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1
2 An act relating to prescription drugs; providing a
3 short title; amending s. 499.005, F.S.; specifying
4 additional prohibited acts related to the Florida Drug
5 and Cosmetic Act; amending s. 499.012, F.S.; providing
6 that prescription drug manufacturer and nonresident
7 prescription drug manufacturer permitholders are
8 subject to specified requirements; creating s.
9 499.026, F.S.; defining terms; requiring certain drug
10 manufacturers to notify the Department of Business and
11 Professional Regulation of reportable drug price
12 increases on a specified form on the effective date of
13 such increase; providing requirements for the form;
14 providing construction; requiring such manufacturers
15 to submit certain reports to the department by a
16 specified date each year; providing requirements for
17 the reports; authorizing the department to request
18 certain additional information from the manufacturer
19 before approving the report; requiring the department
20 to submit the forms and reports to the Agency for
21 Health Care Administration to be posted on the
22 agency's website; prohibiting the agency from posting
23 on its website certain submitted information that is
24 marked as a trade secret; requiring the agency to
25 compile all information from the submitted forms and
26 reports and make it available to the Governor and the
27 Legislature upon request; prohibiting manufacturers
28 from claiming a public records exemption for trade
29 secrets for certain information provided in such forms

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30 or reports; providing that department employees remain
31 protected from liability for releasing the forms and
32 reports as public records; authorizing the department,
33 in consultation with the agency, to adopt rules;
34 providing for emergency rulemaking; amending s.
35 624.307, F.S.; requiring the Division of Consumer
36 Services of the Department of Financial Services to
37 designate an employee as the primary contact for
38 consumer complaints involving pharmacy benefit
39 managers; requiring the division to refer certain
40 complaints to the Office of Insurance Regulation;
41 amending s. 624.490, F.S.; revising the definition of
42 the term "pharmacy benefit manager"; amending s.
43 624.491, F.S.; revising provisions related to pharmacy
44 audits; amending s. 626.88, F.S.; revising the
45 definition of the term "administrator"; defining the
46 term "pharmacy benefit manager"; amending s. 626.8805,
47 F.S.; providing a grandfathering provision for certain
48 pharmacy benefit managers operating as administrators;
49 providing a penalty for certain persons who do not
50 hold a certificate of authority to act as an
51 administrator on or after a specified date; requiring
52 the office to submit a report detailing specified
53 information to the Governor and the Legislature by a
54 specified date; providing additional requirements for
55 pharmacy benefit managers applying for a certificate
56 of authority to act as an administrator; exempting
57 pharmacy benefit managers from certain fees; amending
58 s. 626.8814, F.S.; requiring pharmacy benefit managers

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59 to identify certain ownership affiliations to the
60 office; requiring pharmacy benefit managers to report
61 any change in such information to the office within a
62 specified timeframe; creating s. 626.8825, F.S.;
63 defining terms; providing requirements for certain
64 contracts between a pharmacy benefit manager and a
65 pharmacy benefits plan or program; requiring pharmacy
66 benefits plans and programs, beginning on a specified
67 date, to annually submit a certain attestation to the
68 office; providing requirements for certain contracts
69 between a pharmacy benefit manager and a participating
70 pharmacy; requiring the Financial Services Commission
71 to adopt rules; specifying requirements for certain
72 administrative appeal procedures that such contracts
73 with participating pharmacies must include; requiring
74 pharmacy benefit managers to submit reports on
75 submitted appeals to the office every 90 days;
76 creating s. 626.8827, F.S.; specifying prohibited
77 practices for pharmacy benefit managers; creating s.
78 626.8828, F.S.; authorizing the office to investigate
79 administrators that are pharmacy benefit managers and
80 certain applicants; requiring the office to review
81 certain referrals and investigate them under certain
82 circumstances; providing for biennial reviews of
83 pharmacy benefit managers; requiring the office to
84 submit an annual report of its examinations to the
85 Governor and the Legislature by a specified date;
86 providing requirements for the report, including
87 specified additional requirements for the biennial

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88 reports; authorizing the office to conduct additional
89 examinations; requiring the office to conduct an
90 examination under certain circumstances; providing
91 procedures and requirements for such examinations;
92 defining the terms "contracts" and "knowing and
93 willful"; providing that independent professional
94 examiners under contract with the office may conduct
95 examinations of pharmacy benefit managers; requiring
96 the commission to adopt specified rules; specifying
97 provisions that apply to such investigations and
98 examinations; providing recordkeeping requirements for
99 pharmacy benefit managers; authorizing the office to
100 order the production of such records and other
101 specified information; authorizing the office to take
102 statements under oath; requiring pharmacy benefit
103 managers and applicants subjected to an investigation
104 or examination to pay the associated expenses;
105 specifying covered expenses; providing for collection
106 of such expenses; providing for the deposit of certain
107 moneys into the Insurance Regulatory Trust Fund;
108 authorizing the office to pay examiners,
109 investigators, and other persons from such fund;
110 providing administrative penalties; providing grounds
111 for administrative action against a certificate of
112 authority; amending s. 626.89, F.S.; requiring
113 pharmacy benefit managers to notify the office of
114 specified complaints, settlements, or discipline
115 within a specified timeframe; requiring pharmacy
116 benefit managers to annually submit a certain

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117 attestation statement to the office; amending s.
118 627.42393, F.S.; providing that certain step-therapy
119 protocol requirements apply to a pharmacy benefit
120 manager acting on behalf of a health insurer; amending
121 ss. 627.64741 and 627.6572, F.S.; conforming
122 provisions to changes made by the act; amending s.
123 641.31, F.S.; providing that certain step-therapy
124 protocol requirements apply to a pharmacy benefit
125 manager acting on behalf of a health maintenance
126 organization; amending s. 641.314, F.S.; conforming a
127 provision to changes made by the act; providing
128 legislative intent, construction, and severability;
129 providing appropriations and authorizing positions;
130 providing an effective date.

131

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

133

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

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

138 499.005 Prohibited acts.—It is unlawful for a person to
139 perform or cause the performance of any of the following acts in
140 this state:

141 (29) Failure to accurately complete and timely submit
142 reportable drug price increase forms, reports, and documents as
143 required by s. 499.026 and rules adopted thereunder.

144 Section 3. Subsection (16) is added to section 499.012,
145 Florida Statutes, to read:

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146 499.012 Permit application requirements.—

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

150 Section 4. Section 499.026, Florida Statutes, is created to
151 read:

152 499.026 Notification of manufacturer prescription drug
153 price increases.—

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

155 (a) "Course of therapy" means the recommended daily dose
156 units of a prescription drug pursuant to its prescribing label
157 for 30 days or the recommended daily dose units of a
158 prescription drug pursuant to its prescribing label for a normal
159 course of treatment which is less than 30 days.

160 (b) "Manufacturer" means a person holding a prescription
161 drug manufacturer permit or a nonresident prescription drug
162 manufacturer permit under s. 499.01.

163 (c) "Prescription drug" has the same meaning as in s.
164 499.003 and includes biological products but is limited to those
165 prescription drugs and biological products intended for human
166 use.

167 (d) "Reportable drug price increase" means, for a
168 prescription drug with a wholesale acquisition cost of at least
169 \$100 for a course of therapy before the effective date of an
170 increase:

171 1. Any increase of 15 percent or more of the wholesale
172 acquisition cost during the preceding 12-month period; or

173 2. Any cumulative increase of 30 percent or more of the
174 wholesale acquisition cost during the preceding 3 calendar

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175 years. In calculating the 30 percent threshold, the manufacturer
176 must base the calculation on the wholesale acquisition cost in
177 effect at the end of the 3-year period as compared to the
178 wholesale acquisition cost in effect at the beginning of the
179 same 3-year period.

180 (e) "Wholesale acquisition cost" means, with respect to a
181 prescription drug or biological product, the manufacturer's list
182 price for the prescription drug or biological product to
183 wholesalers or direct purchasers in the United States, not
184 including prompt pay or other discounts, rebates, or reductions
185 in price, for the most recent month for which the information is
186 available, as reported in wholesale price guides or other
187 publications of drug or biological product pricing data.

188 (2) On the effective date of a manufacturer's reportable
189 drug price increase, the manufacturer must provide notification
190 of each reportable drug price increase to the department on a
191 form prescribed by the department. The form must require the
192 manufacturer to specify all of the following:

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

195 (b) The wholesale acquisition cost before the reportable
196 drug price increase.

197 (c) The dollar amount of the reportable drug price
198 increase.

199 (d) The percentage amount of the reportable drug price
200 increase from the wholesale acquisition cost before the
201 reportable drug price increase.

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

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204 (f) If a change or an improvement in the prescription drug
205 necessitates the reportable drug price increase as reported in
206 paragraph (e), the manufacturer must describe the change or
207 improvement.

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

209
210 This subsection does not prohibit a manufacturer from notifying
211 other parties, such as pharmacy benefit managers, of a drug
212 price increase before the effective date of the drug price
213 increase.

214 (3) By April 1 of each year, each manufacturer shall submit
215 a report to the department on a form prescribed by the
216 department. The report must include all of the following:

217 (a) A list of all prescription drugs affected by a
218 reportable drug price increase during the previous calendar year
219 and both the dollar amount of each reportable drug price
220 increase and the percentage increase of each reportable drug
221 price increase relative to the previous wholesale acquisition
222 cost of the prescription drug. The prescription drugs must be
223 identified using their proprietary names and nonproprietary
224 names, as applicable.

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

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

232 (d) The length of time the prescription drug has been

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233 available for purchase.

234 (e) A listing of the factors contributing to each
235 reportable drug price increase. As used in this section, the
236 term "factors" means any of the following: research and
237 development; manufacturing costs; advertising and marketing;
238 whether the drug has more competitive value; an increased rate
239 of inflation or other economic dynamics; changes in market
240 dynamics; supporting regulatory and safety commitments;
241 operating patient assistance and educational programs; rebate
242 increases, including any rebate increase requested by a pharmacy
243 benefit manager; Medicaid, Medicare, or 340B Drug Pricing
244 Program offsets; profit; or other factors. An estimated
245 percentage of the influence of each listed factor must be
246 provided to equal 100 percent.

247 (f) A description of the justification for each factor
248 referenced in paragraph (e) must be provided with such
249 specificity as to explain the need or justification for each
250 reportable drug price increase. The department may request
251 additional information from a manufacturer relating to the need
252 or justification for any reportable drug price increase before
253 approving the manufacturer's report.

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

256 (4) (a) The department shall submit all forms and reports
257 submitted by manufacturers to the Agency for Health Care
258 Administration, to be posted on the agency's website pursuant to
259 s. 408.062. The agency may not post on its website any of the
260 information provided pursuant to paragraph (2) (f), paragraph
261 (3) (f), or paragraph (3) (g) which is marked as a trade secret.

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262 The agency shall compile all information from the forms and
263 reports submitted by manufacturers and make it available upon
264 request to the Governor, the President of the Senate, and the
265 Speaker of the House of Representatives.

266 (b) Except for information provided pursuant to paragraph
267 (2) (f), paragraph (3) (f), or paragraph (3) (g), a manufacturer
268 may not claim a public records exemption for a trade secret
269 under s. 119.0715 for any information required by the department
270 under this section. Department employees remain protected from
271 liability for release of forms and reports pursuant to s.
272 119.0715(4).

273 (5) The department, in consultation with the Agency for
274 Health Care Administration, shall adopt rules to implement this
275 section.

276 (a) The department shall adopt necessary emergency rules
277 pursuant to s. 120.54(4) to implement this section. If an
278 emergency rule adopted under this section is held to be
279 unconstitutional or an invalid exercise of delegated legislative
280 authority and becomes void, the department may adopt an
281 emergency rule pursuant to this section to replace the rule that
282 has become void. If the emergency rule adopted to replace the
283 void emergency rule is also held to be unconstitutional or an
284 invalid exercise of delegated legislative authority and becomes
285 void, the department must follow the nonemergency rulemaking
286 procedures of the Administrative Procedure Act to replace the
287 rule that has become void.

288 (b) For emergency rules adopted under this section, the
289 department need not make the findings required under s.
290 120.54(4) (a). Emergency rules adopted under this section are

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291 also exempt from:

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

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

298 Section 5. Paragraph (a) of subsection (10) of section
299 624.307, Florida Statutes, is amended, and paragraph (b) of that
300 subsection is republished, to read:

301 624.307 General powers; duties.—

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

305 1. Receive inquiries and complaints from consumers.

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

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

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

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

318 6. Designate an employee of the division as the primary
319 contact for consumers and pharmacies on issues relating to

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320 pharmacy benefit managers. The division must refer to the office
321 any consumer complaint that alleges conduct that may constitute
322 a violation of part VII of chapter 626 or for which a pharmacy
323 benefit manager does not respond in accordance with paragraph
324 (b).

325 (b) Any person licensed or issued a certificate of
326 authority by the department or the office shall respond, in
327 writing, to the division within 20 days after receipt of a
328 written request for documents and information from the division
329 concerning a consumer complaint. The response must address the
330 issues and allegations raised in the complaint and include any
331 requested documents concerning the consumer complaint not
332 subject to attorney-client or work-product privilege. The
333 division may impose an administrative penalty for failure to
334 comply with this paragraph of up to \$2,500 per violation upon
335 any entity licensed by the department or the office and \$250 for
336 the first violation, \$500 for the second violation, and up to
337 \$1,000 for the third or subsequent violation upon any individual
338 licensed by the department or the office.

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

341 624.490 Registration of pharmacy benefit managers.—

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

348 Section 7. Subsections (1) and (5) of section 624.491,

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349 Florida Statutes, are amended to read:

350 624.491 Pharmacy audits.—

351 (1) A pharmacy benefits plan or program as defined in s.
352 626.8825 ~~health insurer or health maintenance organization~~
353 providing pharmacy benefits ~~through a major medical individual~~
354 ~~or group health insurance policy or a health maintenance~~
355 ~~contract, respectively,~~ must comply with the requirements of
356 this section when the pharmacy benefits plan or program ~~health~~
357 ~~insurer or health maintenance organization~~ or any person or
358 entity acting on behalf of the pharmacy benefits plan or program
359 ~~health insurer or health maintenance organization~~, including,
360 but not limited to, a pharmacy benefit manager as defined in s.
361 626.88 ~~s. 624.490(1)~~, audits the records of a pharmacy licensed
362 under chapter 465. The person or entity conducting such audit
363 must:

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

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

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

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

376 (e) Allow the pharmacy to use the written and verifiable
377 records of a hospital, physician, or other authorized

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378 practitioner, which are transmitted by any means of
379 communication, to validate the pharmacy records in accordance
380 with state and federal law.

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

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

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

392 (i) Provide the pharmacy with a copy of the final audit
393 report within 6 months after the pharmacy's receipt of the
394 preliminary audit report.

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

398 (5) A pharmacy benefits plan or program ~~health insurer or~~
399 ~~health maintenance organization~~ that, under terms of a contract,
400 transfers to a pharmacy benefit manager the obligation to pay a
401 pharmacy licensed under chapter 465 for any pharmacy benefit
402 claims arising from services provided to or for the benefit of
403 an insured or subscriber remains responsible for a violation of
404 this section.

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

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407 section, to read:

408 626.88 Definitions.—For the purposes of this part, the
409 term:

410 (1) "Administrator" means ~~is~~ any person who directly or
411 indirectly solicits or effects coverage of, collects charges or
412 premiums from, or adjusts or settles claims on residents of this
413 state in connection with authorized commercial self-insurance
414 funds or with insured or self-insured programs which provide
415 life or health insurance coverage or coverage of any other
416 expenses described in s. 624.33(1); ~~or~~ any person who, through a
417 health care risk contract as defined in s. 641.234 with an
418 insurer or health maintenance organization, provides billing and
419 collection services to health insurers and health maintenance
420 organizations on behalf of health care providers; or a pharmacy
421 benefit manager. The term does not include, ~~other than~~ any of
422 the following ~~persons~~:

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

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

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

433 (d) A health care services plan, health maintenance
434 organization, professional service plan corporation, or person
435 in the business of providing continuing care, possessing a valid

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436 certificate of authority issued by the office, and the sales
437 representatives thereof, if the activities of such entity are
438 limited to the activities permitted under the certificate of
439 authority.

440 (e) An entity that is affiliated with an insurer and that
441 only performs the contractual duties, between the administrator
442 and the insurer, of an administrator for the direct and assumed
443 insurance business of the affiliated insurer. The insurer is
444 responsible for the acts of the administrator and is responsible
445 for providing all of the administrator's books and records to
446 the insurance commissioner, upon a request from the insurance
447 commissioner. For purposes of this paragraph, the term "insurer"
448 means a licensed insurance company, health maintenance
449 organization, prepaid limited health service organization, or
450 prepaid health clinic.

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

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

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

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

463 (j) A creditor on behalf of such creditor's debtors with
464 respect to insurance covering a debt between the creditor and

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465 its debtors.

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

469 (l) A trust exempt from taxation under s. 501(a) of the
470 Internal Revenue Code, a trust satisfying the requirements of
471 ss. 624.438 and 624.439, or any governmental trust as defined in
472 s. 624.33(3), and the trustees and employees acting pursuant to
473 such trust, or a custodian and its agents and employees,
474 including individuals representing the trustees in overseeing
475 the activities of a service company or administrator, acting
476 pursuant to a custodial account which meets the requirements of
477 s. 401(f) of the Internal Revenue Code.

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

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

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

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

493 (q) A service company or service agent and its employees,

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494 authorized in accordance with ss. 626.895-626.899, serving only
495 a single employer plan, multiple-employer welfare arrangements,
496 or a combination thereof.

497 (r) Any provider or group practice, as defined in s.
498 456.053, providing services under the scope of the license of
499 the provider or the member of the group practice.

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

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

506
507 A person who provides billing and collection services to health
508 insurers and health maintenance organizations on behalf of
509 health care providers shall comply with the provisions of ss.
510 627.6131, 641.3155, and 641.51(4).

511 (6) "Pharmacy benefit manager" means a person or an entity
512 doing business in this state which contracts to administer
513 prescription drug benefits on behalf of a pharmacy benefits plan
514 or program as defined in s. 626.8825. The term includes, but is
515 not limited to, a person or an entity that performs one or more
516 of the following services on behalf of such plan or program:

517 (a) Pharmacy claims processing.

518 (b) Administration or management of a pharmacy discount
519 card program and performance of any other service listed in this
520 subsection.

521 (c) Managing pharmacy networks or pharmacy reimbursement.

522 (d) Paying or managing claims for pharmacist services

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523 provided to covered persons.

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

526 (f) Pharmacy rebate administration.

527 (g) Managing patient compliance, therapeutic intervention,
528 or generic substitution programs.

529 (h) Administration or management of a mail-order pharmacy
530 program.

531 Section 9. Present subsections (3) through (6) of section
532 626.8805, Florida Statutes, are redesignated as subsections (4)
533 through (7), respectively, a new subsection (3) and subsection
534 (8) are added to that section, and subsection (1) and present
535 subsection (3) of that section are amended, to read:

536 626.8805 Certificate of authority to act as administrator.—

537 (1) It is unlawful for any person to act as or hold himself
538 or herself out to be an administrator in this state without a
539 valid certificate of authority issued by the office pursuant to
540 ss. 626.88-626.894. A pharmacy benefit manager that is
541 registered with the office under s. 624.490 as of June 30, 2023,
542 may continue to operate until January 1, 2024, as an
543 administrator without a certificate of authority and is not in
544 violation of the requirement to possess a valid certificate of
545 authority as an administrator during that timeframe. To qualify
546 for and hold authority to act as an administrator in this state,
547 an administrator must otherwise be in compliance with this code
548 and with its organizational agreement. The failure of any
549 person, excluding a pharmacy benefit manager, to hold such a
550 certificate while acting as an administrator shall subject such
551 person to a fine of not less than \$5,000 or more than \$10,000

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552 for each violation. A person who, on or after January 1, 2024,
553 does not hold a certificate of authority to act as an
554 administrator while operating as a pharmacy benefit manager is
555 subject to a fine of \$10,000 per violation per day. By January
556 15, 2024, the office shall submit to the Governor, the President
557 of the Senate, and the Speaker of the House of Representatives a
558 report detailing whether each pharmacy benefit manager operating
559 in this state on January 1, 2024, obtained a certificate of
560 authority on or before that date as required by this section.

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

563 (a) A complete biographical statement on forms prescribed
564 by the commission.

565 (b) An independent background report as prescribed by the
566 commission.

567 (c) A full set of fingerprints of all of the individuals
568 referenced in paragraph (2) (c) to the office or to a vendor,
569 entity, or agency authorized by s. 943.053(13). The office,
570 vendor, entity, or agency, as applicable, shall forward the
571 fingerprints to the Department of Law Enforcement for state
572 processing, and the Department of Law Enforcement shall forward
573 the fingerprints to the Federal Bureau of Investigation for
574 national processing in accordance with s. 943.053 and 28 C.F.R.
575 s. 20.

576 (d) A self-disclosure of any administrative, civil, or
577 criminal complaints, settlements, or discipline of the
578 applicant, or any of the applicant's affiliates, which relate to
579 a violation of the insurance laws, including pharmacy benefit
580 manager laws, in any state.

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

583 (4) (a) ~~(3)~~ The applicant shall make available for inspection
584 by the office copies of all contracts relating to services
585 provided by the administrator to insurers or other persons using
586 the services of the administrator.

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

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

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

592 (8) A pharmacy benefit manager is exempt from fees
593 associated with the initial application and the annual filing
594 fees in s. 626.89.

595 Section 10. Section 626.8814, Florida Statutes, is amended
596 to read:

597 626.8814 Disclosure of ownership or affiliation.—

598 (1) Each administrator shall identify to the office any
599 ownership interest or affiliation of any kind with any insurance
600 company responsible for providing benefits directly or through
601 reinsurance to any plan for which the administrator provides
602 administrative services.

603 (2) Pharmacy benefit managers shall also identify to the
604 office any ownership affiliation of any kind with any pharmacy
605 which, either directly or indirectly, through one or more
606 intermediaries:

607 (a) Has an investment or ownership interest in a pharmacy
608 benefit manager holding a certificate of authority issued under
609 this part;

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

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

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

618 Section 11. Section 626.8825, Florida Statutes, is created
619 to read:

620 626.8825 Pharmacy benefit manager transparency and
621 accountability.—

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

623 (a) "Adjudication transaction fee" means a fee charged by
624 the pharmacy benefit manager to the pharmacy for electronic
625 claim submissions.

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

628 1. Has an investment or ownership interest in a pharmacy
629 benefit manager holding a certificate of authority issued under
630 this part;

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

633 3. Has an investor or a holder of an ownership interest
634 which is a pharmacy benefit manager holding a certificate of
635 authority issued under this part.

636 (c) "Brand name or generic effective rate" means the
637 contractual rate set forth by a pharmacy benefit manager for the
638 reimbursement of covered brand name or generic drugs, calculated

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639 using the total payments in the aggregate, by drug type, during
640 the performance period. The effective rates are typically
641 calculated as a discount from industry benchmarks, such as
642 average wholesale price or wholesale acquisition cost.

643 (d) "Covered person" means a person covered by,
644 participating in, or receiving the benefit of a pharmacy
645 benefits plan or program.

646 (e) "Direct and indirect remuneration fees" means price
647 concessions that are paid to the pharmacy benefit manager by the
648 pharmacy retrospectively and that cannot be calculated at the
649 point of sale. The term may also include discounts, chargebacks
650 or rebates, cash discounts, free goods contingent on a purchase
651 agreement, upfront payments, coupons, goods in kind, free or
652 reduced-price services, grants, or other price concessions or
653 similar benefits from manufacturers, pharmacies, or similar
654 entities.

655 (f) "Dispensing fee" means a fee intended to cover
656 reasonable costs associated with providing the drug to a covered
657 person. This cost includes the pharmacist's services and the
658 overhead associated with maintaining the facility and equipment
659 necessary to operate the pharmacy.

660 (g) "Effective rate guarantee" means the minimum ingredient
661 cost reimbursement a pharmacy benefit manager guarantees it will
662 pay for pharmacist services during the applicable measurement
663 period.

664 (h) "Erroneous claims" means pharmacy claims submitted in
665 error, including, but not limited to, unintended, incorrect,
666 fraudulent, or test claims.

667 (i) "Group purchasing organization" means an entity

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668 affiliated with a pharmacy benefit manager or a pharmacy
669 benefits plan or program which uses purchasing volume aggregates
670 as leverage to negotiate discounts and rebates for covered
671 prescription drugs with pharmaceutical manufacturers,
672 distributors, and wholesale vendors.

673 (j) "Incentive payment" means a retrospective monetary
674 payment made as a reward or recognition by the pharmacy benefits
675 plan or program or pharmacy benefit manager to a pharmacy for
676 meeting or exceeding predefined pharmacy performance metrics as
677 related to quality measures, such as Healthcare Effectiveness
678 Data and Information Set measures.

679 (k) "Maximum allowable cost appeal pricing adjustment"
680 means a retrospective positive payment adjustment made to a
681 pharmacy by the pharmacy benefits plan or program or by the
682 pharmacy benefit manager pursuant to an approved maximum
683 allowable cost appeal request submitted by the same pharmacy to
684 dispute the amount reimbursed for a drug based on the pharmacy
685 benefit manager's listed maximum allowable cost price.

686 (l) "Monetary recoupments" means rescinded or recouped
687 payments from a pharmacy or provider by the pharmacy benefits
688 plan or program or by the pharmacy benefit manager.

689 (m) "Network" means a group of pharmacies that agree to
690 provide pharmacist services to covered persons on behalf of a
691 pharmacy benefits plan or program or a group of pharmacy
692 benefits plans or programs in exchange for payment for such
693 services. The term includes a pharmacy that generally dispenses
694 outpatient prescription drugs to covered persons.

695 (n) "Network reconciliation offsets" means a process during
696 annual payment reconciliation between a pharmacy benefit manager

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697 and a pharmacy which allows the pharmacy benefit manager to
698 offset an amount for overperformance or underperformance of
699 contractual guarantees across guaranteed line items, channels,
700 networks, or payors, as applicable.

701 (o) "Participation contract" means any agreement between a
702 pharmacy benefit manager and pharmacy for the provision and
703 reimbursement of pharmacist services and any exhibits,
704 attachments, amendments, or addendums to such agreement.

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

709 1. Equivalent to the payments the pharmacy benefit manager
710 makes to a dispensing pharmacy or provider for such drugs,
711 including any contracted professional dispensing fee between the
712 pharmacy benefit manager and its network of pharmacies. Such
713 dispensing fee would be paid if the pharmacy benefits plan or
714 program was making the payments directly.

715 2. Passed through in their entirety by the pharmacy
716 benefits plan or program or by the pharmacy benefit manager to
717 the pharmacy or provider that dispenses the drugs, and the
718 payments are made in a manner that is not offset by any
719 reconciliation.

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

721 (r) "Pharmacist services" means products, goods, and
722 services or any combination of products, goods, and services
723 provided as part of the practice of the profession of pharmacy
724 as defined in s. 465.003 or otherwise covered by a pharmacy
725 benefits plan or program.

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

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

729 (u) "Pharmacy benefits plan or program" means a plan or
730 program that pays for, reimburses, covers the cost of, or
731 provides access to discounts on pharmacist services provided by
732 one or more pharmacies to covered persons who reside in, are
733 employed by, or receive pharmacist services from this state.

734 1. The term includes, but is not limited to, health
735 maintenance organizations, health insurers, self-insured
736 employer health plans, discount card programs, and government-
737 funded health plans, including the Statewide Medicaid Managed
738 Care program established pursuant to part IV of chapter 409 and
739 the state group insurance program pursuant to part I of chapter
740 110.

741 2. The term excludes such a plan or program under chapter
742 440.

743 (v) "Rebate" means all payments that accrue to a pharmacy
744 benefit manager or its pharmacy benefits plan or program client
745 or an affiliated group purchasing organization, directly or
746 indirectly, from a pharmaceutical manufacturer, including, but
747 not limited to, discounts, administration fees, credits,
748 incentives, or penalties associated directly or indirectly in
749 any way with claims administered on behalf of a pharmacy
750 benefits plan or program client.

751 (w) "Spread pricing" is the practice in which a pharmacy
752 benefit manager charges a pharmacy benefits plan or program a
753 different amount for pharmacist services than the amount the
754 pharmacy benefit manager reimburses a pharmacy for such

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755 pharmacist services.

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

759 (2) CONTRACTS BETWEEN A PHARMACY BENEFIT MANAGER AND A
760 PHARMACY BENEFITS PLAN OR PROGRAM.—In addition to any other
761 requirements in the Florida Insurance Code, all contractual
762 arrangements executed, amended, adjusted, or renewed on or after
763 July 1, 2023, which are applicable to pharmacy benefits covered
764 on or after January 1, 2024, between a pharmacy benefit manager
765 and a pharmacy benefits plan or program must include, in
766 substantial form, terms that ensure compliance with all of the
767 following requirements and that, except to the extent not
768 allowed by law, shall supersede any contractual terms to the
769 contrary:

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

772 (b) Exclude terms that allow for the direct or indirect
773 engagement in the practice of spread pricing unless the pharmacy
774 benefit manager passes along the entire amount of such
775 difference to the pharmacy benefits plan or program as allowable
776 under paragraph (a).

777 (c) Ensure that funds received in relation to providing
778 services for a pharmacy benefits plan or program or a pharmacy
779 are used or distributed only pursuant to the pharmacy benefit
780 manager's contract with the pharmacy benefits plan or program or
781 with the pharmacy or as otherwise required by applicable law.

782 (d) Require the pharmacy benefit manager to pass 100
783 percent of all prescription drug manufacturer rebates, including

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784 nonresident prescription drug manufacturer rebates, received to
785 the pharmacy benefits plan or program, if the contractual
786 arrangement delegates the negotiation of rebates to the pharmacy
787 benefit manager, for the sole purpose of offsetting defined cost
788 sharing and reducing premiums of covered persons. Any excess
789 rebate revenue after the pharmacy benefit manager and the
790 pharmacy benefits plan or program have taken all actions
791 required under this paragraph must be used for the sole purpose
792 of offsetting copayments and deductibles of covered persons.
793 This paragraph does not apply to contracts involving Medicaid
794 managed care plans.

795 (e) Include network adequacy requirements that meet or
796 exceed Medicare Part D program standards for convenient access
797 to the network pharmacies set forth in 42 C.F.R. s.
798 423.120(a)(1) and that:

799 1. Do not limit a network to solely include affiliated
800 pharmacies;

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

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

808 b. Designated as cancer centers of excellence under s.
809 381.925, regardless of the pharmacy benefits plan's or program's
810 geographic service area;

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

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813 d. Hospitals licensed as specialty children's hospitals as
814 defined in s. 395.002; or

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

818
819 Such provider contracts must be solely for the administration or
820 dispensing of covered prescription drugs, including biological
821 products, which are administered through infusions,
822 intravenously injected, or inhaled during a surgical procedure
823 or are covered parenteral drugs, as part of onsite outpatient
824 care;

825 3. Do not require a covered person to receive a
826 prescription drug by United States mail, common carrier, local
827 courier, third-party company or delivery service, or pharmacy
828 direct delivery unless the prescription drug cannot be acquired
829 at any retail pharmacy in the pharmacy benefit manager's network
830 for the covered person's pharmacy benefits plan or program. This
831 subparagraph does not prohibit a pharmacy benefit manager from
832 operating mail order or delivery programs on an opt-in basis at
833 the sole discretion of a covered person, provided that the
834 covered person is not penalized through the imposition of any
835 additional retail cost-sharing obligations or a lower allowed-
836 quantity limit for choosing not to select the mail order or
837 delivery programs;

838 4. For the in-person administration of covered prescription
839 drugs, prohibit requiring a covered person to receive pharmacist
840 services from an affiliated pharmacy or an affiliated health
841 care provider; and

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842 5. Prohibit offering or implementing pharmacy networks that
843 require or provide a promotional item or an incentive, defined
844 as anything other than a reduced cost-sharing amount or enhanced
845 quantity limit allowed under the benefit design for a covered
846 drug, to a covered person to use an affiliated pharmacy or an
847 affiliated health care provider for the in-person administration
848 of covered prescription drugs; or advertising, marketing, or
849 promoting an affiliated pharmacy to covered persons. Subject to
850 the foregoing, a pharmacy benefit manager may include an
851 affiliated pharmacy in communications to covered persons
852 regarding network pharmacies and prices, provided that the
853 pharmacy benefit manager includes information, such as links to
854 all nonaffiliated network pharmacies, in such communications and
855 that the information provided is accurate and of equal
856 prominence. This subparagraph may not be construed to prohibit a
857 pharmacy benefit manager from entering into an agreement with an
858 affiliated pharmacy to provide pharmacist services to covered
859 persons.

860 (f) Prohibit the ability of a pharmacy benefit manager to
861 condition participation in one pharmacy network on participation
862 in any other pharmacy network or penalize a pharmacy for
863 exercising its prerogative not to participate in a specific
864 pharmacy network.

865 (g) Prohibit a pharmacy benefit manager from instituting a
866 network that requires a pharmacy to meet accreditation standards
867 inconsistent with or more stringent than applicable federal and
868 state requirements for licensure and operation as a pharmacy in
869 this state. However, a pharmacy benefit manager may specify
870 additional specialty networks that require enhanced standards

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871 related to the safety and competency necessary to meet the
872 United States Food and Drug Administration's limited
873 distribution requirements for dispensing any drug that, on a
874 drug-by-drug basis, requires extraordinary special handling,
875 provider coordination, or clinical care or monitoring when such
876 extraordinary requirements cannot be met by a retail pharmacy.
877 For purposes of this paragraph, drugs requiring extraordinary
878 special handling are limited to drugs that are subject to a risk
879 evaluation and mitigation strategy approved by the United States
880 Food and Drug Administration and that:

881 1. Require special certification of a health care provider
882 to prescribe, receive, dispense, or administer; or

883 2. Require special handling due to the molecular complexity
884 or cytotoxic properties of the biologic or biosimilar product or
885 drug.

886
887 For participation in a specialty network, a pharmacy benefit
888 manager may not require a pharmacy to meet requirements for
889 participation beyond those necessary to demonstrate the
890 pharmacy's ability to dispense the drug in accordance with the
891 United States Food and Drug Administration's approved
892 manufacturer labeling.

893 (h)1. At a minimum, require the pharmacy benefit manager or
894 pharmacy benefits plan or program to, upon revising its
895 formulary of covered prescription drugs during a plan year,
896 provide a 60-day continuity-of-care period in which the covered
897 prescription drug that is being revised from the formulary
898 continues to be provided at the same cost for the patient for a
899 period of 60 days. The 60-day continuity-of-care period

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900 commences upon notification to the patient. This requirement
901 does not apply if the covered prescription drug:

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

905 b. Has been removed or withdrawn from the commercial market
906 by the manufacturer; or

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

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

913 (3) CONTRACTS BETWEEN A PHARMACY BENEFIT MANAGER AND A
914 PARTICIPATING PHARMACY.—In addition to other requirements in the
915 Florida Insurance Code, a participation contract executed,
916 amended, adjusted, or renewed on or after July 1, 2023, that
917 applies to pharmacist services on or after January 1, 2024,
918 between a pharmacy benefit manager and one or more pharmacies or
919 pharmacists, must include, in substantial form, terms that
920 ensure compliance with all of the following requirements, and
921 that, except to the extent not allowed by law, shall supersede
922 any contractual terms in the participation contract to the
923 contrary:

924 (a) At the time of adjudication for electronic claims or
925 the time of reimbursement for nonelectronic claims, the pharmacy
926 benefit manager shall provide the pharmacy with a remittance,
927 including such detailed information as is necessary for the
928 pharmacy or pharmacist to identify the reimbursement schedule

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929 for the specific network applicable to the claim and which is
930 the basis used by the pharmacy benefit manager to calculate the
931 amount of reimbursement paid. This information must include, but
932 is not limited to, the applicable network reimbursement ID or
933 plan ID as defined in the most current version of the National
934 Council for Prescription Drug Programs (NCPDP) Telecommunication
935 Standard Implementation Guide, or its nationally recognized
936 successor industry guide. The commission shall adopt rules to
937 implement this paragraph.

938 (b) The pharmacy benefit manager must ensure that any basis
939 of reimbursement information is communicated to a pharmacy in
940 accordance with the NCPDP Telecommunication Standard
941 Implementation Guide, or its nationally recognized successor
942 industry guide, when performing reconciliation for any effective
943 rate guarantee, and that such basis of reimbursement information
944 communicated is accurate, corresponds with the applicable
945 network rate, and may be relied upon by the pharmacy.

946 (c) A prohibition of financial clawbacks, reconciliation
947 offsets, or offsets to adjudicated claims. A pharmacy benefit
948 manager may not charge, withhold, or recoup direct or indirect
949 remuneration fees, dispensing fees, brand name or generic
950 effective rate adjustments through reconciliation, or any other
951 monetary charge, withholding, or recoupments as related to
952 discounts, multiple network reconciliation offsets, adjudication
953 transaction fees, and any other instance when a fee may be
954 recouped from a pharmacy. This prohibition does not apply to:

955 1. Any incentive payments provided by the pharmacy benefit
956 manager to a network pharmacy for meeting or exceeding
957 predefined quality measures, such as Healthcare Effectiveness

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958 Data and Information Set measures; recoupment due to an
959 erroneous claim, fraud, waste, or abuse; a claim adjudicated in
960 error; a maximum allowable cost appeal pricing adjustment; or an
961 adjustment made as part of a pharmacy audit pursuant to s.
962 624.491.

963 2. Any recoupment that is returned to the state for
964 programs in chapter 409 or the state group insurance program in
965 s. 110.123.

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

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

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

972 2. Mailing or delivering a prescription drug to a covered
973 person upon his or her request.

974 3. Charging a shipping or handling fee to a covered person
975 requesting a prescription drug be mailed or delivered if the
976 pharmacy or pharmacist discloses to the covered person before
977 the mailing or delivery the amount of the fee that will be
978 charged and that the fee may not be reimbursable by the covered
979 person's pharmacy benefits plan or program.

980 (f) The pharmacy benefit manager must provide a pharmacy,
981 upon its request, a list of pharmacy benefits plans or programs
982 in which the pharmacy is a part of the network. Updates to the
983 list must be communicated to the pharmacy within 7 days. The
984 pharmacy benefit manager may not restrict the pharmacy or
985 pharmacist from disclosing this information to the public.

986 (g) The pharmacy benefit manager must ensure that the

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987 Electronic Remittance Advice contains claim level payment
988 adjustments in accordance with the American National Standards
989 Institute Accredited Standards Committee, X12 format, and
990 includes or is accompanied by the appropriate level of detail
991 for the pharmacy to reconcile any debits or credits, including,
992 but not limited to, pharmacy NCPDP or NPI identifier, date of
993 service, prescription number, refill number, adjustment code, if
994 applicable, and transaction amount.

995 (h) The pharmacy benefit manager shall provide a reasonable
996 administrative appeal procedure to allow a pharmacy or
997 pharmacist to challenge the maximum allowable cost pricing
998 information and the reimbursement made under the maximum
999 allowable cost as defined in s. 627.64741 for a specific drug as
1000 being below the acquisition cost available to the challenging
1001 pharmacy or pharmacist.

1002 1. The administrative appeal procedure must include a
1003 telephone number and e-mail address, or a website, for the
1004 purpose of submitting the administrative appeal. The appeal may
1005 be submitted by the pharmacy or an agent of the pharmacy
1006 directly to the pharmacy benefit manager or through a pharmacy
1007 service administration organization. The pharmacy or pharmacist
1008 must be given at least 30 business days after a maximum
1009 allowable cost update or after an adjudication for an electronic
1010 claim or reimbursement for a nonelectronic claim to file the
1011 administrative appeal.

1012 2. The pharmacy benefit manager must respond to the
1013 administrative appeal within 30 business days after receipt of
1014 the appeal.

1015 3. If the appeal is upheld, the pharmacy benefit manager

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1016 must:

1017 a. Update the maximum allowable cost pricing information to
1018 at least the acquisition cost available to the pharmacy;

1019 b. Permit the pharmacy or pharmacist to reverse and rebill
1020 the claim in question;

1021 c. Provide to the pharmacy or pharmacist the national drug
1022 code on which the increase or change is based; and

1023 d. Make the increase or change effective for each similarly
1024 situated pharmacy or pharmacist who is subject to the applicable
1025 maximum allowable cost pricing information.

1026 4. If the appeal is denied, the pharmacy benefit manager
1027 must provide to the pharmacy or pharmacist the national drug
1028 code and the name of the national or regional pharmaceutical
1029 wholesalers operating in this state which have the drug
1030 currently in stock at a price below the maximum allowable cost
1031 pricing information.

1032 5. Every 90 days, a pharmacy benefit manager shall report
1033 to the office the total number of appeals received and denied in
1034 the preceding 90-day period, with an explanation or reason for
1035 each denial, for each specific drug for which an appeal was
1036 submitted pursuant to this paragraph.

1037 Section 12. Section 626.8827, Florida Statutes, is created
1038 to read:

1039 626.8827 Pharmacy benefit manager prohibited practices.—In
1040 addition to other prohibitions in this part, a pharmacy benefit
1041 manager may not do any of the following:

1042 (1) Prohibit, restrict, or penalize in any way a pharmacy
1043 or pharmacist from disclosing to any person any information that
1044 the pharmacy or pharmacist deems appropriate, including, but not

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1045 limited to, information regarding any of the following:
1046 (a) The nature of treatment, risks, or alternatives
1047 thereto.
1048 (b) The availability of alternate treatment, consultations,
1049 or tests.
1050 (c) The decision of utilization reviewers or similar
1051 persons to authorize or deny pharmacist services.
1052 (d) The process used to authorize or deny pharmacist
1053 services or benefits.
1054 (e) Information on financial incentives and structures used
1055 by the pharmacy benefits plan or program.
1056 (f) Information that may reduce the costs of pharmacist
1057 services.
1058 (g) Whether the cost-sharing obligation exceeds the retail
1059 price for a covered prescription drug and the availability of a
1060 more affordable alternative drug, pursuant to s. 465.0244.
1061 (2) Prohibit, restrict, or penalize in any way a pharmacy
1062 or pharmacist from disclosing information to the office, the
1063 Agency for Health Care Administration, Department of Management
1064 Services, law enforcement, or state and federal governmental
1065 officials, provided that the recipient of the information
1066 represents it has the authority, to the extent provided by state
1067 or federal law, to maintain proprietary information as
1068 confidential; and before disclosure of information designated as
1069 confidential, the pharmacist or pharmacy marks as confidential
1070 any document in which the information appears or requests
1071 confidential treatment for any oral communication of the
1072 information.
1073 (3) Communicate at the point-of-sale, or otherwise require,

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1074 a cost-sharing obligation for the covered person in an amount
1075 that exceeds the lesser of:

1076 (a) The applicable cost-sharing amount under the applicable
1077 pharmacy benefits plan or program; or

1078 (b) The usual and customary price, as defined in s.
1079 626.8825, of the pharmacist services.

1080 (4) Transfer or share records relative to prescription
1081 information containing patient-identifiable or prescriber-
1082 identifiable data to an affiliated pharmacy for any commercial
1083 purpose other than the limited purposes of facilitating pharmacy
1084 reimbursement, formulary compliance, or utilization review on
1085 behalf of the applicable pharmacy benefits plan or program.

1086 (5) Fail to make any payment due to a pharmacy for an
1087 adjudicated claim with a date of service before the effective
1088 date of a pharmacy's termination from a pharmacy benefit network
1089 unless payments are withheld because of fraud on the part of the
1090 pharmacy or except as otherwise required by law.

1091 (6) Terminate the contract of, penalize, or disadvantage a
1092 pharmacist or pharmacy due to a pharmacist or pharmacy:

1093 (a) Disclosing information about pharmacy benefit manager
1094 practices in accordance with this act;

1095 (b) Exercising any of its prerogatives under this part; or

1096 (c) Sharing any portion, or all, of the pharmacy benefit
1097 manager contract with the office pursuant to a complaint or a
1098 query regarding whether the contract is in compliance with this
1099 act.

1100 (7) Fail to comply with the requirements in s. 626.8825 or
1101 s. 624.491.

1102 Section 13. Section 626.8828, Florida Statutes, is created

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1103 to read:

1104 626.8828 Investigations and examinations of pharmacy
1105 benefit managers; expenses; penalties.-

1106 (1) The office may investigate administrators who are
1107 pharmacy benefit managers and applicants for authorization as
1108 provided in ss. 624.307 and 624.317. The office shall review any
1109 referral made pursuant to s. 624.307(10) and shall investigate
1110 any referral that, as determined by the Commissioner of
1111 Insurance Regulation or his or her designee, reasonably
1112 indicates a possible violation of this part.

1113 (2) (a) The office shall examine the business and affairs of
1114 each pharmacy benefit manager at least biennially. The biennial
1115 examination of each pharmacy benefit manager must be a
1116 systematic review for the purpose of determining the pharmacy
1117 benefit manager's compliance with all provisions of this part
1118 and all other laws or rules applicable to pharmacy benefit
1119 managers and must include a detailed review of the pharmacy
1120 benefit manager's compliance with ss. 626.8825 and 626.8827. The
1121 first 2-year cycle for conducting biennial reviews begins
1122 January 1, 2025. By January 15, 2026, and each January 15
1123 thereafter, the office shall submit to the Governor, the
1124 President of the Senate, and the Speaker of the House of
1125 Representatives a report summarizing the results of the prior
1126 year's examinations which includes detailed descriptions of any
1127 violations committed by each pharmacy benefit manager and
1128 detailed reporting of actions taken by the office against each
1129 pharmacy benefit manager for such violations. Beginning with the
1130 2027 report, and every 2 years thereafter, the report must
1131 document the office's compliance with the examination timeframe

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1132 requirements as provided in this paragraph. The office must
1133 specify the number and percentage of all examination completed
1134 within the timeframe.

1135 (b) The office also may conduct additional examinations as
1136 often as it deems advisable or necessary for the purpose of
1137 ascertaining compliance with this part and any other laws or
1138 rules applicable to pharmacy benefit managers or applicants for
1139 authorization.

1140 (c) If a referral made pursuant to s. 624.307(10)
1141 reasonably indicates a pattern or practice of violations of this
1142 part by a pharmacy benefit manager, the office must begin an
1143 examination of the pharmacy benefit manager or include findings
1144 related to such referral within an ongoing examination.

1145 (d) Based on the findings of an examination that a pharmacy
1146 benefit manager or an applicant for authorization has exhibited
1147 a pattern or practice of knowing and willful violations of s.
1148 626.8825 or s. 626.8827, the office may, pursuant to chapter
1149 120, order a pharmacy benefit manager to file all contracts
1150 between the pharmacy benefit manager and pharmacies or pharmacy
1151 benefits plans or programs and any policies, guidelines, rules,
1152 protocols, standard operating procedures, instructions, or
1153 directives that govern or guide the manner in which the pharmacy
1154 benefit manager or applicant conducts business related to such
1155 knowing and willful violations for review and inspection for the
1156 following 36-month period. Such documents are public records and
1157 are not trade secrets or otherwise exempt from s. 119.07(1). As
1158 used in this section, the term:

1159 1. "Contracts" means any contract to which s. 626.8825 is
1160 applicable.

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1161 2. "Knowing and willful" means any act of commission or
1162 omission which is committed intentionally, as opposed to
1163 accidentally, and which is committed with knowledge of the act's
1164 unlawfulness or with reckless disregard as to the unlawfulness
1165 of the act.

1166 (e) Examinations may be conducted by an independent
1167 professional examiner under contract to the office, in which
1168 case payment must be made directly to the contracted examiner by
1169 the pharmacy benefit manager examined in accordance with the
1170 rates and terms agreed to by the office and the examiner. The
1171 commission shall adopt rules providing for the types of
1172 independent professional examiners who may conduct examinations
1173 under this section, which types must include, but need not be
1174 limited to, independent certified public accountants, actuaries,
1175 investment specialists, information technology specialists, or
1176 others meeting criteria specified by commission rule. The rules
1177 must also require that:

1178 1. The rates charged to the pharmacy benefit manager being
1179 examined are consistent with rates charged by other firms in a
1180 similar profession and are comparable with the rates charged for
1181 comparable examinations.

1182 2. The firm selected by the office to perform the
1183 examination has no conflicts of interest which might affect its
1184 ability to independently perform its responsibilities for the
1185 examination.

1186 (3) In making investigations and examinations of pharmacy
1187 benefit managers and applicants for authorization, the office
1188 and such pharmacy benefit manager are subject to all of the
1189 following provisions:

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1190 (a) Section 624.318, as to the conduct of examinations.
1191 (b) Section 624.319, as to examination and investigation
1192 reports.
1193 (c) Section 624.321, as to witnesses and evidence.
1194 (d) Section 624.322, as to compelled testimony.
1195 (e) Section 624.324, as to hearings.
1196 (f) Any other provision of chapter 624 applicable to the
1197 investigation or examination of a licensee under this part.
1198 (4) (a) A pharmacy benefit manager must maintain an accurate
1199 record of all contracts and records with all pharmacies and
1200 pharmacy benefits plans or programs for the duration of the
1201 contract, and for 5 years thereafter. Such contracts must be
1202 made available to the office and kept in a form accessible to
1203 the office.
1204 (b) The office may order any pharmacy benefit manager or
1205 applicant to produce any records, books, files, contracts,
1206 advertising and solicitation materials, or other information and
1207 may take statements under oath to determine whether the pharmacy
1208 benefit manager or applicant is in violation of the law or is
1209 acting contrary to the public interest.
1210 (5) (a) Notwithstanding s. 624.307(3), each pharmacy benefit
1211 manager and applicant for authorization must pay to the office
1212 the expenses of the examination or investigation. Such expenses
1213 include actual travel expenses, a reasonable living expense
1214 allowance, compensation of the examiner, investigator, or other
1215 person making the examination or investigation, and necessary
1216 costs of the office directly related to the examination or
1217 investigation. Such travel expenses and living expense
1218 allowances are limited to those expenses necessarily incurred on

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1219 account of the examination or investigation and shall be paid by
1220 the examined pharmacy benefit manager or applicant together with
1221 compensation upon presentation by the office to such pharmacy
1222 benefit manager or applicant of such charges and expenses after
1223 a detailed statement has been filed by the examiner and approved
1224 by the office.

1225 (b) All moneys collected from pharmacy benefit managers and
1226 applicants for authorization pursuant to this subsection shall
1227 be deposited into the Insurance Regulatory Trust Fund, and the
1228 office may make deposits from time to time into such fund from
1229 moneys appropriated for the operation of the office.

1230 (c) Notwithstanding s. 112.061, the office may pay to the
1231 examiner, investigator, or person making such examination or
1232 investigation out of such trust fund the actual travel expenses,
1233 reasonable living expense allowance, and compensation in
1234 accordance with the statement filed with the office by the
1235 examiner, investigator, or other person, as provided in
1236 paragraph (a).

1237 (6) In addition to any other enforcement authority
1238 available to the office, the office shall impose an
1239 administrative fine of \$5,000 for each violation of s. 626.8825
1240 or s. 626.8827. Each instance of a violation of such sections by
1241 a pharmacy benefit manager against each individual pharmacy or
1242 prescription benefits plan or program constitutes a separate
1243 violation. Notwithstanding any other provision of law, there is
1244 no limitation on aggregate fines issued pursuant to this
1245 section. The proceeds from any administrative fine shall be
1246 deposited into the General Revenue Fund.

1247 (7) Failure by a pharmacy benefit manager to pay expenses

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1248 incurred or administrative fines imposed under this section is
1249 grounds for the denial, suspension, or revocation of its
1250 certificate of authority.

1251 Section 14. Section 626.89, Florida Statutes, is amended to
1252 read:

1253 626.89 Annual financial statement and filing fee; notice of
1254 change of ownership; pharmacy benefit manager filings.—

1255 (1) Each authorized administrator shall annually file with
1256 the office a full and true statement of its financial condition,
1257 transactions, and affairs within 3 months after the end of the
1258 administrator's fiscal year or within such extension of time as
1259 the office for good cause may have granted. The statement must
1260 be for the preceding fiscal year and must be in such form and
1261 contain such matters as the commission prescribes and must be
1262 verified by at least two officers of the administrator.

1263 (2) Each authorized administrator shall also file an
1264 audited financial statement performed by an independent
1265 certified public accountant. The audited financial statement
1266 must ~~shall~~ be filed with the office within 5 months after the
1267 end of the administrator's fiscal year and be for the preceding
1268 fiscal year. An audited financial statement prepared on a
1269 consolidated basis must include a columnar consolidating or
1270 combining worksheet that must be filed with the statement and
1271 must comply with the following:

1272 (a) Amounts shown on the consolidated audited financial
1273 statement must be shown on the worksheet;

1274 (b) Amounts for each entity must be stated separately; and

1275 (c) Explanations of consolidating and eliminating entries
1276 must be included.

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1277 (3) At the time of filing its annual statement, the
1278 administrator shall pay a filing fee in the amount specified in
1279 s. 624.501 for the filing of an annual statement by an insurer.

1280 (4) In addition, the administrator shall immediately notify
1281 the office of any material change in its ownership.

1282 (5) A pharmacy benefit manager shall also notify the office
1283 within 30 days after any administrative, civil, or criminal
1284 complaints, settlements, or discipline of the pharmacy benefit
1285 manager or any of its affiliates which relate to a violation of
1286 the insurance laws, including pharmacy benefit laws in any
1287 state.

1288 (6) A pharmacy benefit manager shall also annually submit
1289 to the office a statement attesting to its compliance with the
1290 network requirements of s. 626.8825.

1291 (7) The commission may by rule require all or part of the
1292 statements or filings required under this section to be
1293 submitted by electronic means in a computer-readable form
1294 compatible with the electronic data format specified by the
1295 commission.

1296 Section 15. Subsection (5) is added to section 627.42393,
1297 Florida Statutes, to read:

1298 627.42393 Step-therapy protocol.—

1299 (5) This section applies to a pharmacy benefit manager
1300 acting on behalf of a health insurer.

1301 Section 16. Subsections (2), (3), and (4) of section
1302 627.64741, Florida Statutes, are amended to read:

1303 627.64741 Pharmacy benefit manager contracts.—

1304 (2) In addition to the requirements of part VII of chapter
1305 626, a contract between a health insurer and a pharmacy benefit

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1306 manager must require that the pharmacy benefit manager:

1307 (a) Update maximum allowable cost pricing information at
1308 least every 7 calendar days.

1309 (b) Maintain a process that will, in a timely manner,
1310 eliminate drugs from maximum allowable cost lists or modify drug
1311 prices to remain consistent with changes in pricing data used in
1312 formulating maximum allowable cost prices and product
1313 availability.

1314 ~~(3) A contract between a health insurer and a pharmacy
1315 benefit manager must prohibit the pharmacy benefit manager from
1316 limiting a pharmacist's ability to disclose whether the cost-
1317 sharing obligation exceeds the retail price for a covered
1318 prescription drug, and the availability of a more affordable
1319 alternative drug, pursuant to s. 465.0244.~~

1320 ~~(4) A contract between a health insurer and a pharmacy
1321 benefit manager must prohibit the pharmacy benefit manager from
1322 requiring an insured to make a payment for a prescription drug
1323 at the point of sale in an amount that exceeds the lesser of:~~

1324 ~~(a) The applicable cost sharing amount; or~~

1325 ~~(b) The retail price of the drug in the absence of
1326 prescription drug coverage.~~

1327 Section 17. Subsections (2), (3), and (4) of section
1328 627.6572, Florida Statutes, are amended to read:

1329 627.6572 Pharmacy benefit manager contracts.—

1330 (2) In addition to the requirements of part VII of chapter
1331 626, a contract between a health insurer and a pharmacy benefit
1332 manager must require that the pharmacy benefit manager:

1333 (a) Update maximum allowable cost pricing information at
1334 least every 7 calendar days.

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1335 (b) Maintain a process that will, in a timely manner,
1336 eliminate drugs from maximum allowable cost lists or modify drug
1337 prices to remain consistent with changes in pricing data used in
1338 formulating maximum allowable cost prices and product
1339 availability.

1340 ~~(3) A contract between a health insurer and a pharmacy~~
1341 ~~benefit manager must prohibit the pharmacy benefit manager from~~
1342 ~~limiting a pharmacist's ability to disclose whether the cost-~~
1343 ~~sharing obligation exceeds the retail price for a covered~~
1344 ~~prescription drug, and the availability of a more affordable~~
1345 ~~alternative drug, pursuant to s. 465.0244.~~

1346 ~~(4) A contract between a health insurer and a pharmacy~~
1347 ~~benefit manager must prohibit the pharmacy benefit manager from~~
1348 ~~requiring an insured to make a payment for a prescription drug~~
1349 ~~at the point of sale in an amount that exceeds the lesser of:~~

1350 ~~(a) The applicable cost sharing amount; or~~

1351 ~~(b) The retail price of the drug in the absence of~~
1352 ~~prescription drug coverage.~~

1353 Section 18. Paragraph (e) is added to subsection (46) of
1354 section 641.31, Florida Statutes, to read:

1355 641.31 Health maintenance contracts.—

1356 (46)

1357 (e) This subsection applies to a pharmacy benefit manager
1358 acting on behalf of a health maintenance organization.

1359 Section 19. Subsections (2), (3), and (4) of section
1360 641.314, Florida Statutes, are amended to read:

1361 641.314 Pharmacy benefit manager contracts.—

1362 (2) In addition to the requirements of part VII of chapter
1363 626, a contract between a health maintenance organization and a

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1364 pharmacy benefit manager must require that the pharmacy benefit
1365 manager:

1366 (a) Update maximum allowable cost pricing information at
1367 least every 7 calendar days.

1368 (b) Maintain a process that will, in a timely manner,
1369 eliminate drugs from maximum allowable cost lists or modify drug
1370 prices to remain consistent with changes in pricing data used in
1371 formulating maximum allowable cost prices and product
1372 availability.

1373 ~~(3) A contract between a health maintenance organization
1374 and a pharmacy benefit manager must prohibit the pharmacy
1375 benefit manager from limiting a pharmacist's ability to disclose
1376 whether the cost-sharing obligation exceeds the retail price for
1377 a covered prescription drug, and the availability of a more
1378 affordable alternative drug, pursuant to s. 465.0244.~~

1379 ~~(4) A contract between a health maintenance organization
1380 and a pharmacy benefit manager must prohibit the pharmacy
1381 benefit manager from requiring a subscriber to make a payment
1382 for a prescription drug at the point of sale in an amount that
1383 exceeds the lesser of:~~

1384 ~~(a) The applicable cost-sharing amount; or~~

1385 ~~(b) The retail price of the drug in the absence of
1386 prescription drug coverage.~~

1387 Section 20. (1) This act establishes requirements for
1388 pharmacy benefit managers as defined in s. 626.88, Florida
1389 Statutes, including, without limitation, pharmacy benefit
1390 managers in their performance of services for or otherwise on
1391 behalf of a pharmacy benefits plan or program as defined in s.
1392 626.8825, Florida Statutes, which includes coverage pursuant to

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1393 Titles XVIII, XIX, or XXI of the Social Security Act, 42 U.S.C.
1394 ss. 1395 et seq., 1396 et seq., and 1397aa et seq., known as
1395 Medicare, Medicaid, or any other similar coverage under a state
1396 or Federal Government funded health plan, including the
1397 Statewide Medicaid Managed Care program established pursuant to
1398 part IV of chapter 409, Florida Statutes, and the state group
1399 insurance program pursuant to part I of chapter 110, Florida
1400 Statutes.

1401 (2) This act is not intended, nor may it be construed, to
1402 conflict with existing, relevant federal law.

1403 (3) If any provision of this act or its application to any
1404 person or circumstances is held invalid, the invalidity does not
1405 affect other provisions or applications of this act which can be
1406 given effect without the invalid provision or application, and
1407 to this end the provisions of this act are severable.

1408 Section 21. For the 2023-2024 fiscal year, the sum of
1409 \$980,705 in recurring funds and \$146,820 in nonrecurring funds
1410 from the Insurance Regulatory Trust Fund are appropriated to the
1411 Office of Insurance Regulation, and 10 full-time equivalent
1412 positions with associated salary rate of 644,877 are authorized,
1413 for the purpose of implementing this act.

1414 Section 22. This act shall take effect July 1, 2023.