

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

26 | consultation with the agency, to adopt rules;
27 | providing for emergency rulemaking; amending s.
28 | 624.307, F.S.; requiring the Division of Consumer
29 | Services of the Department of Financial Services to
30 | designate an employee of the division as the primary
31 | contact for consumers and pharmacies on issues
32 | relating to pharmacy benefit managers; requiring the
33 | division to refer certain consumer complaints to the
34 | Office of Insurance Regulation; amending s. 624.490,
35 | F.S.; revising the definition of the term "pharmacy
36 | benefit manager"; amending s. 624.491, F.S.; providing
37 | requirements for pharmacy benefits plans and programs,
38 | rather than health insurers and health maintenance
39 | organizations, that provide pharmacy benefits; amending
40 | s. 626.88, F.S.; revising the definition of the term
41 | "administrator" to include pharmacy benefit managers;
42 | defining the term "pharmacy benefit manager"; amending
43 | s. 626.8805, F.S.; providing a grandfathering
44 | provision for certain pharmacy benefit managers
45 | operating as administrators; providing a penalty for
46 | certain persons who do not hold a certificate of
47 | authority to act as an administrator on or after a
48 | specified date; providing additional requirements for
49 | pharmacy benefit managers applying for a certificate
50 | of authority to act as administrators; exempting

51 pharmacy benefit managers from certain fees; amending
52 s. 626.8814, F.S.; requiring pharmacy benefit managers
53 to identify certain ownership affiliations to the
54 office; requiring pharmacy benefit managers to report
55 any change in such information to the office within a
56 specified timeframe; creating s. 626.8825, F.S.;
57 defining terms; providing requirements for certain
58 contracts between a pharmacy benefit manager and a
59 pharmacy benefits plan or program and for certain
60 contracts between a pharmacy benefit manager and a
61 participating pharmacy; providing reporting
62 requirements for pharmacy benefit managers; creating
63 s. 626.8827, F.S.; providing prohibited practices for
64 pharmacy benefit managers; creating s. 626.8828, F.S.;
65 authorizing the office to investigate administrators
66 that are pharmacy benefit managers and certain
67 applicants; requiring the office to review certain
68 referrals and investigate them under certain
69 circumstances; requiring biennial examinations of
70 pharmacy benefit managers; providing procedures and
71 requirements for such examinations; providing
72 reporting requirements; authorizing the office to
73 conduct additional examinations; defining the terms
74 "contract" and "knowing and willful"; requiring the
75 Financial Services Commission to adopt rules;

76 providing requirements for such rules; specifying
77 provisions that apply to such investigations and
78 examinations; providing recordkeeping requirements for
79 pharmacy benefit managers; authorizing the office to
80 order the production of such records and other
81 specified information; authorizing the office to take
82 statements under oath; requiring pharmacy benefit
83 managers and certain applicants subjected to an
84 investigation or examination to pay the associated
85 expenses; specifying covered expenses; providing for
86 the deposit of such expenses; providing for the
87 deposit of certain moneys into the Insurance
88 Regulatory Trust Fund; authorizing the office to pay
89 examiners, investigators, and other persons conducting
90 examinations or investigations out of such trust fund;
91 providing fines; providing grounds for administrative
92 action against a pharmacy benefit manager's
93 certificate of authority; amending s. 626.89, F.S.;
94 requiring pharmacy benefit managers to notify the
95 office of specified complaints, settlements, or
96 discipline within a specified timeframe; requiring
97 pharmacy benefit managers to annually submit a certain
98 attestation statement to the office; amending s.
99 627.42393, F.S.; providing that certain step-therapy
100 protocol requirements apply to pharmacy benefit

101 managers acting on behalf of a health insurer;
 102 amending ss. 627.64741 and 627.6572, F.S.; conforming
 103 provisions to changes made by the act; amending s.
 104 641.31, F.S.; providing that certain step-therapy
 105 protocol requirements apply to a pharmacy benefit
 106 manager acting on behalf of a health maintenance
 107 organization; amending s. 641.314, F.S.; conforming a
 108 provision to changes made by the act; providing
 109 legislative intent, construction, and severability;
 110 providing appropriations and authorizing positions;
 111 providing an effective date.

112

113 Be It Enacted by the Legislature of the State of Florida:

114

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

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

119 499.005 Prohibited acts.—It is unlawful for a person to
 120 perform or cause the performance of any of the following acts in
 121 this state:

122 (29) Failure to accurately complete and timely submit
 123 reportable drug price increase forms and reports as required
 124 under this part and rules adopted thereunder.

125 Section 3. Subsection (16) is added to section 499.012,

126 Florida Statutes, to read:

127 499.012 Permit application requirements.—

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

131 Section 4. Section 499.026, Florida Statutes, is created
132 to read:

133 499.026 Notification of manufacturer prescription drug
134 price increases.—

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

136 (a) "Course of therapy" means the recommended daily dose
137 units of a prescription drug pursuant to its prescribing label
138 for 30 days or the recommended daily dose units of a
139 prescription drug pursuant to its prescribing label for a normal
140 course of treatment which is less than 30 days.

141 (b) "Manufacturer" means a person holding a prescription
142 drug manufacturer permit or a nonresident prescription drug
143 manufacturer permit under s. 499.01.

144 (c) "Prescription drug" has the same meaning as in s.
145 499.003 and includes biological products, but is limited to
146 those prescription drugs and biological products intended for
147 human use.

148 (d) "Reportable drug price increase" means, for a
149 prescription drug with a wholesale acquisition cost of at least
150 \$40 for a course of therapy before the effective date of an

151 increase, a price increase by more than 10 percent by the
152 manufacturer. In calculating the 10 percent threshold, the
153 manufacturer includes the proposed increase and the cumulative
154 increases that occurred within the previous 24 months before the
155 effective date of the increase.

156 (e) "Wholesale acquisition cost" means, with respect to a
157 prescription drug or biological product, the manufacturer's list
158 price for the prescription drug or biological product to
159 wholesalers or direct purchasers in the United States, not
160 including prompt pay or other discounts, rebates, or reductions
161 in price, for the most recent month for which the information is
162 available, as reported in wholesale price guides or other
163 publications of drug or biological product pricing data.

164 (2) On the effective date of a manufacturer's reportable
165 drug price increase, the manufacturer must provide notification
166 of each reportable drug price increase to the department on a
167 form prescribed by the department. The form must require the
168 manufacturer to specify all of the following:

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

171 (b) The wholesale acquisition cost before the reportable
172 drug price increase.

173 (c) The dollar amount of the reportable drug price
174 increase.

175 (d) The percentage amount of the reportable drug price

176 increase from the wholesale acquisition cost before the
177 reportable drug price increase.

178 (e) A statement regarding whether a change or improvement
179 in the prescription drug necessitates the reportable drug price
180 increase. If so, the manufacturer must describe the change or
181 improvement.

182 (f) The intended uses of the prescription drug.

183

184 This subsection does not prohibit a manufacturer from notifying
185 other parties, such as pharmacy benefit managers, of a drug
186 price increase before the effective date of the drug price
187 increase.

188 (3) By April 1 of each year, each manufacturer shall
189 submit a report to the department on a form prescribed by the
190 department. A report is not deemed to be submitted until
191 approved by the department. The report must include all of the
192 following:

193 (a) A list of all prescription drugs affected by a
194 reportable drug price increase during the previous calendar year
195 and both the dollar amount of each reportable drug price
196 increase and the percentage increase of each reportable drug
197 price increase relative to the previous wholesale acquisition
198 cost of the prescription drug. The prescription drugs must be
199 identified using their proprietary names and nonproprietary
200 names, as applicable.

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

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

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

210 (e) A list of the factors contributing to each reportable
 211 drug price increase.

212 (f) A description that describes the justification of each
 213 reportable drug price increase referenced in paragraph (e). The
 214 factors must be provided with such specificity as to explain the
 215 need or justification for each reportable drug price increase.
 216 The department may request additional information from a
 217 manufacturer relating to the need or justification of any
 218 reportable drug price increase before approving the
 219 manufacturer's report.

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

222 (4) (a) The department shall submit all forms and reports
 223 submitted by manufacturers to the Agency for Health Care
 224 Administration, to be posted on the agency's website pursuant to
 225 s. 408.062.

226 (b) A manufacturer may not claim a public records
227 exemption for a trade secret under s. 119.0715 for any
228 information required by the department under this section.
229 Department employees remain protected from liability for release
230 of forms and reports pursuant to s. 119.0715(4).

231 (5) The department, in consultation with the Agency for
232 Health Care Administration, shall adopt rules to implement this
233 section.

234 (a) The department shall adopt necessary emergency rules
235 pursuant to s. 120.54(4) to implement this section. If an
236 emergency rule adopted under this section is held to be
237 unconstitutional or an invalid exercise of delegated legislative
238 authority and becomes void, the department may adopt an
239 emergency rule under this section to replace the rule that has
240 become void. If the emergency rule adopted to replace the void
241 emergency rule is also held to be unconstitutional or an invalid
242 exercise of delegated legislative authority and becomes void,
243 the department must follow the nonemergency rulemaking
244 procedures of the Administrative Procedure Act to replace the
245 rule that has become void.

246 (b) For emergency rules adopted under this section, the
247 department need not make the findings required under s.
248 120.54(4) (a). Emergency rules adopted under this section are
249 also exempt from:

250 1. Sections 120.54(3) (b) and 120.541. Challenges to

251 emergency rules adopted under this section are subject to the
 252 time schedules provided in s. 120.56(5).

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

256 Section 5. Paragraph (a) of subsection (10) of section
 257 624.307, Florida Statutes, is amended, and paragraph (b) of that
 258 subsection is republished, to read:

259 624.307 General powers; duties.—

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

- 263 1. Receive inquiries and complaints from consumers.
- 264 2. Prepare and disseminate information that the department
 265 deems appropriate to inform or assist consumers.
- 266 3. Provide direct assistance to and advocacy for consumers
 267 who request such assistance or advocacy.
- 268 4. With respect to apparent or potential violations of law
 269 or applicable rules committed by a person or entity licensed by
 270 the department or office, report apparent or potential
 271 violations to the office or to the appropriate division of the
 272 department, which may take any additional action it deems
 273 appropriate.
- 274 5. Designate an employee of the division as the primary
 275 contact for consumers on issues relating to sinkholes.

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

283 (b) Any person licensed or issued a certificate of
284 authority by the department or the office shall respond, in
285 writing, to the division within 20 days after receipt of a
286 written request for documents and information from the division
287 concerning a consumer complaint. The response must address the
288 issues and allegations raised in the complaint and include any
289 requested documents concerning the consumer complaint not
290 subject to attorney-client or work-product privilege. The
291 division may impose an administrative penalty for failure to
292 comply with this paragraph of up to \$2,500 per violation upon
293 any entity licensed by the department or the office and \$250 for
294 the first violation, \$500 for the second violation, and up to
295 \$1,000 for the third or subsequent violation upon any individual
296 licensed by the department or the office.

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

299 624.490 Registration of pharmacy benefit managers.—

300 (1) As used in this section, the term "pharmacy benefit

301 manager" has the same meaning as in s. 626.88 ~~means a person or~~
 302 ~~entity doing business in this state which contracts to~~
 303 ~~administer prescription drug benefits on behalf of a health~~
 304 ~~insurer or a health maintenance organization to residents of~~
 305 ~~this state.~~

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

308 624.491 Pharmacy audits.—

309 (1) A pharmacy benefits plan or program as defined in s.
 310 626.8825 ~~health insurer or health maintenance organization~~
 311 ~~providing pharmacy benefits through a major medical individual~~
 312 ~~or group health insurance policy or a health maintenance~~
 313 ~~contract, respectively,~~ must comply with the requirements of
 314 this section when the pharmacy benefits plan or program ~~health~~
 315 ~~insurer or health maintenance organization~~ or any person or
 316 entity acting on behalf of the pharmacy benefits plan or program
 317 ~~health insurer or health maintenance organization,~~ including,
 318 but not limited to, a pharmacy benefit manager as defined in s.
 319 626.88 ~~s. 624.490 (1),~~ audits the records of a pharmacy licensed
 320 under chapter 465. The person or entity conducting such audit
 321 must:

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

325 (b) Not schedule an onsite audit during the first 3

326 calendar days of a month unless the pharmacist consents
327 otherwise.

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

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

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

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

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

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

350 (i) Provide the pharmacy with a copy of the final audit

351 report within 6 months after the pharmacy's receipt of the
 352 preliminary audit report.

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

356 (5) A pharmacy benefits plan or program ~~health insurer or~~
 357 ~~health maintenance organization~~ that, under terms of a contract,
 358 transfers to a pharmacy benefit manager the obligation to pay a
 359 pharmacy licensed under chapter 465 for any pharmacy benefit
 360 claims arising from services provided to or for the benefit of
 361 an insured or subscriber remains responsible for a violation of
 362 this section.

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

366 626.88 Definitions.—For the purposes of this part, the
 367 term:

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

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

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

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

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

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

398 (e) An entity that is affiliated with an insurer and that
 399 only performs the contractual duties, between the administrator
 400 and the insurer, of an administrator for the direct and assumed

401 insurance business of the affiliated insurer. The insurer is
402 responsible for the acts of the administrator and is responsible
403 for providing all of the administrator's books and records to
404 the insurance commissioner, upon a request from the insurance
405 commissioner. For purposes of this paragraph, the term "insurer"
406 means a licensed insurance company, health maintenance
407 organization, prepaid limited health service organization, or
408 prepaid health clinic.

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

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

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

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

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

424 (k) A trust and its trustees, agents, and employees acting
425 pursuant to such trust established in conformity with 29 U.S.C.

426 s. 186.

427 (l) A trust exempt from taxation under s. 501(a) of the
 428 Internal Revenue Code, a trust satisfying the requirements of
 429 ss. 624.438 and 624.439, or any governmental trust as defined in
 430 s. 624.33(3), and the trustees and employees acting pursuant to
 431 such trust, or a custodian and its agents and employees,
 432 including individuals representing the trustees in overseeing
 433 the activities of a service company or administrator, acting
 434 pursuant to a custodial account which meets the requirements of
 435 s. 401(f) of the Internal Revenue Code.

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

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

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

450 (p) A person approved by the department who administers

451 only self-insured workers' compensation plans.

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

456 (r) Any provider or group practice, as defined in s.
 457 456.053, providing services under the scope of the license of
 458 the provider or the member of the group practice.

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

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

465
 466 A person who provides billing and collection services to health
 467 insurers and health maintenance organizations on behalf of
 468 health care providers shall comply with the provisions of ss.
 469 627.6131, 641.3155, and 641.51(4).

470 (6) "Pharmacy benefit manager" means a person or entity
 471 doing business in this state which contracts to administer
 472 prescription drug benefits on behalf of a pharmacy benefits plan
 473 or program as defined in s. 626.8825. The term includes, but is
 474 not limited to, a person or entity that performs one or more of
 475 the following services:

- 476 (a) Pharmacy claims processing.
- 477 (b) Administration or management of pharmacy discount card
 478 programs.
- 479 (c) Managing pharmacy networks or pharmacy reimbursements.
- 480 (d) Paying or managing claims for pharmacist services
 481 provided to covered persons.
- 482 (e) Developing or managing a clinical formulary, including
 483 utilization management or quality assurance programs.
- 484 (f) Pharmacy rebate administration.
- 485 (g) Managing patient compliance, therapeutic intervention,
 486 or generic substitution programs.
- 487 (h) Administration or management of a mail order pharmacy
 488 program.
- 489 Section 9. Subsections (3) through (6) of section
 490 626.8805, Florida Statutes, are renumbered as subsections (4)
 491 through (7), respectively, subsection (1) and present subsection
 492 (3) are amended, and a new subsection (3) and subsection (8) are
 493 added to that section, to read:
- 494 626.8805 Certificate of authority to act as
 495 administrator.—
- 496 (1) It is unlawful for any person to act as or hold
 497 himself or herself out to be an administrator in this state
 498 without a valid certificate of authority issued by the office
 499 pursuant to ss. 626.88-626.894. A pharmacy benefit manager that
 500 is registered with the office under s. 624.490 as of June 30,

501 2023, may continue to operate until January 1, 2024, as an
502 administrator without a certificate of authority and is not in
503 violation of the requirement to possess a valid certificate of
504 authority as an administrator during that timeframe. To qualify
505 for and hold authority to act as an administrator in this state,
506 an administrator must otherwise be in compliance with this code
507 and with its organizational agreement. The failure of any
508 person, excluding a pharmacy benefit manager, to hold such a
509 certificate while acting as an administrator shall subject such
510 person to a fine of not less than \$5,000 or more than \$10,000
511 for each violation. A person who, on or after January 1, 2024,
512 does not hold a certificate of authority to act as an
513 administrator while operating as a pharmacy benefit manager is
514 subject to a fine of \$10,000 per violation per day.

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

517 (a) A complete biographical statement on forms prescribed
518 by the commission, an independent investigation report, and
519 fingerprints obtained pursuant to chapter 624 of all of the
520 individuals referred to in paragraph (2) (c).

521 (b) A self-disclosure of any administrative, civil, or
522 criminal complaints, settlements, or discipline of the
523 applicant, or any of the applicant's affiliates, which relates
524 to a violation of the insurance laws, including pharmacy benefit
525 manager laws, in any state.

526 (c) A statement attesting to compliance with the network
 527 requirements in s. 626.8825 beginning January 1, 2024.

528 (4) (a) ~~(3)~~ The applicant shall make available for
 529 inspection by the office copies of all contracts relating to
 530 services provided by the administrator to insurers or other
 531 persons using the services of the administrator.

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

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

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

537 (8) A pharmacy benefit manager is exempt from fees
 538 associated with the initial application and the annual filing
 539 fees in s. 626.89.

540 Section 10. Section 626.8814, Florida Statutes, is amended
 541 to read:

542 626.8814 Disclosure of ownership or affiliation.—

543 (1) Each administrator shall identify to the office any
 544 ownership interest or affiliation of any kind with any insurance
 545 company responsible for providing benefits directly or through
 546 reinsurance to any plan for which the administrator provides
 547 administrative services.

548 (2) Pharmacy benefit managers shall also identify to the
 549 office any ownership affiliation of any kind with any pharmacy
 550 which, directly or indirectly, through one or more

551 intermediaries:

552 (a) Has an investment or ownership interest in a pharmacy
 553 benefit manager holding a certificate of authority issued under
 554 this part;

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

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

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

564 Section 11. Section 626.8825, Florida Statutes, is created
 565 to read:

566 626.8825 Pharmacy benefit manager transparency and
 567 accountability.—

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

569 (a) "Adjudication transaction fee" means a fee charged by
 570 a pharmacy benefit manager to a pharmacy for electronic claim
 571 submissions.

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

574 1. Has an investment or ownership interest in a pharmacy
 575 benefit manager holding a certificate of authority issued under

576 this part;

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

579 3. Has an investor or a holder of an ownership interest
580 which is a pharmacy benefit manager holding a certificate of
581 authority issued under this part.

582 (c) "Brand name or generic effective rate" means the
583 contractual rate set forth by a pharmacy benefit manager for the
584 reimbursement of covered brand name or generic drugs, calculated
585 using the total payments in the aggregate, by drug type, during
586 the performance period. The effective rates are typically
587 calculated as a discount from industry benchmarks such as
588 average wholesale price or wholesale acquisition cost.

589 (d) "Covered person" means a person covered by,
590 participating in, or receiving the benefit of a pharmacy
591 benefits plan or program.

592 (e) "Direct and indirect remuneration fees" means price
593 concessions that are paid to the pharmacy benefit manager by the
594 pharmacy retrospectively and that cannot be calculated at the
595 point of sale. The term may also include discounts, chargebacks,
596 rebates, cash discounts, free goods contingent on a purchase
597 agreement, upfront payments, coupons, goods in kind, free or
598 reduced-price services, grants, or other price concessions or
599 similar benefits from manufacturers, pharmacies, or similar
600 entities.

601 (f) "Dispensing fee" means a fee intended to cover
602 reasonable costs associated with providing the drug to a covered
603 person. These costs include the pharmacist services and the
604 overhead associated with maintaining the facility and equipment
605 necessary to operate the pharmacy.

606 (g) "Effective rate guarantee" means the minimum
607 ingredient cost reimbursement a pharmacy benefit manager
608 guarantees it will pay for pharmacist services during the
609 applicable measurement period.

610 (h) "Erroneous claim" means a pharmacy claim submitted in
611 error, including, but not limited to, an unintended, incorrect,
612 fraudulent, or test claim.

613 (i) "Group purchasing organization" means an entity
614 affiliated with a pharmacy benefit manager or a pharmacy
615 benefits plan or program in which purchasing volume aggregates
616 to leverage negotiating discounts and rebates for covered
617 prescription drugs with pharmaceutical manufacturers,
618 distributors, and wholesale vendors.

619 (j) "Incentive payment" means a retrospective monetary
620 payment made as a reward or recognition by a pharmacy benefits
621 plan or program or pharmacy benefit manager to a pharmacy for
622 meeting or exceeding predefined pharmacy performance metrics as
623 related to quality measures such as the Healthcare Effectiveness
624 Data and Information Set measures.

625 (k) "Maximum allowable cost appeal pricing adjustment"

626 means a retrospective positive payment adjustment made to a
627 pharmacy by the pharmacy benefits plan or program or pharmacy
628 benefit manager pursuant to an approved maximum allowable cost
629 appeal request submitted by the same pharmacy to dispute the
630 amount reimbursed for a drug based on the pharmacy benefit
631 manager's listed maximum allowable cost price.

632 (l) "Monetary recoupments" means rescinded or recouped
633 payments from a pharmacy or provider by the pharmacy benefits
634 plan or program or by the pharmacy benefit manager.

635 (m) "Network" means a group of pharmacies that agree to
636 provide pharmacist services to covered persons on behalf of a
637 pharmacy benefits plan or program or group of pharmacy benefits
638 plans or programs in exchange for payment for such services. The
639 term includes a pharmacy that generally dispenses outpatient
640 prescription drugs to covered persons.

641 (n) "Network reconciliation offsets" means a process
642 during annual payment reconciliation between a pharmacy benefit
643 manager and a pharmacy which allows the pharmacy benefit manager
644 to offset an amount for overperformance or underperformance of
645 contractual guarantees across guaranteed line items, channels,
646 networks, or payers, as applicable.

647 (o) "Participation contract" means any agreement between a
648 pharmacy benefit manager and pharmacy for the provision and
649 reimbursement of pharmacist services and any exhibits,
650 attachments, amendments, or addendums to such agreement.

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

655 1. Equivalent to the payments the pharmacy benefit manager
 656 makes to a dispensing pharmacy or provider for such drugs,
 657 including any contracted professional dispensing fee between the
 658 pharmacy benefit manager and its network. Such dispensing fee
 659 would be paid if the pharmacy benefits plan or program was
 660 making the payments directly.

661 2. Passed through in their entirety by the pharmacy
 662 benefits plan or program or by the pharmacy benefit manager to
 663 the pharmacy or provider that dispenses the drugs, and the
 664 payments are made in a manner that is not offset by any
 665 reconciliation.

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

667 (r) "Pharmacist services" means products, goods, and
 668 services or any combination of products, goods, and services
 669 provided as part of the practice of the profession of pharmacy
 670 as defined in s. 465.003 or otherwise covered by a pharmacy
 671 benefits plan or program.

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

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

675 (u) "Pharmacy benefits plan or program" means a plan or

676 program that pays for, reimburses, covers the cost of, or
677 provides access to discounts on pharmacist services provided by
678 one or more pharmacies to covered persons who reside in, are
679 employed by, or receive pharmacist services from this state. The
680 term includes, but is not limited to, health maintenance
681 organizations, health insurers, self-insured employer plans,
682 discount card programs, and government-funded health plans,
683 including the Statewide Medicaid Managed Care program
684 established pursuant to part IV of chapter 409 and the state
685 group insurance program established pursuant to part I of
686 chapter 110.

687 (v) "Rebate" means all payments that accrue to a pharmacy
688 benefit manager or its pharmacy benefits plan or program client
689 or an affiliated group purchasing organization, directly or
690 indirectly, from a pharmaceutical manufacturer, including, but
691 not limited to, discounts, administration fees, credits,
692 incentives, or penalties associated directly or indirectly in
693 any way with claims administered on behalf of a pharmacy
694 benefits plan or program client.

695 (w) "Spread pricing" is the practice in which a pharmacy
696 benefit manager charges a pharmacy benefits plan or program a
697 different amount for pharmacist services than the amount the
698 pharmacy benefit manager reimburses a pharmacy for such
699 pharmacist services.

700 (x) "Usual and customary price" means the amount charged

701 to cash customers for a pharmacist service exclusive of sales
702 tax or other amounts claimed.

703 (2) CONTRACTS BETWEEN A PHARMACY BENEFIT MANAGER AND A
704 PHARMACY BENEFITS PLAN OR PROGRAM.—

705 (a) In addition to any other requirements in the Florida
706 Insurance Code, all contractual arrangements executed, amended,
707 adjusted, or renewed on or after July 1, 2023, which apply to
708 pharmacy benefits covered on or after January 1, 2024, between a
709 pharmacy benefit manager and a pharmacy benefits plan or program
710 must:

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

713 2. Exclude terms that allow for the direct or indirect
714 engagement in the practice of spread pricing unless the pharmacy
715 benefit manager passes along the entire amount of such
716 difference to the pharmacy benefits plan or program as allowable
717 under subparagraph 1.

718 3. Ensure that funds received in relation to providing
719 services for a pharmacy benefits plan or program or a pharmacy
720 are received by the pharmacy benefit manager in trust for the
721 pharmacy benefits plan or program or pharmacy, as applicable,
722 and are used or distributed only pursuant to the pharmacy
723 benefit manager's contract with the pharmacy benefits plan or
724 program or with the pharmacy or as otherwise required by
725 applicable law.

726 4. Require the pharmacy benefit manager to pass 100
727 percent of all prescription drug manufacturer rebates received,
728 including nonresident manufacturer rebates, to the pharmacy
729 benefits plan or program if the contractual arrangement
730 delegates the negotiation of rebates to the pharmacy benefit
731 manager, for the sole purpose of offsetting defined cost sharing
732 and reducing premiums of covered persons. Any excess rebate
733 revenue after the pharmacy benefit manager and the pharmacy
734 benefits plan or program have taken all actions required under
735 this subparagraph must be used for the sole purpose of
736 offsetting copayments and deductibles of covered persons. This
737 subparagraph does not apply to contracts involving Medicaid
738 managed care plans.

739 5. Include network adequacy requirements that meet or
740 exceed the Medicare Part D program standards for convenient
741 access to network pharmacies set forth in 42 C.F.R. s. 423.120
742 and that:

743 a. Do not limit a network to include solely affiliated
744 pharmacies;

745 b. Require a pharmacy benefit manager to offer a provider
746 contract to licensed pharmacies physically located on the
747 physical site of providers that are:

748 (I) Within the pharmacy benefits plan's or program's
749 geographic service area and that have been specifically
750 designated as essential providers by the Agency for Health Care

751 Administration pursuant to s. 409.975(1)(a);
752 (II) Designated as a cancer center of excellence under s.
753 381.925, regardless of the pharmacy benefits plan's or program's
754 geographic service area;
755 (III) Organ transplant hospitals, regardless of the
756 pharmacy benefits plan's or program's geographic service area;
757 (IV) Hospitals licensed as children's specialty hospitals,
758 as defined in s. 395.002; or
759 (V) Regional perinatal intensive care centers as defined
760 in s. 383.16(2), regardless of the pharmacy benefits plan's or
761 program's geographic service area.

762

763 Such provider contracts must be solely for the administration or
764 dispensing of covered prescription drugs, including biological
765 products, which are administered through infusions,
766 intravenously injected, or inhaled during a surgical procedure,
767 or covered parenteral drugs, as part of onsite outpatient care;

768 c. Do not require a covered person to receive a
769 prescription drug by United States mail, common carrier, local
770 courier, third-party company or delivery service, or pharmacy
771 direct delivery. This sub-subparagraph does not prohibit a
772 pharmacy benefit manager from operating mail order or delivery
773 programs on an opt-in basis at the sole discretion of a covered
774 person; or

775 d. Prohibit a requirement for a covered person to receive

776 pharmacist services from an affiliated pharmacy or an affiliated
777 health care provider for the in-person administration of covered
778 prescription drugs; offering or implementing pharmacy networks
779 that require or provide a promotional item or an incentive to a
780 covered person to use an affiliated pharmacy or an affiliated
781 health care provider for the in-person administration of covered
782 prescription drugs; or advertising, marketing, or promoting an
783 affiliated pharmacy to covered persons. Subject to the
784 foregoing, a pharmacy benefit manager may include an affiliated
785 pharmacy in communications to covered persons regarding network
786 pharmacies and prices, provided that the pharmacy benefit
787 manager includes information such as links to all nonaffiliated
788 network pharmacies in such communications and that the
789 information provided is accurate and of equal prominence. This
790 subparagraph may not be construed to prohibit a pharmacy benefit
791 manager from entering into an agreement with an affiliated
792 pharmacy to provide pharmacist services to covered persons. As
793 used in this sub-subparagraph, the term "incentive" does not
794 include a reduced copayment or premium of a covered drug.

795 6. Prohibit the ability of a pharmacy benefit manager to
796 condition participation in one pharmacy network on participation
797 in any other pharmacy network or penalize a pharmacy for
798 exercising its prerogative not to participate in a specific
799 pharmacy network.

800 7. Prohibit a pharmacy benefit manager from instituting a

801 network that requires a pharmacy to meet accreditation standards
802 inconsistent with or more stringent than applicable federal and
803 state requirements for licensure and operation as a pharmacy in
804 this state.

805 8. At a minimum, require the pharmacy benefit manager or
806 pharmacy benefits plan or program to, upon revising its
807 formulary of covered prescription drugs during a plan year,
808 provide a 60-day continuity of care period in which the covered
809 prescription drug that is being revised from the formulary
810 continues to be provided at the same cost for the patient for a
811 period of 60 days. The 60-day continuity of care period shall
812 commence upon notification to the patient. This requirement does
813 not apply if the covered prescription drug:

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

817 b. Has been removed or withdrawn from the commercial
818 market by the manufacturer; or

819 c. Is subject to an involuntary recall by state or federal
820 authorities and is no longer available on the commercial market.

821 (b) Beginning January 1, 2024, and annually thereafter,
822 the pharmacy benefits plan or program shall submit to the
823 office, under the penalty of perjury, a statement attesting to
824 its compliance with the requirements of this subsection.

825 (3) CONTRACTS BETWEEN A PHARMACY BENEFIT MANAGER AND A

826 PARTICIPATING PHARMACY.—In addition to other requirements in the
827 Florida Insurance Code, a participation contract executed,
828 amended, adjusted, or renewed on or after July 1, 2023, which
829 applies to pharmacist services on or after January 1, 2024,
830 between a pharmacy benefit manager and one or more pharmacies or
831 pharmacists must include, in substantial form, terms that ensure
832 compliance with all of the following requirements and that,
833 except to the extent not allowed by law, shall supersede any
834 contractual terms in the participation contract to the contrary:

835 (a) At the time of adjudication for electronic claims or
836 the time of reimbursement for nonelectronic claims, the pharmacy
837 benefit manager must provide the pharmacy with a remittance
838 including such detailed information as is necessary for the
839 pharmacy or pharmacist to identify the reimbursement schedule
840 for the specific network applicable to the claim and which is
841 the basis used by the pharmacy benefit manager to calculate the
842 amount of reimbursement paid. This information must include, but
843 is not limited to, the applicable network reimbursement
844 identification or plan identification as defined in the most
845 current version of the National Council for Prescription Drug
846 Programs (NCPDP) Telecommunication Standard Implementation Guide
847 or its nationally recognized successor industry guide. The
848 commission shall adopt rules to implement this paragraph.

849 (b) The pharmacy benefit manager must ensure that any
850 basis of reimbursement information is communicated to a pharmacy

851 in accordance with the NCPDP Telecommunication Standard
852 Implementation Guide, or its nationally recognized successor
853 industry guide, when performing reconciliation for any effective
854 rate guarantee, and that such basis of reimbursement information
855 communicated is accurate, corresponds with the applicable
856 network rate, and may be relied upon by the pharmacy.

857 (c) The pharmacy benefit manager may not recoup direct or
858 indirect remuneration fees, dispensing fees, brand name or
859 generic effective rate adjustments through reconciliation, or
860 any other monetary recoupments as related to discounts,
861 financial clawbacks, multiple network reconciliation offsets,
862 adjudication transaction fees, and any other instance when a fee
863 may be recouped from a pharmacy. For purposes of this paragraph,
864 the terms "financial clawbacks" and "reconciliation offsets" do
865 not include any incentive payments provided by the pharmacy
866 benefit manager to a network pharmacy for meeting or exceeding
867 predefined quality measures such as the Healthcare Effectiveness
868 Data and Information Set measures; recoupment due to an
869 erroneous claim, fraud, waste, or abuse; a claim adjudicated in
870 error; a maximum allowable cost appeal pricing adjustment; or an
871 adjustment made as part of a pharmacy audit pursuant to s.
872 624.491.

873 (d) The pharmacy benefit manager may not unilaterally
874 change the terms of any participation contract.

875 (e) Unless otherwise prohibited by law, a pharmacy benefit

876 manager may not prohibit a pharmacy or pharmacist from:
 877 1. Offering mail or delivery services on an opt-in basis
 878 at the sole discretion of the covered person.
 879 2. Mailing or delivering a prescription drug to a covered
 880 person upon his or her request.
 881 3. Charging a shipping or handling fee to a covered person
 882 requesting a prescription drug be mailed or delivered if the
 883 pharmacy or pharmacist discloses to the covered person before
 884 the mailing or delivery the amount of the fee that will be
 885 charged and that the fee may not be reimbursable by the covered
 886 person's pharmacy benefits plan or program.
 887 (f) The pharmacy benefit manager must provide a pharmacy,
 888 upon its request, a list of pharmacy benefits plans or programs
 889 in which the pharmacy is a part of the network. Updates to the
 890 list must be communicated to the pharmacy within 7 days. The
 891 pharmacy benefit manager may not restrict the pharmacy or
 892 pharmacist from disclosing this information to the public.
 893 (g) The pharmacy benefit manager must ensure that the
 894 electronic remittance advice contains claim level payment
 895 adjustments in accordance with the American National Standards
 896 Institute's Accredited Standards Committee X12 format and
 897 includes or is accompanied by appropriate level of detail for
 898 the pharmacy to reconcile any debits or credits, including, but
 899 not limited to, the NCPDP pharmacy identification number or
 900 National Provider Identifier, date of service, prescription

901 number, refill number, adjustment code if applicable, and
902 transaction amount.

903 (h) The pharmacy benefit manager must provide a reasonable
904 administrative appeal procedure to allow a pharmacy or
905 pharmacist to challenge the maximum allowable cost pricing
906 information and the reimbursement made under the maximum
907 allowable cost as defined in s. 627.64741(1) for a specific drug
908 as being below the acquisition cost available to the challenging
909 pharmacy or pharmacist.

910 1. The administrative appeal procedure must include a
911 telephone number and e-mail address, or a website, for the
912 purpose of submitting the administrative appeal. The appeal may
913 be submitted by the pharmacy or an agent of the pharmacy
914 directly to the pharmacy benefit manager or through a pharmacy
915 service administration organization. The pharmacy or pharmacist
916 must be given at least 30 business days after a maximum
917 allowable cost update or after an adjudication for an electronic
918 claim or reimbursement for a nonelectronic claim to file the
919 administrative appeal.

920 2. The pharmacy benefit manager must respond to the
921 administrative appeal within 30 business days after receipt of
922 the appeal.

923 3. If the appeal is upheld, the pharmacy benefit manager
924 must:

925 a. Update the maximum allowable cost pricing information

926 to at least the acquisition cost available to the pharmacy;
927 b. Permit the pharmacy or pharmacist to reverse and rebill
928 the claim in question;
929 c. Provide to the pharmacy or pharmacist the national drug
930 code on which the increase or change is based; and
931 d. Make the increase or change effective for each
932 similarly situated pharmacy or pharmacist that is subject to the
933 applicable maximum allowable cost pricing information.
934 4. If the appeal is denied, the pharmacy benefit manager
935 must provide to the pharmacy or pharmacist the national drug
936 code and the name of the national or regional pharmaceutical
937 wholesalers operating in this state which have the drug
938 currently in stock at a price below the maximum allowable cost
939 pricing information.
940 5. If the drug with the national drug code provided by the
941 pharmacy benefit manager is not available below the acquisition
942 cost to the pharmacy or pharmacist from the pharmaceutical
943 wholesaler from whom the pharmacy or pharmacist purchases the
944 majority of drugs for resale, the pharmacy benefit manager must
945 adjust the maximum allowable cost pricing information above the
946 acquisition cost to the pharmacy or pharmacist and permit the
947 pharmacy or pharmacist to reverse and rebill each claim affected
948 by the pharmacy's or pharmacist's inability to procure the drug
949 at a cost that is equal to or less than the previously
950 challenged maximum allowable cost.

951 6. Every 90 days, the pharmacy benefit manager shall
 952 report to the office the total number of appeals received and
 953 denied in the preceding 90-day period for each specific drug for
 954 which an appeal was submitted pursuant to this paragraph.

955 Section 12. Section 626.8827, Florida Statutes, is created
 956 to read:

957 626.8827 Pharmacy benefit manager prohibited practices.—In
 958 addition to other prohibitions in this part, a pharmacy benefit
 959 manager may not do any of the following:

960 (1) Prohibit, restrict, or penalize in any way a pharmacy
 961 or pharmacist from disclosing to any person any information that
 962 the pharmacy or pharmacist deems appropriate, including, but not
 963 limited to, information regarding any of the following:

964 (a) The nature of or risks from treatment, or alternatives
 965 thereto.

966 (b) The availability of alternative treatments,
 967 consultations, or tests.

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

970 (d) The process that is used to authorize or deny
 971 pharmacist services or pharmacy benefits.

972 (e) Information on financial incentives and structures
 973 used by the pharmacy benefits plan or program.

974 (f) Information that may reduce the costs of pharmacist
 975 services.

976 (g) Whether the cost-sharing obligation exceeds the retail
 977 price for a covered prescription drug and the availability of a
 978 more affordable alternative drug pursuant to s. 465.0244.

979 (2) Prohibit, restrict, or penalize in any way a pharmacy
 980 or pharmacist from disclosing information to the office, the
 981 Agency for Health Care Administration, the Department of
 982 Management Services, a law enforcement officer, or a state or
 983 federal government official, provided that the recipient of the
 984 information has the authority, to the extent provided by state
 985 or federal law, to maintain proprietary information as
 986 confidential; and provided that, before the disclosure of
 987 information designated as confidential, the pharmacist or
 988 pharmacy marks as confidential any document in which the
 989 information appears or the pharmacist or pharmacy requests
 990 confidential treatment for any oral communication of the
 991 information.

992 (3) Communicate at the point of sale, or otherwise
 993 require, a cost-sharing obligation for the covered person in an
 994 amount that exceeds the lesser of:

995 (a) The applicable cost-sharing amount under the
 996 applicable pharmacy benefits plan or program; or

997 (b) The usual and customary price, as defined in s.
 998 626.8825, of the pharmacist services.

999 (4) Transfer or share records relative to prescription
 1000 information containing patient-identifiable or prescriber-

1001 identifiable data to an affiliated pharmacy for any commercial
 1002 purpose other than the limited purposes of facilitating pharmacy
 1003 reimbursement, formulary compliance, or utilization review on
 1004 behalf of the applicable pharmacy benefits plan or program.

1005 (5) Fail to make any payment due to a pharmacy for an
 1006 adjudicated claim with a date of service before the effective
 1007 date of a pharmacy's termination from a pharmacy benefit network
 1008 unless payments are withheld because of actual fraud on the part
 1009 of the pharmacy or otherwise required by law.

1010 (6) Terminate the contract of, penalize, or disadvantage a
 1011 pharmacist or pharmacy due to a pharmacist or pharmacy:

1012 (a) Disclosing information about pharmacy benefit manager
 1013 practices in accordance with this part;

1014 (b) Exercising any of its prerogatives under this part; or

1015 (c) Sharing any portion, or all, of the pharmacy benefit
 1016 manager contract with the office pursuant to a complaint or a
 1017 query regarding whether the contract complies with this part.

1018 (7) Fail to comply with the requirements of s. 624.491 or
 1019 s. 626.8825.

1020 Section 13. Section 626.8828, Florida Statutes, is created
 1021 to read:

1022 626.8828 Investigations and examinations of pharmacy
 1023 benefit managers; expenses; penalties.—

1024 (1) The office may investigate administrators that are
 1025 pharmacy benefit managers and applicants for authorization to

1026 become pharmacy benefit managers, as provided in ss. 624.307 and
1027 624.317. The office must review any referral made pursuant to s.
1028 624.307(10) and must investigate any referral that, as
1029 determined by the Commissioner of Insurance Regulation or the
1030 commissioner's designee, reasonably indicates a possible
1031 violation of this part.

1032 (2)(a) The office shall examine the business and affairs
1033 of each pharmacy benefit manager at least biennially. The
1034 biennial examination of each pharmacy benefit manager must be a
1035 systematic review for the purpose of determining the pharmacy
1036 benefit manager's compliance with this part and other laws or
1037 rules applicable to pharmacy benefit managers and must include a
1038 detailed review of the pharmacy benefit manager's compliance
1039 with ss. 626.8825 and 626.8827. The first 2-year cycle for
1040 conducting biennial reviews begins July 1, 2023. By January 1 of
1041 the year following a 2-year cycle, the office must deliver to
1042 the Governor, the President of the Senate, and the Speaker of
1043 the House of Representatives a report summarizing the results of
1044 the biennial examinations during the most recent 2-year cycle
1045 which includes detailed descriptions of any violations committed
1046 by each pharmacy benefit manager and detailed reporting of
1047 actions taken by the office against each pharmacy benefit
1048 manager for such violations.

1049 (b) The office may also conduct additional examinations as
1050 often as it deems advisable or necessary for the purpose of

1051 determining compliance with this part and any other laws or
1052 rules applicable to pharmacy benefit managers or applicants for
1053 authorization.

1054 (c) If a referral made pursuant to s. 624.307(10)
1055 reasonably indicates a pattern or practice of violations of this
1056 part by a pharmacy benefit manager, the office must conduct an
1057 examination of the pharmacy benefit manager or include findings
1058 related to such referral within an ongoing examination.

1059 (d) Based on the findings of an examination that a
1060 pharmacy benefit manager or applicant for authorization has
1061 exhibited a pattern or practice of knowing and willful
1062 violations of s. 626.8825 or s. 626.8827, the office may order a
1063 pharmacy benefit manager pursuant to chapter 120 to file all
1064 contracts between the pharmacy benefit manager and pharmacies or
1065 pharmacy benefits plans or programs and any policies,
1066 guidelines, rules, protocols, standard operating procedures,
1067 instructions, or directives that govern or guide the manner in
1068 which the pharmacy benefit manager or applicant conducts
1069 business related to such knowing and willful violations for
1070 review and inspection for the following 36-month period. Such
1071 documents are public records and are not trade secrets or
1072 otherwise exempt from s. 119.07(1). As used in this section, the
1073 term:

1074 1. "Contract" means any contract to which s. 626.8825
1075 applies.

1076 2. "Knowing and willful" means any act of commission or
1077 omission which is committed intentionally, as opposed to
1078 accidentally, and which is committed with knowledge of the act's
1079 unlawfulness or with reckless disregard as to the unlawfulness
1080 of the act.

1081 (e) Examinations may be conducted by an independent
1082 professional examiner under contract with the office, in which
1083 case payment must be made directly to the contracted examiner by
1084 the pharmacy benefit manager examined in accordance with the
1085 rates and terms agreed to by the office and the examiner. The
1086 commission shall adopt rules providing for the types of
1087 independent professional examiners who may conduct examinations
1088 under this section, which types must include, but need not be
1089 limited to, independent certified public accountants, actuaries,
1090 investment specialists, information technology specialists, or
1091 others meeting criteria specified by commission rule. The rules
1092 must also require that:

1093 1. The rates charged to the pharmacy benefit manager being
1094 examined be consistent with rates charged by other firms in a
1095 similar profession and comparable with the rates charged for
1096 comparable examinations.

1097 2. The firm selected by the office to perform the
1098 examination have no conflicts of interest which might affect its
1099 ability to independently perform its responsibilities for the
1100 examination.

1101 (3) In conducting investigations and examinations of
1102 pharmacy benefit managers and applicants for authorization, the
1103 office and such pharmacy benefit managers and applicants are
1104 subject to all of the following provisions:

1105 (a) Section 624.318, relating to the conduct of
1106 examinations and investigations, access to records, correction
1107 of accounts, and appraisals.

1108 (b) Section 624.319, relating to examination and
1109 investigation reports.

1110 (c) Section 624.321, relating to witnesses and evidence.

1111 (d) Section 624.322, relating to compelled testimony and
1112 immunity from prosecution.

1113 (e) Section 624.324, relating to hearings.

1114 (f) Section 624.34, relating to fingerprinting.

1115 (g) Any other provision of chapter 624 applicable to the
1116 investigation or examination of a licensee under this part.

1117 (4)(a) A pharmacy benefit manager must maintain an
1118 accurate record of all contracts and records with all pharmacies
1119 and pharmacy benefits plans or programs for the duration of the
1120 contracts and for 5 years thereafter. Such contracts must be
1121 made available to the office and kept in a form accessible to
1122 the office.

1123 (b) The office may order any pharmacy benefit manager or
1124 applicant to produce any records, books, files, contracts,
1125 advertising and solicitation materials, or other information and

1126 may take statements under oath to determine whether the pharmacy
1127 benefit manager or applicant is in violation of any law or is
1128 acting contrary to the public interest.

1129 (5)(a) Notwithstanding s. 624.307(3), each pharmacy
1130 benefit manager and applicant for authorization must pay to the
1131 office the expenses of the examination or investigation. Such
1132 expenses include actual travel expenses; a reasonable living
1133 expense allowance; compensation of the examiner, investigator,
1134 or other person conducting such examination or investigation;
1135 and necessary costs of the office directly related to the
1136 examination or investigation. Such travel expenses and living
1137 expense allowance must be limited to those expenses necessarily
1138 incurred on account of the examination or investigation and
1139 shall be paid by the examined pharmacy benefit manager or
1140 applicant together with compensation upon presentation by the
1141 office to such pharmacy benefit manager or applicant of such
1142 charges and expenses after a detailed statement has been filed
1143 by the examiner and approved by the office.

1144 (b) All moneys collected from pharmacy benefit managers
1145 and applicants for authorization pursuant to this subsection
1146 shall be deposited into the Insurance Regulatory Trust Fund, and
1147 the office may make deposits from time to time into such fund
1148 from moneys appropriated for the operation of the office.

1149 (c) Notwithstanding s. 112.061, the office may pay to the
1150 examiner, investigator, or other person conducting the

1151 examination or investigation out of such trust fund the actual
 1152 travel expenses, reasonable living expense allowance, and
 1153 compensation in accordance with the statement filed with the
 1154 office by the examiner, investigator, or other person conducting
 1155 such examination or investigation, as provided in paragraph (a).

1156 (6) In addition to any other enforcement authority
 1157 available to the office, the office shall impose an
 1158 administrative fine of \$5,000 for each violation of s. 626.8825
 1159 or s. 626.8827. Each instance of a violation of either section
 1160 by a pharmacy benefit manager against each individual pharmacy
 1161 or prescription benefits plan or program constitutes a separate
 1162 violation. Notwithstanding any other provision of law, there is
 1163 no limitation on aggregate fines issued under this subsection.
 1164 The proceeds from any administrative fine imposed under this
 1165 subsection shall be deposited into the General Revenue Fund.

1166 (7) Failure by a pharmacy benefit manager to pay expenses
 1167 incurred or administrative fines imposed under this section is
 1168 grounds for the denial, suspension, or revocation of its
 1169 certificate of authority.

1170 Section 14. Section 626.89, Florida Statutes, is amended
 1171 to read:

1172 626.89 Annual financial statement and filing fee; notice
 1173 of change of ownership; pharmacy benefit manager filings.—

1174 (1) Each authorized administrator shall annually file with
 1175 the office a full and true statement of its financial condition,

1176 transactions, and affairs within 3 months after the end of the
1177 administrator's fiscal year or within such extension of time as
1178 the office for good cause may have granted. The statement must
1179 be for the preceding fiscal year and must be in such form and
1180 contain such matters as the commission prescribes and must be
1181 verified by at least two officers of the administrator.

1182 (2) Each authorized administrator shall also file an
1183 audited financial statement performed by an independent
1184 certified public accountant. The audited financial statement
1185 shall be filed with the office within 5 months after the end of
1186 the administrator's fiscal year and be for the preceding fiscal
1187 year. An audited financial statement prepared on a consolidated
1188 basis must include a columnar consolidating or combining
1189 worksheet that must be filed with the statement and must comply
1190 with the following:

1191 (a) Amounts shown on the consolidated audited financial
1192 statement must be shown on the worksheet;

1193 (b) Amounts for each entity must be stated separately; and

1194 (c) Explanations of consolidating and eliminating entries
1195 must be included.

1196 (3) At the time of filing its annual statement, the
1197 administrator shall pay a filing fee in the amount specified in
1198 s. 624.501 for the filing of an annual statement by an insurer.

1199 (4) In addition, the administrator shall immediately
1200 notify the office of any material change in its ownership.

1201 (5) A pharmacy benefit manager shall also notify the
 1202 office within 30 days after any administrative, civil, or
 1203 criminal complaints, settlements, or discipline of the pharmacy
 1204 benefit manager or any of its affiliates which relate to a
 1205 violation of the insurance laws, including pharmacy benefit
 1206 laws, in any state.

1207 (6) A pharmacy benefit manager shall also annually submit
 1208 to the office a statement attesting to its compliance with the
 1209 network requirements of s. 626.8825.

1210 (7)~~(5)~~ The commission may by rule require all or part of
 1211 the statements or filings required under this section to be
 1212 submitted by electronic means in a computer-readable form
 1213 compatible with the electronic data format specified by the
 1214 commission.

1215 Section 15. Subsection (5) is added to section 627.42393,
 1216 Florida Statutes, to read:

1217 627.42393 Step-therapy protocol.—

1218 (5) This section applies to a pharmacy benefit manager
 1219 acting on behalf of a health insurer.

1220 Section 16. Subsection (5) of section 627.64741, Florida
 1221 Statutes, is renumbered as subsection (3), and subsection (2),
 1222 present subsection (3), and subsection (4) of that section are
 1223 amended to read:

1224 627.64741 Pharmacy benefit manager contracts.—

1225 (2) In addition to the requirements of part VII of chapter

1226 626, a contract between a health insurer and a pharmacy benefit
1227 manager must require that the pharmacy benefit manager:

1228 (a) Update maximum allowable cost pricing information at
1229 least every 7 calendar days.

1230 (b) Maintain a process that will, in a timely manner,
1231 eliminate drugs from maximum allowable cost lists or modify drug
1232 prices to remain consistent with changes in pricing data used in
1233 formulating maximum allowable cost prices and product
1234 availability.

1235 ~~(3) A contract between a health insurer and a pharmacy
1236 benefit manager must prohibit the pharmacy benefit manager from
1237 limiting a pharmacist's ability to disclose whether the cost-
1238 sharing obligation exceeds the retail price for a covered
1239 prescription drug, and the availability of a more affordable
1240 alternative drug, pursuant to s. 465.0244.~~

1241 ~~(4) A contract between a health insurer and a pharmacy
1242 benefit manager must prohibit the pharmacy benefit manager from
1243 requiring an insured to make a payment for a prescription drug
1244 at the point of sale in an amount that exceeds the lesser of:~~

1245 ~~(a) The applicable cost-sharing amount; or~~

1246 ~~(b) The retail price of the drug in the absence of
1247 prescription drug coverage.~~

1248 Section 17. Subsection (5) of section 627.6572, Florida
1249 Statutes, is renumbered as subsection (3), and subsection (2),
1250 present subsection (3), and subsection (4) of that section are

1251 amended to read:

1252 627.6572 Pharmacy benefit manager contracts.—

1253 (2) In addition to the requirements of part VII of chapter
 1254 626, a contract between a health insurer and a pharmacy benefit
 1255 manager must require that the pharmacy benefit manager:

1256 (a) Update maximum allowable cost pricing information at
 1257 least every 7 calendar days.

1258 (b) Maintain a process that will, in a timely manner,
 1259 eliminate drugs from maximum allowable cost lists or modify drug
 1260 prices to remain consistent with changes in pricing data used in
 1261 formulating maximum allowable cost prices and product
 1262 availability.

1263 ~~(3) A contract between a health insurer and a pharmacy~~
 1264 ~~benefit manager must prohibit the pharmacy benefit manager from~~
 1265 ~~limiting a pharmacist's ability to disclose whether the cost-~~
 1266 ~~sharing obligation exceeds the retail price for a covered~~
 1267 ~~prescription drug, and the availability of a more affordable~~
 1268 ~~alternative drug, pursuant to s. 465.0244.~~

1269 ~~(4) A contract between a health insurer and a pharmacy~~
 1270 ~~benefit manager must prohibit the pharmacy benefit manager from~~
 1271 ~~requiring an insured to make a payment for a prescription drug~~
 1272 ~~at the point of sale in an amount that exceeds the lesser of:~~

1273 ~~(a) The applicable cost-sharing amount; or~~

1274 ~~(b) The retail price of the drug in the absence of~~
 1275 ~~prescription drug coverage.~~

1276 Section 18. Paragraph (e) is added to subsection (46) of
 1277 section 641.31, Florida Statutes, to read:

1278 641.31 Health maintenance contracts.—

1279 (46)

1280 (e) This subsection applies to a pharmacy benefit manager
 1281 acting on behalf of a health maintenance organization.

1282 Section 19. Subsection (5) of section 641.314, Florida
 1283 Statutes, is renumbered as subsection (3), and subsection (2),
 1284 present subsection (3), and subsection (4) of that section are
 1285 amended to read:

1286 641.314 Pharmacy benefit manager contracts.—

1287 (2) In addition to the requirements of part VII of chapter
 1288 626, a contract between a health maintenance organization and a
 1289 pharmacy benefit manager must require that the pharmacy benefit
 1290 manager:

1291 (a) Update maximum allowable cost pricing information at
 1292 least every 7 calendar days.

1293 (b) Maintain a process that will, in a timely manner,
 1294 eliminate drugs from maximum allowable cost lists or modify drug
 1295 prices to remain consistent with changes in pricing data used in
 1296 formulating maximum allowable cost prices and product
 1297 availability.

1298 ~~(3) A contract between a health maintenance organization~~
 1299 ~~and a pharmacy benefit manager must prohibit the pharmacy~~
 1300 ~~benefit manager from limiting a pharmacist's ability to disclose~~

1301 ~~whether the cost-sharing obligation exceeds the retail price for~~
 1302 ~~a covered prescription drug, and the availability of a more~~
 1303 ~~affordable alternative drug, pursuant to s. 465.0244.~~

1304 ~~(4) A contract between a health maintenance organization~~
 1305 ~~and a pharmacy benefit manager must prohibit the pharmacy~~
 1306 ~~benefit manager from requiring a subscriber to make a payment~~
 1307 ~~for a prescription drug at the point of sale in an amount that~~
 1308 ~~exceeds the lesser of:~~

1309 ~~(a) The applicable cost-sharing amount; or~~

1310 ~~(b) The retail price of the drug in the absence of~~
 1311 ~~prescription drug coverage.~~

1312 Section 20. (1) This act establishes requirements for
 1313 pharmacy benefit managers as defined in s. 626.88, Florida
 1314 Statutes, including, without limitation, pharmacy benefit
 1315 managers in their performance of services for or otherwise on
 1316 behalf of a pharmacy benefits plan or program as defined in s.
 1317 626.8825, Florida Statutes, which includes coverage pursuant to
 1318 Titles XVIII, XIX, or XXI of the Social Security Act, 42 U.S.C.
 1319 ss. 1395 et seq., 1396 et seq., and 1397aa et seq., known as
 1320 Medicare, Medicaid, or any other similar coverage under a state
 1321 or Federal Government funded health plan, including the
 1322 Statewide Medicaid Managed Care program established pursuant to
 1323 part IV of chapter 409, Florida Statutes, and the state group
 1324 insurance program pursuant to part I of chapter 110, Florida
 1325 Statutes.

1326 (2) This act is not intended, nor may it be construed, to
 1327 conflict with existing, relevant federal law.

1328 (3) If any provision of this act or its application to any
 1329 person or circumstances is held invalid, the invalidity does not
 1330 affect other provisions or applications of this act which can be
 1331 given effect without the invalid provision or application, and
 1332 to this end the provisions of this act are severable.

1333 Section 21. For the 2023-2024 fiscal year, the sums of
 1334 \$980,705 in recurring funds and \$146,820 in nonrecurring funds
 1335 from the Insurance Regulatory Trust Fund are appropriated to the
 1336 Office of Insurance Regulation, and 10 full-time equivalent
 1337 positions with associated salary rate of 644,877 are authorized,
 1338 for the purpose of implementing this act.

1339 Section 22. This act shall take effect July 1, 2023.