification
61 of each reportable drug price increase to the department on a
62 form prescribed by the department. The form must require the
63 manufacturer to specify all of the following:

64 (a) The proprietary and nonproprietary names of the
65 prescription drug, as applicable.

66 (b) The wholesale acquisition cost before the reportable
67 drug price increase.

68 (c) The dollar amount of the reportable drug price



281818

69 increase.

70 (d) The percentage amount of the reportable drug price
71 increase from the wholesale acquisition cost before the
72 reportable drug price increase.

73 (e) Whether a change or an improvement in the prescription
74 drug necessitates the reportable drug price increase.

75 (f) If a change or an improvement in the prescription drug
76 necessitates the reportable drug price increase as reported in
77 paragraph (e), the manufacturer must describe the change or
78 improvement.

79 (g) The intended uses of the prescription drug.

80
81 This subsection does not prohibit a manufacturer from notifying
82 other parties, such as pharmacy benefit managers, of a drug
83 price increase before the effective date of the drug price
84 increase.

85 (3) By April 1 of each year, each manufacturer shall submit
86 a report to the department on a form prescribed by the
87 department. A report is not deemed to be submitted until
88 approved by the department. The report must include all of the
89 following:

90 (a) A list of all prescription drugs affected by a
91 reportable drug price increase during the previous calendar year
92 and both the dollar amount of each reportable drug price
93 increase and the percentage increase of each reportable drug
94 price increase relative to the previous wholesale acquisition
95 cost of the prescription drug. The prescription drugs must be
96 identified using their proprietary names and nonproprietary
97 names, as applicable.



281818

98 (b) If more than one form has been filed under this section
99 for previous reportable drug price increases, the percentage
100 increase of the prescription drug from the earliest form filed
101 to the most recent form filed.

102 (c) The intended uses of each prescription drug listed in
103 the report and whether the prescription drug manufacturer
104 benefits from market exclusivity for such drug.

105 (d) The length of time the prescription drug has been
106 available for purchase.

107 (e) A listing of the factors contributing to each
108 reportable drug price increase. As used in this section, the
109 term "factors" means any of the following: research and
110 development; manufacturing costs; advertising and marketing;
111 whether the drug has more competitive value; an increased rate
112 of inflation or other economic dynamics; changes in market
113 dynamics; supporting regulatory and safety commitments;
114 operating patient assistance and educational programs; rebate
115 increases, including any rebate increase requested by a pharmacy
116 benefit manager; Medicaid, Medicare, or 340B Drug Pricing
117 Program offsets; profit; or other factors. An estimated
118 percentage of the influence of each listed factor must be
119 provided to equal 100 percent.

120 (f) A description of the justification for each factor
121 referenced in paragraph (e) must be provided with such
122 specificity as to explain the need or justification for each
123 reportable drug price increase. The department may request
124 additional information from a manufacturer relating to the need
125 or justification for any reportable drug price increase before
126 approving the manufacturer's report.



281818

127 (g) Any action that the manufacturer has filed to extend a
128 patent report after the first extension has been granted.

129 (4) (a) The department shall submit all forms and reports
130 submitted by manufacturers to the Agency for Health Care
131 Administration, to be posted on the agency's website pursuant to
132 s. 408.062. The agency may not post on its website any of the
133 information provided pursuant to paragraph (2) (f), paragraph
134 (3) (f), or paragraph (3) (g) which is marked as a trade secret.
135 The agency shall compile all information from the forms and
136 reports submitted by manufacturers and make it available upon
137 request to the Governor, the President of the Senate, and the
138 Speaker of the House of Representatives.

139 (b) Except for information provided pursuant to paragraph
140 (2) (f), paragraph (3) (f), or paragraph (3) (g), a manufacturer
141 may not claim a public records exemption for a trade secret
142 under s. 119.0715 for any information required by the department
143 under this section. Department employees remain protected from
144 liability for release of forms and reports pursuant to s.
145 119.0715(4).

146 (5) The department, in consultation with the Agency for
147 Health Care Administration, shall adopt rules to implement this
148 section.

149 (a) The department shall adopt necessary emergency rules
150 pursuant to s. 120.54(4) to implement this section. If an
151 emergency rule adopted under this section is held to be
152 unconstitutional or an invalid exercise of delegated legislative
153 authority and becomes void, the department may adopt an
154 emergency rule pursuant to this section to replace the rule that
155 has become void. If the emergency rule adopted to replace the



156 void emergency rule is also held to be unconstitutional or an
157 invalid exercise of delegated legislative authority and becomes
158 void, the department must follow the nonemergency rulemaking
159 procedures of the Administrative Procedure Act to replace the
160 rule that has become void.

161 (b) For emergency rules adopted under this section, the
162 department need not make the findings required under s.
163 120.54(4) (a). Emergency rules adopted under this section are
164 also exempt from:

165 1. Sections 120.54(3) (b) and 120.541. Challenges to
166 emergency rules adopted under this section are subject to the
167 time schedules provided in s. 120.56(5).

168 2. Section 120.54(4) (c) and remain in effect until replaced
169 by rules adopted under the nonemergency rulemaking procedures of
170 the Administrative Procedure Act.

171 Section 5. Paragraph (a) of subsection (10) of section
172 624.307, Florida Statutes, is amended, and paragraph (b) of that
173 subsection is republished, to read:

174 624.307 General powers; duties.—

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

178 1. Receive inquiries and complaints from consumers.

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

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

183 4. With respect to apparent or potential violations of law
184 or applicable rules committed by a person or an entity licensed



281818

185 by the department or office, report apparent or potential
186 violations to the office or to the appropriate division of the
187 department, which may take any additional action it deems
188 appropriate.

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

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

198 (b) Any person licensed or issued a certificate of
199 authority by the department or the office shall respond, in
200 writing, to the division within 20 days after receipt of a
201 written request for documents and information from the division
202 concerning a consumer complaint. The response must address the
203 issues and allegations raised in the complaint and include any
204 requested documents concerning the consumer complaint not
205 subject to attorney-client or work-product privilege. The
206 division may impose an administrative penalty for failure to
207 comply with this paragraph of up to \$2,500 per violation upon
208 any entity licensed by the department or the office and \$250 for
209 the first violation, \$500 for the second violation, and up to
210 \$1,000 for the third or subsequent violation upon any individual
211 licensed by the department or the office.

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



214 624.490 Registration of pharmacy benefit managers.—
215 (1) As used in this section, the term “pharmacy benefit
216 manager” has the same meaning as in s. 626.88 ~~means a person or~~
217 ~~entity doing business in this state which contracts to~~
218 ~~administer prescription drug benefits on behalf of a health~~
219 ~~insurer or a health maintenance organization to residents of~~
220 ~~this state.~~

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

223 624.491 Pharmacy audits.—

224 (1) A pharmacy benefits plan or program as defined in s.
225 626.88 ~~25 health insurer or health maintenance organization~~
226 ~~providing pharmacy benefits through a major medical individual~~
227 ~~or group health insurance policy or a health maintenance~~
228 ~~contract, respectively,~~ must comply with the requirements of
229 this section when the pharmacy benefits plan or program ~~health~~
230 ~~insurer or health maintenance organization~~ or any person or
231 entity acting on behalf of the pharmacy benefits plan or program
232 ~~health insurer or health maintenance organization~~, including,
233 but not limited to, a pharmacy benefit manager as defined in s.
234 626.88 ~~s. 624.490(1)~~, audits the records of a pharmacy licensed
235 under chapter 465. The person or entity conducting such audit
236 must:

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

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



281818

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

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

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

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

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

262 (h) Allow the pharmacy to produce documentation to address
263 a discrepancy or audit finding within 10 business days after the
264 preliminary audit report is delivered to the pharmacy.

265 (i) Provide the pharmacy with a copy of the final audit
266 report within 6 months after the pharmacy's receipt of the
267 preliminary audit report.

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

271 (5) A pharmacy benefits plan or program ~~health insurer or~~



281818

272 ~~health maintenance organization~~ that, under terms of a contract,
273 transfers to a pharmacy benefit manager the obligation to pay a
274 pharmacy licensed under chapter 465 for any pharmacy benefit
275 claims arising from services provided to or for the benefit of
276 an insured or subscriber remains responsible for a violation of
277 this section.

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

281 626.88 Definitions.—For the purposes of this part, the
282 term:

283 (1) "Administrator" means ~~is~~ any person who directly or
284 indirectly solicits or effects coverage of, collects charges or
285 premiums from, or adjusts or settles claims on residents of this
286 state in connection with authorized commercial self-insurance
287 funds or with insured or self-insured programs which provide
288 life or health insurance coverage or coverage of any other
289 expenses described in s. 624.33(1); ~~or~~ any person who, through a
290 health care risk contract as defined in s. 641.234 with an
291 insurer or health maintenance organization, provides billing and
292 collection services to health insurers and health maintenance
293 organizations on behalf of health care providers; or a pharmacy
294 benefit manager. The term does not include, ~~other than~~ any of
295 the following ~~persons~~:

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

300 (b) A union on behalf of its members.



281818

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

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

313 (e) An entity that is affiliated with an insurer and that
314 only performs the contractual duties, between the administrator
315 and the insurer, of an administrator for the direct and assumed
316 insurance business of the affiliated insurer. The insurer is
317 responsible for the acts of the administrator and is responsible
318 for providing all of the administrator's books and records to
319 the insurance commissioner, upon a request from the insurance
320 commissioner. For purposes of this paragraph, the term "insurer"
321 means a licensed insurance company, health maintenance
322 organization, prepaid limited health service organization, or
323 prepaid health clinic.

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

329 (g) An insurance agent licensed in this state whose



330 activities are limited exclusively to the sale of insurance.

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

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

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

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

342 (l) A trust exempt from taxation under s. 501(a) of the
343 Internal Revenue Code, a trust satisfying the requirements of
344 ss. 624.438 and 624.439, or any governmental trust as defined in
345 s. 624.33(3), and the trustees and employees acting pursuant to
346 such trust, or a custodian and its agents and employees,
347 including individuals representing the trustees in overseeing
348 the activities of a service company or administrator, acting
349 pursuant to a custodial account which meets the requirements of
350 s. 401(f) of the Internal Revenue Code.

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

356 (n) A credit card issuing company which advances for and
357 collects premiums or charges from its credit card holders who
358 have authorized such collection if such company does not adjust



281818

359 or settle claims.

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

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

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

370 (r) Any provider or group practice, as defined in s.
371 456.053, providing services under the scope of the license of
372 the provider or the member of the group practice.

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

376 (t) A corporation not for profit whose membership consists
377 entirely of local governmental units authorized to enter into
378 risk management consortiums under s. 112.08.

379
380 A person who provides billing and collection services to health
381 insurers and health maintenance organizations on behalf of
382 health care providers shall comply with the provisions of ss.
383 627.6131, 641.3155, and 641.51(4).

384 (6) "Pharmacy benefit manager" means a person or an entity
385 doing business in this state which contracts to administer
386 prescription drug benefits on behalf of a pharmacy benefits plan
387 or program as defined in s. 626.8825. The term includes, but is



281818

388 not limited to, a person or an entity that performs one or more
389 of the following services on behalf of such plan or program:

390 (a) Pharmacy claims processing.

391 (b) Administration or management of a pharmacy discount
392 card program and performance of any other service listed in this
393 subsection.

394 (c) Managing pharmacy networks or pharmacy reimbursement.

395 (d) Paying or managing claims for pharmacist services
396 provided to covered persons.

397 (e) Developing or managing a clinical formulary, including
398 utilization management or quality assurance programs.

399 (f) Pharmacy rebate administration.

400 (g) Managing patient compliance, therapeutic intervention,
401 or generic substitution programs.

402 (h) Administration or management of a mail-order pharmacy
403 program.

404 Section 9. Present subsections (3) through (6) of section
405 626.8805, Florida Statutes, are redesignated as subsections (4)
406 through (7), respectively, a new subsection (3) and subsection
407 (8) are added to that section, and subsection (1) and present
408 subsection (3) of that section are amended, to read:

409 626.8805 Certificate of authority to act as administrator.—

410 (1) It is unlawful for any person to act as or hold himself
411 or herself out to be an administrator in this state without a
412 valid certificate of authority issued by the office pursuant to
413 ss. 626.88-626.894. A pharmacy benefit manager that is
414 registered with the office under s. 624.490 as of June 30, 2023,
415 may continue to operate until January 1, 2024, as an
416 administrator without a certificate of authority and is not in



417 violation of the requirement to possess a valid certificate of
418 authority as an administrator during that timeframe. To qualify
419 for and hold authority to act as an administrator in this state,
420 an administrator must otherwise be in compliance with this code
421 and with its organizational agreement. The failure of any
422 person, excluding a pharmacy benefit manager, to hold such a
423 certificate while acting as an administrator shall subject such
424 person to a fine of not less than \$5,000 or more than \$10,000
425 for each violation. A person who, on or after January 1, 2024,
426 does not hold a certificate of authority to act as an
427 administrator while operating as a pharmacy benefit manager is
428 subject to a fine of \$10,000 per violation per day. By January
429 15, 2024, the office shall submit to the Governor, the President
430 of the Senate, and the Speaker of the House of Representatives a
431 report detailing whether each pharmacy benefit manager operating
432 in this state on January 1, 2024, obtained a certificate of
433 authority on or before that date as required by this section.

434 (3) An applicant that is a pharmacy benefit manager must
435 also submit all of the following:

436 (a) A complete biographical statement on forms prescribed
437 by the commission.

438 (b) An independent background report as prescribed by the
439 commission.

440 (c) A full set of fingerprints of all of the individuals
441 referenced in paragraph (2) (c) to the office or to a vendor,
442 entity, or agency authorized by s. 943.053(13). The office,
443 vendor, entity, or agency, as applicable, shall forward the
444 fingerprints to the Department of Law Enforcement for state
445 processing, and the Department of Law Enforcement shall forward



281818

446 the fingerprints to the Federal Bureau of Investigation for
447 national processing in accordance with s. 943.053 and 28 C.F.R.
448 s. 20.

449 (d) A self-disclosure of any administrative, civil, or
450 criminal complaints, settlements, or discipline of the
451 applicant, or any of the applicant's affiliates, which relate to
452 a violation of the insurance laws, including pharmacy benefit
453 manager laws, in any state.

454 (e) A statement attesting to compliance with the network
455 requirements in s. 626.8825 beginning January 1, 2024.

456 (4) (a) ~~(3)~~ The applicant shall make available for inspection
457 by the office copies of all contracts relating to services
458 provided by the administrator to insurers or other persons using
459 the services of the administrator.

460 (b) An applicant that is a pharmacy benefit manager shall
461 also make available for inspection by the office:

462 1. Copies of all contract templates with any pharmacy as
463 defined in s. 465.003; and

464 2. Copies of all subcontracts to support its operations.

465 (8) A pharmacy benefit manager is exempt from fees
466 associated with the initial application and the annual filing
467 fees in s. 626.89.

468 Section 10. Section 626.8814, Florida Statutes, is amended
469 to read:

470 626.8814 Disclosure of ownership or affiliation.—

471 (1) Each administrator shall identify to the office any
472 ownership interest or affiliation of any kind with any insurance
473 company responsible for providing benefits directly or through
474 reinsurance to any plan for which the administrator provides



281818

475 administrative services.

476 (2) Pharmacy benefit managers shall also identify to the
477 office any ownership affiliation of any kind with any pharmacy
478 which, either directly or indirectly, through one or more
479 intermediaries:

480 (a) Has an investment or ownership interest in a pharmacy
481 benefit manager holding a certificate of authority issued under
482 this part;

483 (b) Shares common ownership with a pharmacy benefit manager
484 holding a certificate of authority issued under this part; or

485 (c) Has an investor or a holder of an ownership interest
486 which is a pharmacy benefit manager holding a certificate of
487 authority issued under this part.

488 (3) A pharmacy benefit manager shall report any change in
489 information required by subsection (2) to the office in writing
490 within 60 days after the change occurs.

491 Section 11. Section 626.8825, Florida Statutes, is created
492 to read:

493 626.8825 Pharmacy benefit manager transparency and
494 accountability.—

495 (1) DEFINITIONS.—As used in this section, the term:

496 (a) "Adjudication transaction fee" means a fee charged by
497 the pharmacy benefit manager to the pharmacy for electronic
498 claim submissions.

499 (b) "Affiliated pharmacy" means a pharmacy that, either
500 directly or indirectly through one or more intermediaries:

501 1. Has an investment or ownership interest in a pharmacy
502 benefit manager holding a certificate of authority issued under
503 this part;



504 2. Shares common ownership with a pharmacy benefit manager
505 holding a certificate of authority issued under this part; or

506 3. Has an investor or a holder of an ownership interest
507 which is a pharmacy benefit manager holding a certificate of
508 authority issued under this part.

509 (c) "Brand name or generic effective rate" means the
510 contractual rate set forth by a pharmacy benefit manager for the
511 reimbursement of covered brand name or generic drugs, calculated
512 using the total payments in the aggregate, by drug type, during
513 the performance period. The effective rates are typically
514 calculated as a discount from industry benchmarks, such as
515 average wholesale price or wholesale acquisition cost.

516 (d) "Covered person" means a person covered by,
517 participating in, or receiving the benefit of a pharmacy
518 benefits plan or program.

519 (e) "Direct and indirect remuneration fees" means price
520 concessions that are paid to the pharmacy benefit manager by the
521 pharmacy retrospectively and that cannot be calculated at the
522 point of sale. The term may also include discounts, chargebacks
523 or rebates, cash discounts, free goods contingent on a purchase
524 agreement, upfront payments, coupons, goods in kind, free or
525 reduced-price services, grants, or other price concessions or
526 similar benefits from manufacturers, pharmacies, or similar
527 entities.

528 (f) "Dispensing fee" means a fee intended to cover
529 reasonable costs associated with providing the drug to a covered
530 person. This cost includes the pharmacist's services and the
531 overhead associated with maintaining the facility and equipment
532 necessary to operate the pharmacy.



281818

533 (g) "Effective rate guarantee" means the minimum ingredient
534 cost reimbursement a pharmacy benefit manager guarantees it will
535 pay for pharmacist services during the applicable measurement
536 period.

537 (h) "Erroneous claims" means pharmacy claims submitted in
538 error, including, but not limited to, unintended, incorrect,
539 fraudulent, or test claims.

540 (i) "Group purchasing organization" means an entity
541 affiliated with a pharmacy benefit manager or a pharmacy
542 benefits plan or program which uses purchasing volume aggregates
543 as leverage to negotiate discounts and rebates for covered
544 prescription drugs with pharmaceutical manufacturers,
545 distributors, and wholesale vendors.

546 (j) "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 measures, such as Healthcare Effectiveness
551 Data and Information Set measures.

552 (k) "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 (l) "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 (m) "Network" means a group of pharmacies that agree to
563 provide pharmacist services to covered persons on behalf of a
564 pharmacy benefits plan or program or a group of pharmacy
565 benefits plans or programs in exchange for payment for such
566 services. The term includes a pharmacy that generally dispenses
567 outpatient prescription drugs to covered persons.

568 (n) "Network reconciliation offsets" means a process during
569 annual payment reconciliation between a pharmacy benefit manager
570 and a pharmacy which allows the pharmacy benefit manager to
571 offset an amount for overperformance or underperformance of
572 contractual guarantees across guaranteed line items, channels,
573 networks, or payors, as applicable.

574 (o) "Participation contract" means any agreement between a
575 pharmacy benefit manager and pharmacy for the provision and
576 reimbursement of pharmacist services and any exhibits,
577 attachments, amendments, or addendums to such agreement.

578 (p) "Pass-through pricing model" means a payment model used
579 by a pharmacy benefit manager in which the payments made by the
580 pharmacy benefits plan or program to the pharmacy benefit
581 manager for the covered outpatient drugs are:

582 1. Equivalent to the payments the pharmacy benefit manager
583 makes to a dispensing pharmacy or provider for such drugs,
584 including any contracted professional dispensing fee between the
585 pharmacy benefit manager and its network of pharmacies. Such
586 dispensing fee would be paid if the pharmacy benefits plan or
587 program was making the payments directly.

588 2. Passed through in their entirety by the pharmacy
589 benefits plan or program or by the pharmacy benefit manager to
590 the pharmacy or provider that dispenses the drugs, and the



281818

591 payments are made in a manner that is not offset by any
592 reconciliation.

593 (q) "Pharmacist" has the same meaning as in s. 465.003.

594 (r) "Pharmacist services" means products, goods, and
595 services or any combination of products, goods, and services
596 provided as part of the practice of the profession of pharmacy
597 as defined in s. 465.003 or otherwise covered by a pharmacy
598 benefits plan or program.

599 (s) "Pharmacy" has the same meaning as in s. 465.003.

600 (t) "Pharmacy benefit manager" has the same meaning as in
601 s. 626.88.

602 (u) "Pharmacy benefits plan or program" means a plan or
603 program that pays for, reimburses, covers the cost of, or
604 provides access to discounts on pharmacist services provided by
605 one or more pharmacies to covered persons who reside in, are
606 employed by, or receive pharmacist services from this state. The
607 term includes, but is not limited to, health maintenance
608 organizations, health insurers, self-insured employer health
609 plans, discount card programs, and government-funded health
610 plans, including the Statewide Medicaid Managed Care program
611 established pursuant to part IV of chapter 409 and the state
612 group insurance program pursuant to part I of chapter 110.

613 (v) "Rebate" means all payments that accrue to a pharmacy
614 benefit manager or its pharmacy benefits plan or program client
615 or an affiliated group purchasing organization, directly or
616 indirectly, from a pharmaceutical manufacturer, including, but
617 not limited to, discounts, administration fees, credits,
618 incentives, or penalties associated directly or indirectly in
619 any way with claims administered on behalf of a pharmacy



281818

620 benefits plan or program client.

621 (w) "Spread pricing" is the practice in which a pharmacy
622 benefit manager charges a pharmacy benefits plan or program a
623 different amount for pharmacist services than the amount the
624 pharmacy benefit manager reimburses a pharmacy for such
625 pharmacist services.

626 (x) "Usual and customary price" means the amount charged to
627 cash customers for a pharmacist service exclusive of sales tax
628 or other amounts claimed.

629 (2) CONTRACTS BETWEEN A PHARMACY BENEFIT MANAGER AND A
630 PHARMACY BENEFITS PLAN OR PROGRAM.—In addition to any other
631 requirements in the Florida Insurance Code, all contractual
632 arrangements executed, amended, adjusted, or renewed on or after
633 July 1, 2023, which are applicable to pharmacy benefits covered
634 on or after January 1, 2024, between a pharmacy benefit manager
635 and a pharmacy benefits plan or program must:

636 (a) Use a pass-through pricing model, remaining consistent
637 with the prohibition in paragraph (3) (c).

638 (b) Exclude terms that allow for the direct or indirect
639 engagement in the practice of spread pricing unless the pharmacy
640 benefit manager passes along the entire amount of such
641 difference to the pharmacy benefits plan or program as allowable
642 under paragraph (a).

643 (c) Ensure that funds received in relation to providing
644 services for a pharmacy benefits plan or program or a pharmacy
645 are received by the pharmacy benefit manager in trust for the
646 pharmacy benefits plan or program or pharmacy, as applicable,
647 and are used or distributed only pursuant to the pharmacy
648 benefit manager's contract with the pharmacy benefits plan or



281818

649 program or with the pharmacy or as otherwise required by
650 applicable law.

651 (d) Require the pharmacy benefit manager to pass 100
652 percent of all prescription drug manufacturer rebates, including
653 nonresident manufacturer rebates, received to the pharmacy
654 benefits plan or program, if the contractual arrangement
655 delegates the negotiation of rebates to the pharmacy benefit
656 manager, for the sole purpose of offsetting defined cost sharing
657 and reducing premiums of covered persons. Any excess rebate
658 revenue after the pharmacy benefit manager and the pharmacy
659 benefits plan or program have taken all actions required under
660 this paragraph must be used for the sole purpose of offsetting
661 copayments and deductibles of covered persons. This paragraph
662 does not apply to contracts involving Medicaid managed care
663 plans.

664 (e) Include network adequacy requirements that meet or
665 exceed the Medicare Part D program standards for convenient
666 access to network pharmacies set forth in 42 C.F.R. s. 423.120,
667 and that:

668 1. Do not limit a network to solely include affiliated
669 pharmacies;

670 2. Require a pharmacy benefit manager to offer a provider
671 contract to licensed pharmacies physically located on the
672 physical site of providers that are:

673 a. Within the pharmacy benefits plan's or program's
674 geographic service area and that have been specifically
675 designated as essential providers by the Agency for Health Care
676 Administration pursuant to s. 409.975(1)(a);

677 b. Designated as a Cancer Center of Excellence under s.



281818

678 381.925, regardless of the pharmacy benefits plan's or program's
679 geographic service area;

680 c. Organ transplant hospitals, regardless of the pharmacy
681 benefits plan's or program's geographic service area;

682 d. Hospitals licensed as specialty children's hospitals as
683 defined in s. 395.002; or

684 e. Regional perinatal intensive care centers as defined in
685 s. 383.16(2), regardless of the pharmacy benefits plan's or
686 program's geographic service area.

687
688 Such provider contracts must be solely for the administration or
689 dispensing of covered prescription drugs, including biological
690 products, that are administered through infusions, intravenously
691 injected, inhaled during a surgical procedure, or a covered
692 parenteral drug, as part of onsite outpatient care;

693 3. Do not require a covered person to receive a
694 prescription drug by United States mail, common carrier, local
695 courier, third-party company or delivery service, or pharmacy
696 direct delivery; unless the prescription drug cannot be acquired
697 at any retail pharmacy in the pharmacy benefit manager's network
698 for the covered person's pharmacy benefits plan or program. This
699 subparagraph does not prohibit a pharmacy benefit manager from
700 operating mail order or delivery programs on an opt-in basis at
701 the sole discretion of a covered person;

702 4. Prohibit a requirement for a covered person to receive
703 pharmacist services from an affiliated pharmacy or an affiliated
704 health care provider for the in-person administration of covered
705 prescription drugs; offering or implementing pharmacy networks
706 that require or provide a promotional item or an incentive,



707 defined as anything other than a reduced cost-sharing amount or
708 enhanced quantity limit allowed under the benefit design for a
709 covered drug, to a covered person to use an affiliated pharmacy
710 or an affiliated health care provider for the in-person
711 administration of covered prescription drugs; or advertising,
712 marketing, or promoting an affiliated pharmacy to covered
713 persons. Subject to the foregoing, a pharmacy benefit manager
714 may include an affiliated pharmacy in communications to covered
715 persons regarding network pharmacies and prices, provided that
716 the pharmacy benefit manager includes information, such as links
717 to all nonaffiliated network pharmacies, in such communications
718 and that the information provided is accurate and of equal
719 prominence. This paragraph may not be construed to prohibit a
720 pharmacy benefit manager from entering into an agreement with an
721 affiliated pharmacy to provide pharmacist services to covered
722 persons.

723 (f) Prohibit the ability of a pharmacy benefit manager to
724 condition participation in one pharmacy network on participation
725 in any other pharmacy network or penalize a pharmacy for
726 exercising its prerogative not to participate in a specific
727 pharmacy network.

728 (g) Prohibit a pharmacy benefit manager from instituting a
729 network that requires a pharmacy to meet accreditation standards
730 inconsistent with or more stringent than applicable federal and
731 state requirements for licensure and operation as a pharmacy in
732 this state. However, a pharmacy benefit manager may specify
733 additional specialty networks that require enhanced standards
734 related to the safety and competency necessary to meet the
735 United States Food and Drug Administration's limited



736 distribution requirements for dispensing any covered drug, on a
737 drug-by-drug basis, that requires extraordinary special
738 handling, provider coordination, clinical care or monitoring, or
739 patient education when such extraordinary requirements cannot be
740 met by a network pharmacy. For purposes of this paragraph, drugs
741 requiring extraordinary special handling include, but are not
742 limited to, drugs that are subject to a risk evaluation and
743 mitigation strategy approved by the United States Food and Drug
744 Administration; require special certification of a health care
745 provider to prescribe, receive, dispense, or administer; require
746 special handling due to the molecular complexity or cytotoxic
747 properties of the biologic or biosimilar product or drug;
748 require cold chain storage and shipping or specialized equipment
749 to dispense; or require other conditions of a similar gravity.

750 (h)1. At a minimum, require the pharmacy benefit manager or
751 pharmacy benefits plan or program to, upon revising its
752 formulary of covered prescription drugs during a plan year,
753 provide a 60-day continuity-of-care period in which the covered
754 prescription drug that is being revised from the formulary
755 continues to be provided at the same cost for the patient for a
756 period of 60 days. The 60-day continuity-of-care period
757 commences upon notification to the patient. This requirement
758 does not apply if the covered prescription drug:

759 a. Has been approved and made available over the counter by
760 the United States Food and Drug Administration and has entered
761 the commercial market as such;

762 b. Has been removed or withdrawn from the commercial market
763 by the manufacturer; or

764 c. Is subject to an involuntary recall by state or federal



765 authorities and is no longer available on the commercial market.

766 2. Beginning January 1, 2024, and annually thereafter, the
767 pharmacy benefits plan or program shall submit to the office,
768 under the penalty of perjury, a statement attesting to its
769 compliance with the requirements of this subsection.

770 (3) CONTRACTS BETWEEN A PHARMACY BENEFIT MANAGER AND A
771 PARTICIPATING PHARMACY.—In addition to other requirements in the
772 Florida Insurance Code, a participation contract executed,
773 amended, adjusted, or renewed on or after July 1, 2023, that
774 applies to pharmacist services on or after January 1, 2024,
775 between a pharmacy benefit manager and one or more pharmacies or
776 pharmacists, must include, in substantial form, terms that
777 ensure compliance with all of the following requirements, and
778 that, except to the extent not allowed by law, shall supersede
779 any contractual terms in the participation contract to the
780 contrary:

781 (a) At the time of adjudication for electronic claims or
782 the time of reimbursement for nonelectronic claims, the pharmacy
783 benefit manager shall provide the pharmacy with a remittance,
784 including such detailed information as is necessary for the
785 pharmacy or pharmacist to identify the reimbursement schedule
786 for the specific network applicable to the claim and which is
787 the basis used by the pharmacy benefit manager to calculate the
788 amount of reimbursement paid. This information must include, but
789 is not limited to, the applicable network reimbursement ID or
790 plan ID as defined in the most current version of the National
791 Council for Prescription Drug Programs (NCPDP) Telecommunication
792 Standard Implementation Guide, or its nationally recognized
793 successor industry guide. The commission shall adopt rules to



281818

794 implement this paragraph.

795 (b) The pharmacy benefit manager must ensure that any basis
796 of reimbursement information is communicated to a pharmacy in
797 accordance with the NCPDP Telecommunication Standard
798 Implementation Guide, or its nationally recognized successor
799 industry guide, when performing reconciliation for any effective
800 rate guarantee, and that such basis of reimbursement information
801 communicated is accurate, corresponds with the applicable
802 network rate, and may be relied upon by the pharmacy.

803 (c) A prohibition of financial clawbacks, reconciliation
804 offsets, or offsets to adjudicated claims. A pharmacy benefit
805 manager may not charge, withhold, or recoup direct or indirect
806 remuneration fees, dispensing fees, brand name or generic
807 effective rate adjustments through reconciliation, or any other
808 monetary charge, withholding, or recoupments as related to
809 discounts, multiple network reconciliation offsets, adjudication
810 transaction fees, and any other instance when a fee may be
811 recouped from a pharmacy. This prohibition does not apply to:

812 1. Any incentive payments provided by the pharmacy benefit
813 manager to a network pharmacy for meeting or exceeding
814 predefined quality measures, such as Healthcare Effectiveness
815 Data and Information Set measures; recoupment due to an
816 erroneous claim, fraud, waste, or abuse; a claim adjudicated in
817 error; a maximum allowable cost appeal pricing adjustment; or an
818 adjustment made as part of a pharmacy audit pursuant to s.
819 624.491.

820 2. Any recoupment that is returned to the state for
821 programs in chapter 409 or the state group insurance program in
822 s. 110.123.



281818

823 (d) A pharmacy benefit manager may not unilaterally change
824 the terms of any participation contract.

825 (e) Unless otherwise prohibited by law, a pharmacy benefit
826 manager may not prohibit a pharmacy or pharmacist from:

827 1. Offering mail or delivery services on an opt-in basis at
828 the sole discretion of the covered person.

829 2. Mailing or delivering a prescription drug to a covered
830 person upon his or her request.

831 3. Charging a shipping or handling fee to a covered person
832 requesting a prescription drug be mailed or delivered if the
833 pharmacy or pharmacist discloses to the covered person before
834 the mailing or delivery the amount of the fee that will be
835 charged and that the fee may not be reimbursable by the covered
836 person's pharmacy benefits plan or program.

837 (f) The pharmacy benefit manager must provide a pharmacy,
838 upon its request, a list of pharmacy benefits plans or programs
839 in which the pharmacy is a part of the network. Updates to the
840 list must be communicated to the pharmacy within 7 days. The
841 pharmacy benefit manager may not restrict the pharmacy or
842 pharmacist from disclosing this information to the public.

843 (g) The pharmacy benefit manager must ensure that the
844 Electronic Remittance Advice contains claim level payment
845 adjustments in accordance with the American National Standards
846 Institute Accredited Standards Committee, X12 format, and
847 includes or is accompanied by the appropriate level of detail
848 for the pharmacy to reconcile any debits or credits, including,
849 but not limited to, pharmacy NCPDP or NPI identifier, date of
850 service, prescription number, refill number, adjustment code, if
851 applicable, and transaction amount.



281818

852 (h) The pharmacy benefit manager shall provide a reasonable
853 administrative appeal procedure to allow a pharmacy or
854 pharmacist to challenge the maximum allowable cost pricing
855 information and the reimbursement made under the maximum
856 allowable cost as defined in s. 627.64741 for a specific drug as
857 being below the acquisition cost available to the challenging
858 pharmacy or pharmacist.

859 1. The administrative appeal procedure must include a
860 telephone number and e-mail address, or a website, for the
861 purpose of submitting the administrative appeal. The appeal may
862 be submitted by the pharmacy or an agent of the pharmacy
863 directly to the pharmacy benefit manager or through a pharmacy
864 service administration organization. The pharmacy or pharmacist
865 must be given at least 30 business days after a maximum
866 allowable cost update or after an adjudication for an electronic
867 claim or reimbursement for a nonelectronic claim to file the
868 administrative appeal.

869 2. The pharmacy benefit manager must respond to the
870 administrative appeal within 30 business days after receipt of
871 the appeal.

872 3. If the appeal is upheld, the pharmacy benefit manager
873 must:

874 a. Update the maximum allowable cost pricing information to
875 at least the acquisition cost available to the pharmacy;

876 b. Permit the pharmacy or pharmacist to reverse and rebill
877 the claim in question;

878 c. Provide to the pharmacy or pharmacist the national drug
879 code on which the increase or change is based; and

880 d. Make the increase or change effective for each similarly



281818

881 situated pharmacy or pharmacist who is subject to the applicable
882 maximum allowable cost pricing information.

883 4. If the appeal is denied, the pharmacy benefit manager
884 must provide to the pharmacy or pharmacist the national drug
885 code and the name of the national or regional pharmaceutical
886 wholesalers operating in this state which have the drug
887 currently in stock at a price below the maximum allowable cost
888 pricing information.

889 5. Every 90 days, a pharmacy benefit manager shall report
890 to the office the total number of appeals received and denied in
891 the preceding 90-day period, with an explanation or reason for
892 each denial, for each specific drug for which an appeal was
893 submitted pursuant to this paragraph.

894 Section 12. Section 626.8827, Florida Statutes, is created
895 to read:

896 626.8827 Pharmacy benefit manager prohibited practices.—In
897 addition to other prohibitions in this part, a pharmacy benefit
898 manager may not do any of the following:

899 (1) Prohibit, restrict, or penalize in any way a pharmacy
900 or pharmacist from disclosing to any person any information that
901 the pharmacy or pharmacist deems appropriate, including, but not
902 limited to, information regarding any of the following:

903 (a) The nature of treatment, risks, or alternatives
904 thereto.

905 (b) The availability of alternate treatment, consultations,
906 or tests.

907 (c) The decision of utilization reviewers or similar
908 persons to authorize or deny pharmacist services.

909 (d) The process used to authorize or deny pharmacist



910 services or benefits.
911 (e) Information on financial incentives and structures used
912 by the pharmacy benefits plan or program.
913 (f) Information that may reduce the costs of pharmacist
914 services.
915 (g) Whether the cost-sharing obligation exceeds the retail
916 price for a covered prescription drug and the availability of a
917 more affordable alternative drug, pursuant to s. 465.0244.
918 (2) Prohibit, restrict, or penalize in any way a pharmacy
919 or pharmacist from disclosing information to the office, the
920 Agency for Health Care Administration, Department of Management
921 Services, law enforcement, or state and federal governmental
922 officials, provided that the recipient of the information
923 represents it has the authority, to the extent provided by state
924 or federal law, to maintain proprietary information as
925 confidential; and before disclosure of information designated as
926 confidential, the pharmacist or pharmacy marks as confidential
927 any document in which the information appears or requests
928 confidential treatment for any oral communication of the
929 information.
930 (3) Communicate at the point-of-sale, or otherwise require,
931 a cost-sharing obligation for the covered person in an amount
932 that exceeds the lesser of:
933 (a) The applicable cost-sharing amount under the applicable
934 pharmacy benefits plan or program; or
935 (b) The usual and customary price, as defined in s.
936 626.8825, of the pharmacist services.
937 (4) Transfer or share records relative to prescription
938 information containing patient-identifiable or prescriber-



281818

939 identifiable data to an affiliated pharmacy for any commercial
940 purpose other than the limited purposes of facilitating pharmacy
941 reimbursement, formulary compliance, or utilization review on
942 behalf of the applicable pharmacy benefits plan or program.

943 (5) Fail to make any payment due to a pharmacy for an
944 adjudicated claim with a date of service before the effective
945 date of a pharmacy's termination from a pharmacy benefit network
946 unless payments are withheld because of actual fraud on the part
947 of the pharmacy or except as otherwise required by law.

948 (6) Terminate the contract of, penalize, or disadvantage a
949 pharmacist or pharmacy due to a pharmacist or pharmacy:

950 (a) Disclosing information about pharmacy benefit manager
951 practices in accordance with this act;

952 (b) Exercising any of its prerogatives under this part; or

953 (c) Sharing any portion, or all, of the pharmacy benefit
954 manager contract with the office pursuant to a complaint or a
955 query regarding whether the contract is in compliance with this
956 act.

957 (7) Fail to comply with the requirements in s. 626.8825 or
958 s. 624.491.

959 Section 13. Section 626.8828, Florida Statutes, is created
960 to read:

961 626.8828 Investigations and examinations of pharmacy
962 benefit managers; expenses; penalties.—

963 (1) The office may investigate administrators who are
964 pharmacy benefit managers and applicants for authorization as
965 provided in ss. 624.307 and 624.317. The office shall review any
966 referral made pursuant to s. 624.307(10) and shall investigate
967 any referral that, as determined by the Commissioner of



968 Insurance Regulation or his or her designee, reasonably
969 indicates a possible violation of this part.

970 (2) (a) The office shall examine the business and affairs of
971 each pharmacy benefit manager at least biennially. The biennial
972 examination of each pharmacy benefit manager must be a
973 systematic review for the purpose of determining the pharmacy
974 benefit manager's compliance with all provisions of this part
975 and all other laws or rules applicable to pharmacy benefit
976 managers and must include a detailed review of the pharmacy
977 benefit manager's compliance with ss. 626.8825 and 626.8827. The
978 first 2-year cycle for conducting biennial reviews begins
979 January 1, 2025. By January 15, 2026, and each January 15
980 thereafter, the office shall submit to the Governor, the
981 President of the Senate, and the Speaker of the House of
982 Representatives a report summarizing the results of the prior
983 year's examinations which includes detailed descriptions of any
984 violations committed by each pharmacy benefit manager and
985 detailed reporting of actions taken by the office against each
986 pharmacy benefit manager for such violations. Beginning with the
987 2027 report, and every 2 years thereafter, the report must
988 document the office's compliance with the examination timeframe
989 requirements as provided in this paragraph. The office must
990 specify the number and percentage of all examination completed
991 within the timeframe.

992 (b) The office also may conduct additional examinations as
993 often as it deems advisable or necessary for the purpose of
994 ascertaining compliance with this part and any other laws or
995 rules applicable to pharmacy benefit managers or applicants for
996 authorization.



281818

997 (c) If a referral made pursuant to s. 624.307(10)
998 reasonably indicates a pattern or practice of violations of this
999 part by a pharmacy benefit manager, the office must begin an
1000 examination of the pharmacy benefit manager or include findings
1001 related to such referral within an ongoing examination.

1002 (d) Based on the findings of an examination that a pharmacy
1003 benefit manager or an applicant for authorization has exhibited
1004 a pattern or practice of knowing and willful violations of s.
1005 626.8825 or s. 626.8827, the office may, pursuant to chapter
1006 120, order a pharmacy benefit manager to file all contracts
1007 between the pharmacy benefit manager and pharmacies or pharmacy
1008 benefits plans or programs and any policies, guidelines, rules,
1009 protocols, standard operating procedures, instructions, or
1010 directives that govern or guide the manner in which the pharmacy
1011 benefit manager or applicant conducts business related to such
1012 knowing and willful violations for review and inspection for the
1013 following 36-month period. Such documents are public records and
1014 are not trade secrets or otherwise exempt from s. 119.07(1). As
1015 used in this section, the term:

1016 1. "Contracts" means any contract to which s. 626.8825 is
1017 applicable.

1018 2. "Knowing and willful" means any act of commission or
1019 omission which is committed intentionally, as opposed to
1020 accidentally, and which is committed with knowledge of the act's
1021 unlawfulness or with reckless disregard as to the unlawfulness
1022 of the act.

1023 (e) Examinations may be conducted by an independent
1024 professional examiner under contract to the office, in which
1025 case payment must be made directly to the contracted examiner by



281818

1026 the pharmacy benefit manager examined in accordance with the
1027 rates and terms agreed to by the office and the examiner. The
1028 commission shall adopt rules providing for the types of
1029 independent professional examiners who may conduct examinations
1030 under this section, which types must include, but need not be
1031 limited to, independent certified public accountants, actuaries,
1032 investment specialists, information technology specialists, or
1033 others meeting criteria specified by commission rule. The rules
1034 must also require that:

1035 1. The rates charged to the pharmacy benefit manager being
1036 examined are consistent with rates charged by other firms in a
1037 similar profession and are comparable with the rates charged for
1038 comparable examinations.

1039 2. The firm selected by the office to perform the
1040 examination has no conflicts of interest which might affect its
1041 ability to independently perform its responsibilities for the
1042 examination.

1043 (3) In making investigations and examinations of pharmacy
1044 benefit managers and applicants for authorization, the office
1045 and such pharmacy benefit manager are subject to all of the
1046 following provisions:

1047 (a) Section 624.318, as to the conduct of examinations.

1048 (b) Section 624.319, as to examination and investigation
1049 reports.

1050 (c) Section 624.321, as to witnesses and evidence.

1051 (d) Section 624.322, as to compelled testimony.

1052 (e) Section 624.324, as to hearings.

1053 (f) Any other provision of chapter 624 applicable to the
1054 investigation or examination of a licensee under this part.



1055 (4) (a) A pharmacy benefit manager must maintain an accurate
1056 record of all contracts and records with all pharmacies and
1057 pharmacy benefits plans or programs for the duration of the
1058 contract, and for 5 years thereafter. Such contracts must be
1059 made available to the office and kept in a form accessible to
1060 the office.

1061 (b) The office may order any pharmacy benefit manager or
1062 applicant to produce any records, books, files, contracts,
1063 advertising and solicitation materials, or other information and
1064 may take statements under oath to determine whether the pharmacy
1065 benefit manager or applicant is in violation of the law or is
1066 acting contrary to the public interest.

1067 (5) (a) Notwithstanding s. 624.307(3), each pharmacy benefit
1068 manager and applicant for authorization must pay to the office
1069 the expenses of the examination or investigation. Such expenses
1070 include actual travel expenses, a reasonable living expense
1071 allowance, compensation of the examiner, investigator, or other
1072 person making the examination or investigation, and necessary
1073 costs of the office directly related to the examination or
1074 investigation. Such travel expenses and living expense
1075 allowances are limited to those expenses necessarily incurred on
1076 account of the examination or investigation and shall be paid by
1077 the examined pharmacy benefit manager or applicant together with
1078 compensation upon presentation by the office to such pharmacy
1079 benefit manager or applicant of such charges and expenses after
1080 a detailed statement has been filed by the examiner and approved
1081 by the office.

1082 (b) All moneys collected from pharmacy benefit managers and
1083 applicants for authorization pursuant to this subsection shall



281818

1084 be deposited into the Insurance Regulatory Trust Fund, and the
1085 office may make deposits from time to time into such fund from
1086 moneys appropriated for the operation of the office.

1087 (c) Notwithstanding s. 112.061, the office may pay to the
1088 examiner, investigator, or person making such examination or
1089 investigation out of such trust fund the actual travel expenses,
1090 reasonable living expense allowance, and compensation in
1091 accordance with the statement filed with the office by the
1092 examiner, investigator, or other person, as provided in
1093 paragraph (a).

1094 (6) In addition to any other enforcement authority
1095 available to the office, the office shall impose an
1096 administrative fine of \$5,000 for each violation of s. 626.8825
1097 or s. 626.8827. Each instance of a violation of such sections by
1098 a pharmacy benefit manager against each individual pharmacy or
1099 prescription benefits plan or program constitutes a separate
1100 violation. Notwithstanding any other provision of law, there is
1101 no limitation on aggregate fines issued pursuant to this
1102 section. The proceeds from any administrative fine shall be
1103 deposited into the General Revenue Fund.

1104 (7) Failure by a pharmacy benefit manager to pay expenses
1105 incurred or administrative fines imposed under this section is
1106 grounds for the denial, suspension, or revocation of its
1107 certificate of authority.

1108 Section 14. Section 626.89, Florida Statutes, is amended to
1109 read:

1110 626.89 Annual financial statement and filing fee; notice of
1111 change of ownership; pharmacy benefit manager filings.—

1112 (1) Each authorized administrator shall annually file with



281818

1113 the office a full and true statement of its financial condition,
1114 transactions, and affairs within 3 months after the end of the
1115 administrator's fiscal year or within such extension of time as
1116 the office for good cause may have granted. The statement must
1117 be for the preceding fiscal year and must be in such form and
1118 contain such matters as the commission prescribes and must be
1119 verified by at least two officers of the administrator.

1120 (2) Each authorized administrator shall also file an
1121 audited financial statement performed by an independent
1122 certified public accountant. The audited financial statement
1123 must ~~shall~~ be filed with the office within 5 months after the
1124 end of the administrator's fiscal year and be for the preceding
1125 fiscal year. An audited financial statement prepared on a
1126 consolidated basis must include a columnar consolidating or
1127 combining worksheet that must be filed with the statement and
1128 must comply with the following:

1129 (a) Amounts shown on the consolidated audited financial
1130 statement must be shown on the worksheet;

1131 (b) Amounts for each entity must be stated separately; and

1132 (c) Explanations of consolidating and eliminating entries
1133 must be included.

1134 (3) At the time of filing its annual statement, the
1135 administrator shall pay a filing fee in the amount specified in
1136 s. 624.501 for the filing of an annual statement by an insurer.

1137 (4) In addition, the administrator shall immediately notify
1138 the office of any material change in its ownership.

1139 (5) A pharmacy benefit manager shall also notify the office
1140 within 30 days after any administrative, civil, or criminal
1141 complaints, settlements, or discipline of the pharmacy benefit



281818

1142 manager or any of its affiliates which relate to a violation of
1143 the insurance laws, including pharmacy benefit laws in any
1144 state.

1145 (6) A pharmacy benefit manager shall also annually submit
1146 to the office a statement attesting to its compliance with the
1147 network requirements of s. 626.8825.

1148 (7) The commission may by rule require all or part of the
1149 statements or filings required under this section to be
1150 submitted by electronic means in a computer-readable form
1151 compatible with the electronic data format specified by the
1152 commission.

1153 Section 15. Subsection (5) is added to section 627.42393,
1154 Florida Statutes, to read:

1155 627.42393 Step-therapy protocol.—

1156 (5) This section applies to a pharmacy benefit manager
1157 acting on behalf of a health insurer.

1158 Section 16. Subsections (2), (3), and (4) of section
1159 627.64741, Florida Statutes, are amended to read:

1160 627.64741 Pharmacy benefit manager contracts.—

1161 (2) In addition to the requirements of part VII of chapter
1162 626, a contract between a health insurer and a pharmacy benefit
1163 manager must require that the pharmacy benefit manager:

1164 (a) Update maximum allowable cost pricing information at
1165 least every 7 calendar days.

1166 (b) Maintain a process that will, in a timely manner,
1167 eliminate drugs from maximum allowable cost lists or modify drug
1168 prices to remain consistent with changes in pricing data used in
1169 formulating maximum allowable cost prices and product
1170 availability.



1171 ~~(3) A contract between a health insurer and a pharmacy~~
1172 ~~benefit manager must prohibit the pharmacy benefit manager from~~
1173 ~~limiting a pharmacist's ability to disclose whether the cost-~~
1174 ~~sharing obligation exceeds the retail price for a covered~~
1175 ~~prescription drug, and the availability of a more affordable~~
1176 ~~alternative drug, pursuant to s. 465.0244.~~

1177 ~~(4) A contract between a health insurer and a pharmacy~~
1178 ~~benefit manager must prohibit the pharmacy benefit manager from~~
1179 ~~requiring an insured to make a payment for a prescription drug~~
1180 ~~at the point of sale in an amount that exceeds the lesser of:~~

1181 ~~(a) The applicable cost-sharing amount; or~~

1182 ~~(b) The retail price of the drug in the absence of~~
1183 ~~prescription drug coverage.~~

1184 Section 17. Subsections (2), (3), and (4) of section
1185 627.6572, Florida Statutes, are amended to read:

1186 627.6572 Pharmacy benefit manager contracts.—

1187 (2) In addition to the requirements of part VII of chapter
1188 626, a contract between a health insurer and a pharmacy benefit
1189 manager must require that the pharmacy benefit manager:

1190 (a) Update maximum allowable cost pricing information at
1191 least every 7 calendar days.

1192 (b) Maintain a process that will, in a timely manner,
1193 eliminate drugs from maximum allowable cost lists or modify drug
1194 prices to remain consistent with changes in pricing data used in
1195 formulating maximum allowable cost prices and product
1196 availability.

1197 ~~(3) A contract between a health insurer and a pharmacy~~
1198 ~~benefit manager must prohibit the pharmacy benefit manager from~~
1199 ~~limiting a pharmacist's ability to disclose whether the cost-~~



1200 ~~sharing obligation exceeds the retail price for a covered~~
1201 ~~prescription drug, and the availability of a more affordable~~
1202 ~~alternative drug, pursuant to s. 465.0244.~~

1203 ~~(4) A contract between a health insurer and a pharmacy~~
1204 ~~benefit manager must prohibit the pharmacy benefit manager from~~
1205 ~~requiring an insured to make a payment for a prescription drug~~
1206 ~~at the point of sale in an amount that exceeds the lesser of:~~

1207 ~~(a) The applicable cost-sharing amount; or~~

1208 ~~(b) The retail price of the drug in the absence of~~
1209 ~~prescription drug coverage.~~

1210 Section 18. Paragraph (e) is added to subsection (46) of
1211 section 641.31, Florida Statutes, to read:

1212 641.31 Health maintenance contracts.-

1213 (46)

1214 (e) This subsection applies to a pharmacy benefit manager
1215 acting on behalf of a health maintenance organization.

1216 Section 19. Subsections (2), (3), and (4) of section
1217 641.314, Florida Statutes, are amended to read:

1218 641.314 Pharmacy benefit manager contracts.-

1219 (2) In addition to the requirements of part VII of chapter
1220 626, a contract between a health maintenance organization and a
1221 pharmacy benefit manager must require that the pharmacy benefit
1222 manager:

1223 (a) Update maximum allowable cost pricing information at
1224 least every 7 calendar days.

1225 (b) Maintain a process that will, in a timely manner,
1226 eliminate drugs from maximum allowable cost lists or modify drug
1227 prices to remain consistent with changes in pricing data used in
1228 formulating maximum allowable cost prices and product



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1229 availability.

1230 ~~(3) A contract between a health maintenance organization~~
1231 ~~and a pharmacy benefit manager must prohibit the pharmacy~~
1232 ~~benefit manager from limiting a pharmacist's ability to disclose~~
1233 ~~whether the cost-sharing obligation exceeds the retail price for~~
1234 ~~a covered prescription drug, and the availability of a more~~
1235 ~~affordable alternative drug, pursuant to s. 465.0244.~~

1236 ~~(4) A contract between a health maintenance organization~~
1237 ~~and a pharmacy benefit manager must prohibit the pharmacy~~
1238 ~~benefit manager from requiring a subscriber to make a payment~~
1239 ~~for a prescription drug at the point of sale in an amount that~~
1240 ~~exceeds the lesser of:~~

1241 ~~(a) The applicable cost-sharing amount; or~~

1242 ~~(b) The retail price of the drug in the absence of~~
1243 ~~prescription drug coverage.~~

1244 Section 20. (1) This act establishes requirements for
1245 pharmacy benefit managers as defined in s. 626.88, Florida
1246 Statutes, including, without limitation, pharmacy benefit
1247 managers in their performance of services for or otherwise on
1248 behalf of a pharmacy benefits plan or program as defined in s.
1249 626.8825, Florida Statutes, which includes coverage pursuant to
1250 Titles XVIII, XIX, or XXI of the Social Security Act, 42 U.S.C.
1251 ss. 1395 et seq., 1396 et seq., and 1397aa et seq., known as
1252 Medicare, Medicaid, or any other similar coverage under a state
1253 or Federal Government funded health plan, including the
1254 Statewide Medicaid Managed Care program established pursuant to
1255 part IV of chapter 409, Florida Statutes, and the state group
1256 insurance program pursuant to part I of chapter 110, Florida
1257 Statutes.



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1258 (2) This act is not intended, nor may it be construed, to
1259 conflict with existing, relevant federal law.

1260 (3) If any provision of this act or its application to any
1261 person or circumstances is held invalid, the invalidity does not
1262 affect other provisions or applications of this act which can be
1263 given effect without the invalid provision or application, and
1264 to this end the provisions of this act are severable.

1265 Section 21. For the 2023-2024 fiscal year, the sum of
1266 \$980,705 in recurring funds and \$146,820 in nonrecurring funds
1267 from the Insurance Regulatory Trust Fund are appropriated to the
1268 Office of Insurance Regulation, and 10 full-time equivalent
1269 positions with associated salary rate of 644,877 are authorized,
1270 for the purpose of implementing this act.

1271 Section 22. This act shall take effect July 1, 2023.

1272
1273 ===== T I T L E A M E N D M E N T =====

1274 And the title is amended as follows:

1275 Delete everything before the enacting clause
1276 and insert:

1277 A bill to be entitled
1278 An act relating to prescription drugs; providing a
1279 short title; amending s. 499.005, F.S.; specifying
1280 additional prohibited acts related to the Florida Drug
1281 and Cosmetic Act; amending s. 499.012, F.S.; providing
1282 that prescription drug manufacturer and nonresident
1283 prescription drug manufacturer permitholders are
1284 subject to specified requirements; creating s.
1285 499.026, F.S.; defining terms; requiring certain drug
1286 manufacturers to notify the Department of Business and



1287 Professional Regulation of reportable drug price
1288 increases on a specified form on the effective date of
1289 such increase; providing requirements for the form;
1290 providing construction; requiring such manufacturers
1291 to submit certain reports to the department by a
1292 specified date each year; providing requirements for
1293 the reports; authorizing the department to request
1294 certain additional information from the manufacturer
1295 before approving the report; requiring the department
1296 to submit the forms and reports to the Agency for
1297 Health Care Administration to be posted on the
1298 agency's website; prohibiting the agency from posting
1299 on its website certain submitted information that is
1300 marked as a trade secret; requiring the agency to
1301 compile all information from the submitted forms and
1302 reports and make it available to the Governor and the
1303 Legislature upon request; prohibiting manufacturers
1304 from claiming a public records exemption for trade
1305 secrets for certain information provided in such forms
1306 or reports; providing that department employees remain
1307 protected from liability for releasing the forms and
1308 reports as public records; authorizing the department,
1309 in consultation with the agency, to adopt rules;
1310 providing for emergency rulemaking; amending s.
1311 624.307, F.S.; requiring the Division of Consumer
1312 Services of the Department of Financial Services to
1313 designate an employee as the primary contact for
1314 consumer complaints involving pharmacy benefit
1315 managers; requiring the division to refer certain



1316 complaints to the Office of Insurance Regulation;
1317 amending s. 624.490, F.S.; revising the definition of
1318 the term "pharmacy benefit manager"; amending s.
1319 624.491, F.S.; revising provisions related to pharmacy
1320 audits; amending s. 626.88, F.S.; revising the
1321 definition of the term "administrator"; defining the
1322 term "pharmacy benefit manager"; amending s. 626.8805,
1323 F.S.; providing a grandfathering provision for certain
1324 pharmacy benefit managers operating as administrators;
1325 providing a penalty for certain persons who do not
1326 hold a certificate of authority to act as an
1327 administrator on or after a specified date; requiring
1328 the office to submit a report detailing specified
1329 information to the Governor and the Legislature by a
1330 specified date; providing additional requirements for
1331 pharmacy benefit managers applying for a certificate
1332 of authority to act as an administrator; exempting
1333 pharmacy benefit managers from certain fees; amending
1334 s. 626.8814, F.S.; requiring pharmacy benefit managers
1335 to identify certain ownership affiliations to the
1336 office; requiring pharmacy benefit managers to report
1337 any change in such information to the office within a
1338 specified timeframe; creating s. 626.8825, F.S.;
1339 defining terms; providing requirements for certain
1340 contracts between a pharmacy benefit manager and a
1341 pharmacy benefits plan or program; requiring pharmacy
1342 benefits plans and programs, beginning on a specified
1343 date, to annually submit a certain attestation to the
1344 office; providing requirements for certain contracts



1345 between a pharmacy benefit manager and a participating
1346 pharmacy; specifying requirements for certain
1347 administrative appeal procedures that such contracts
1348 with participating pharmacies must include; requiring
1349 pharmacy benefit managers to submit reports on
1350 submitted appeals to the office every 90 days;
1351 creating s. 626.8827, F.S.; specifying prohibited
1352 practices for pharmacy benefit managers; creating s.
1353 626.8828, F.S.; authorizing the office to investigate
1354 administrators that are pharmacy benefit managers and
1355 certain applicants; requiring the office to review
1356 certain referrals and investigate them under certain
1357 circumstances; providing for biennial reviews of
1358 pharmacy benefit managers; requiring the office to
1359 submit an annual report of its examinations to the
1360 Governor and the Legislature by a specified date;
1361 providing requirements for the report, including
1362 specified additional requirements for the biennial
1363 reports; authorizing the office to conduct additional
1364 examinations; requiring the office to conduct an
1365 examination under certain circumstances; providing
1366 procedures and requirements for such examinations;
1367 defining the terms "contracts" and "knowing and
1368 willful"; providing that independent professional
1369 examiners under contract with the office may conduct
1370 examinations of pharmacy benefit managers; requiring
1371 the Financial Services Commission to adopt specified
1372 rules; specifying provisions that apply to such
1373 investigations and examinations; providing



281818

1374 recordkeeping requirements for pharmacy benefit
1375 managers; authorizing the office to order the
1376 production of such records and other specified
1377 information; authorizing the office to take statements
1378 under oath; requiring pharmacy benefit managers and
1379 applicants subjected to an investigation or
1380 examination to pay the associated expenses; specifying
1381 covered expenses; providing for collection of such
1382 expenses; providing for the deposit of certain moneys
1383 into the Insurance Regulatory Trust Fund; authorizing
1384 the office to pay examiners, investigators, and other
1385 persons from such fund; providing administrative
1386 penalties; providing grounds for administrative action
1387 against a certificate of authority; amending s.
1388 626.89, F.S.; requiring pharmacy benefit managers to
1389 notify the office of specified complaints,
1390 settlements, or discipline within a specified
1391 timeframe; requiring pharmacy benefit managers to
1392 annually submit a certain attestation statement to the
1393 office; amending s. 627.42393, F.S.; providing that
1394 certain step-therapy protocol requirements apply to a
1395 pharmacy benefit manager acting on behalf of a health
1396 insurer; amending ss. 627.64741 and 627.6572, F.S.;
1397 conforming provisions to changes made by the act;
1398 amending s. 641.31, F.S.; providing that certain step-
1399 therapy protocol requirements apply to a pharmacy
1400 benefit manager acting on behalf of a health
1401 maintenance organization; amending s. 641.314, F.S.;
1402 conforming a provision to changes made by the act;



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1403 providing legislative intent, construction, and
1404 severability; providing appropriations and authorizing
1405 positions; providing an effective date.