

1 A bill to be entitled
2 An act relating to prescription drug price
3 transparency; amending s. 499.012, F.S.; prohibiting
4 permits for prescription drug manufacturers and
5 nonresident prescription drug manufacturers and for
6 certain wholesale distributors of prescription drugs
7 from being renewed unless specified requirements are
8 met; authorizing the Department of Business and
9 Professional Regulation to suspend or revoke
10 manufacturer permits and wholesale distributor permits
11 under specified circumstances; amending s. 499.0121,
12 F.S.; defining the term "price"; providing reporting
13 requirements for certain entities that engage in
14 wholesale distributions of prescription drugs;
15 authorizing the department to request certain
16 documentation and information; requiring the
17 department to prescribe by rule specified timeframes;
18 authorizing the department to extend specified
19 timeframes; specifying what constitutes violations of
20 specified laws; providing penalties and fines for
21 violations; providing disposition of such fines;
22 creating s. 499.026, F.S.; providing definitions;
23 providing requirements for notifications by
24 manufacturers of prescription drug price increases
25 under certain circumstances; providing reporting

26 requirements; requiring the department to compile a
27 list of specified drugs; authorizing the department to
28 request certain documentation and information;
29 requiring the department to prescribe by rule
30 specified timeframes; authorizing the department to
31 extend specified timeframes; providing duties of the
32 department; specifying what constitutes violations of
33 specified laws; prohibiting certain prescription drugs
34 from being included in specified drug formularies;
35 providing an exception; providing penalties and fines
36 for violations; providing disposition of such fines;
37 requiring the department to adopt rules; amending s.
38 499.05, F.S.; requiring the department to adopt rules;
39 conforming provisions to changes made by the act;
40 amending s. 624.490, F.S.; providing definitions;
41 providing reporting requirements for registered
42 pharmacy benefit managers; authorizing the Office of
43 Insurance Regulation to request certain documentation
44 and information; requiring the Financial Services
45 Commission to prescribe by rule specified timeframes;
46 authorizing the office to extend specified timeframes;
47 requiring registered pharmacy benefit managers to
48 maintain a website for a specified purpose and to
49 update the information on the website under certain
50 circumstances; specifying what constitutes violations

51 of specified laws; providing penalties and fines for
52 violations; providing disposition of such fines;
53 creating ss. 627.42384 and 641.3131, F.S.; requiring
54 certain health insurers and health maintenance
55 organizations, respectively, to submit and update
56 contact information for single points of contact for a
57 specified use; requiring the office to maintain and
58 publish such points of contact; requiring such health
59 insurers and health maintenance organizations to
60 notify certain insureds and subscribers, respectively,
61 within a specified timeframe of drug formulary
62 changes; providing applicability; amending ss.
63 627.64741, 627.6572, and 641.314, F.S.; defining the
64 term "net price"; providing additional requirements
65 for contracts between pharmacy benefit managers and
66 individual health insurers, group health insurers, and
67 health maintenance organizations, respectively;
68 providing applicability; amending ss. 110.12315,
69 409.815, 409.91195, 409.912, and 499.067, F.S.;
70 conforming provisions to changes made by the act;
71 providing an effective date.

72
73 Be It Enacted by the Legislature of the State of Florida:
74

75 Section 1. Paragraph (f) is added to subsection (1) of

76 | section 499.012, Florida Statutes, to read:

77 | 499.012 Permit application requirements.—

78 | (1)

79 | (f)1. A permit for a prescription drug manufacturer or
 80 | nonresident prescription drug manufacturer may not be renewed
 81 | unless the prescription drug manufacturer or nonresident
 82 | prescription drug manufacturer meets the requirements of s.
 83 | 499.026. The department may suspend or revoke the permit of a
 84 | manufacturer that fails to comply with the requirements of s.
 85 | 499.026.

86 | 2. A permit for a prescription drug wholesale distributor,
 87 | out-of-state prescription drug wholesale distributor, retail
 88 | pharmacy drug wholesale distributor, veterinary prescription
 89 | drug wholesale distributor, or limited prescription drug
 90 | veterinary wholesale distributor may not be renewed unless the
 91 | wholesale distributor meets the requirements of s. 499.0121(16).
 92 | The department may suspend or revoke the permit of a wholesale
 93 | distributor that fails to comply with the requirements of s.
 94 | 499.0121(16).

95 | Section 2. Subsection (16) is added to section 499.0121,
 96 | Florida Statutes, to read:

97 | 499.0121 Storage and handling of prescription drugs;
 98 | recordkeeping; prescription drug price report requirements;
 99 | penalties for noncompliance.—The department shall adopt rules to
 100 | implement this section as necessary to protect the public

101 health, safety, and welfare. Such rules shall include, but not
 102 be limited to, requirements for the storage and handling of
 103 prescription drugs and for the establishment and maintenance of
 104 prescription drug distribution records.

105 (16) PRESCRIPTION DRUG PRICE REPORT AND PENALTIES FOR
 106 NONCOMPLIANCE.—

107 (a) As used in this subsection, the term "price" means the
 108 manufacturer's list price for a prescription drug to wholesalers
 109 or direct purchasers in the United States, not including prompt
 110 pay or other discounts, rebates, or reductions in price, for the
 111 most recent month for which the information is available, as
 112 reported in wholesale price guides or other publications of drug
 113 or biological pricing data.

114 (b) By July 1 of each year, each prescription drug
 115 wholesale distributor, out-of-state prescription drug wholesale
 116 distributor, retail pharmacy drug wholesale distributor,
 117 prescription drug wholesale distributor, veterinary prescription
 118 drug wholesale distributor, or limited prescription drug
 119 veterinary wholesale distributor, or each manufacturer or
 120 repackager that engages in the wholesale distribution of
 121 prescription drugs, shall submit a report to the department on
 122 each prescription drug for which the price, during the previous
 123 calendar year:

124 1. Was \$100 or more for a 30-day supply or for a course of
 125 treatment lasting less than 30 days; or

126 2. Increased by at least 10 percent over the previous
127 price.

128 (c) The report must include, at a minimum, the following
129 information:

130 1. The name and the price at the time of the report of
131 each prescription drug specified in paragraph (b) and the
132 cumulative percentage price increase during the previous
133 calendar year.

134 2. The length of time the prescription drug has been on
135 the market.

136 3. The factors that contributed to the price increase.

137 4. The name of any generic version of the prescription drug
138 available on the market.

139 5. The total sales revenue for the prescription drug
140 during the previous calendar year.

141 6. The introductory price of the prescription drug when it
142 was approved by the United States Food and Drug Administration
143 and the cumulative yearly increase, by calendar year, in the
144 price of the drug during the previous 5 years or during the
145 number of years the drug has been on the market, whichever is
146 less.

147 7. Any prompt pay or discount, rebate, or reduction in
148 price provided by the reporting wholesale distributor or
149 manufacturer or repackager that engages in the wholesale
150 distribution of prescription drugs when selling a prescription

151 drug to a manufacturer, pharmacy, pharmacy benefit manager, and
152 other entities.

153 8. The documentation necessary to support the information
154 reported under this paragraph.

155 (d) The department may make a written request to the
156 reporting wholesale distributor, manufacturer, or repackager for
157 supporting documentation or additional information concerning
158 the report. The department shall prescribe by rule the
159 timeframes for the department's request for documentation or
160 information and for the response by the reporting wholesale
161 distributor, manufacturer, or repackager. The department may
162 extend the timeframe, if necessary, for the response by the
163 wholesale distributor, manufacturer, or repackager.

164 (e) A wholesale distributor, or a manufacturer or
165 repackager that engages in the wholesale distribution of
166 prescription drugs, violates this subsection if the wholesale
167 distributor, manufacturer, or repackager:

168 1. Fails to timely submit the report required under this
169 subsection;

170 2. Fails to provide information required under this
171 subsection;

172 3. Fails to timely respond to a written request by the
173 department with regard to the report required under this
174 subsection; or

175 4. Provides inaccurate or incomplete information in the

176 report required under this subsection.

177 (f)1. The department may deny an application for a renewal
178 permit or registration or suspend or revoke a registration
179 certificate or a permit of a prescription drug wholesale
180 distributor, or a manufacturer or repackager that engages in the
181 wholesale distribution of prescription drugs, for violating this
182 subsection.

183 2.a. The department may also impose an administrative
184 fine, not to exceed \$5,000 per violation per day, for a
185 violation of this subsection or a rule adopted to administer
186 this subsection. Each day the violation continues constitutes a
187 separate violation, and each such separate violation is subject
188 to a separate fine.

189 b. In determining the amount of fine to be levied for a
190 violation of this subsection, the department must consider the
191 following factors:

192 (I) The severity of the violation.

193 (II) Any action taken by the permittee to correct the
194 violation or to remedy complaints.

195 (III) Any previous violation.

196 c. All fines collected under this subparagraph shall be
197 deposited into the Public Medical Assistance Trust Fund
198 administered by the Agency for Health Care Administration, to be
199 used to help the uninsured pay for health care.

200 Section 3. Section 499.026, Florida Statutes, is created

201 to read:

202 499.026 Prescription drug price transparency.-

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

204 (a) "Agency" means the Agency for Health Care
 205 Administration.

206 (b) "Division" means the Division of Consumer Services of
 207 the Department of Agriculture and Consumer Services.

208 (c) "Drug" means a prescription drug.

209 (d) "Health insurer" means a health insurer issuing major
 210 medical coverage through an individual or group policy or a
 211 health maintenance organization issuing major medical coverage
 212 through an individual or group contract, regulated under chapter
 213 627 or chapter 641.

214 (e) "Medicaid" means the Agency for Health Care
 215 Administration Medicaid program.

216 (f) "Office" means the Office of Insurance Regulation of
 217 the Financial Services Commission.

218 (g) "Price" means the manufacturer's list price for a drug
 219 to wholesalers or direct purchasers in the United States, not
 220 including prompt pay or other discounts, rebates, or reductions
 221 in price, for the most recent month for which the information is
 222 available, as reported in wholesale price guides or other
 223 publications of drug or biological pricing data.

224 (2)(a) At least 120 days before the effective date of any
 225 single manufacturer increase of at least 10 percent in the price

226 of a drug, a manufacturer must provide notice of the upcoming
227 drug price increase to:

228 1. The department, the Department of Health, the agency,
229 the division, and the office.

230 2. Every health insurer that covers the drug. The
231 manufacturer shall use the contact list published by the office
232 under ss. 627.42384 and 641.3131 to provide notice to health
233 insurers. Notification shall be presumed to occur on the date
234 that the manufacturer attempts to communicate with the
235 applicable point of contact published by the office.

236 (b) The notices must include, at a minimum, the following
237 information:

238 1. The name and current price of the drug.

239 2. The date that the increase will become effective.

240 3. The dollar amount of the intended increase in the price
241 of the drug.

242 4. The percentage price increase.

243 5. A statement of whether the price increase is
244 necessitated by a change or improvement of the drug and, if so,
245 a description of the change or improvement.

246 6. A description of any other factors that contributed to
247 the price increase.

248 7. The documentation necessary to support the information
249 reported under subparagraphs 5. and 6.

250 (3) (a) By July 1 of each year, a manufacturer shall submit

251 a report to the department, the Department of Health, the
252 agency, the division, and the office on each drug for which the
253 price, during the previous calendar year:

254 1. Was \$100 or more for a 30-day supply or for a course of
255 treatment lasting less than 30 days; or

256 2. Increased by at least 10 percent over the previous
257 price in a single manufacturer price.

258 (b) The report must include, at a minimum, the following
259 information:

260 1. The name and the price at the time of the report of
261 each drug specified in paragraph (a) and the cumulative
262 percentage price increase during the previous calendar year.

263 2. The length of time the drug has been on the market.

264 3. The factors that contributed to the price increase.

265 4. The name of any generic version of the drug available on
266 the market.

267 5. The research and development costs associated with the
268 drug that were paid using public funds.

269 6. The direct costs incurred by the manufacturer to
270 manufacture, market, and distribute the drug and to ensure
271 ongoing safety and effectiveness research associated with the
272 drug.

273 7. The total sales revenue for the drug during the
274 previous calendar year.

275 8. The manufacturer's profit attributable to the drug

276 during the previous calendar year.

277 9. The introductory price of the drug when it was approved
278 by the United States Food and Drug Administration and the
279 cumulative yearly increase, by calendar year, in the price of
280 the drug during the previous 5 years or during the number of
281 years the drug has been on the market, whichever is less.

282 10. The 10 highest prices paid for the drug during the
283 previous year in other countries.

284 11. The documentation necessary to support the information
285 reported under this paragraph.

286 (4) (a) Before reviewing the data in the report filed under
287 subsection (3), the department, in consultation with the
288 Department of Health, the agency, and the office, shall compile
289 a list of drugs that have a significant cost to the state or
290 that are designated as being critical to public health. Such
291 drugs may be sourced from the Medicaid drug utilization data and
292 drug spending data, the division's drug spending data, and the
293 drug spending data of health insurers and health plans and their
294 pharmacy benefit managers.

295 (b) After receiving the report required under subsection
296 (3), the department:

297 1. May make a written request to the manufacturer for
298 supporting documentation or additional information concerning
299 the report. The department shall prescribe by rule the
300 timeframes for the department's request for documentation or

301 information and for the manufacturer's response to the request.
302 The department may extend the timeframe, if necessary, for the
303 manufacturer's response.

304 2. Shall review the costs and the factors contributing to
305 each drug price or drug price increase in the report.

306 3. Shall review the price and price increase of each drug
307 on the list compiled under paragraph (a) and each drug on the
308 lists reported by wholesale distributors and other entities
309 engaged in wholesale distribution of prescription drugs and by
310 registered pharmacy benefit managers under ss. 499.0121(16) and
311 624.490(6)(b), respectively, to make sure that any drug on the
312 compiled and reported lists which fits the criterion in
313 subparagraph (3)(a)1. or subparagraph (3)(a)2. is also reported
314 by the drug's manufacturer under subsection (3).

315 4. Shall, in consultation with the Department of Health,
316 the division, and the office, determine whether the manufacturer
317 has violated this section.

318 (5) A manufacturer violates this section if the
319 manufacturer:

320 (a) Fails to timely submit notices or reports required
321 under this section;

322 (b) Fails to provide information required under this
323 section;

324 (c) Fails to timely respond to a written request by the
325 department with regard to the notices or report required under

326 this section; or

327 (d) Provides inaccurate or incomplete information in the
 328 notices or report required under this section.

329 (6) A drug for which the manufacturer does not comply with
 330 the notification or reporting requirements under this section
 331 may not be included in the Medicaid's and state group health
 332 insurance's drug formularies unless the drug is the most
 333 clinically appropriate, clinically effective, and lowest net-
 334 cost drug.

335 (7) (a) The department may deny an application for a
 336 renewal permit or suspend or revoke a permit of a prescription
 337 drug manufacturer or nonresident prescription drug manufacturer
 338 for violating this section.

339 (b)1. The department may also impose an administrative
 340 fine, not to exceed \$5,000 per violation per day, for a
 341 violation of this section or a rule adopted under this section.
 342 Each day the violation continues constitutes a separate
 343 violation, and each such separate violation is subject to a
 344 separate fine.

345 2. In determining the amount of fine to be levied for a
 346 violation of this section, the department, in consultation with
 347 the Department of Health, the agency, the division, and the
 348 office, must consider the following factors:

349 a. The severity of the violation.

350 b. Any action taken by the permittee to correct the

351 violation or to remedy complaints.

352 c. Any previous violation.

353 3. All fines collected under this section shall be
 354 deposited into the Public Medical Assistance Trust Fund
 355 administered by the agency, to be used to help the uninsured pay
 356 for health care.

357 (8) The department shall adopt rules to administer this
 358 section.

359 Section 4. Paragraph (m) of subsection (1) of section
 360 499.05, Florida Statutes, is amended, and paragraph (o) is added
 361 to that subsection, to read:

362 499.05 Rules.—

363 (1) The department shall adopt rules to implement and
 364 enforce this chapter with respect to:

365 (m) Wholesale distributor reporting requirements of s.
 366 499.0121(14) and (16) ~~s. 499.0121(14)~~.

367 (o) Manufacturer notification and reporting requirements
 368 of s. 499.026(2) and (3).

369 Section 5. Subsection (6) of section 624.490, Florida
 370 Statutes, is renumbered as subsection (7), and a new subsection
 371 (6) is added to that section, to read:

372 624.490 Registration of pharmacy benefit managers;
 373 prescription drug price report and public access requirements;
 374 penalties for noncompliance.—

375 (6) (a) As used in this subsection, the term:

376 1. "Negotiated price" means the value at which a
377 prescription drug is sold by a prescription drug manufacturer,
378 prescription drug wholesale distributor, or pharmacy, under a
379 prescription drug benefits coverage administered by a pharmacy
380 benefit manager, before any tax or cost is added and any
381 discount, rebate, or reduction in price, including a rebate
382 offered to the pharmacy benefit manager, is subtracted.

383 2. "Net price" means the value at which a prescription
384 drug is sold by a prescription drug manufacturer, prescription
385 drug wholesale distributor, or pharmacy, under a prescription
386 drug benefits coverage administered by a pharmacy benefit
387 manager, after all taxes and other costs are added and all
388 discounts, rebates, and reductions in price are subtracted,
389 including any rebate offered to the pharmacy benefit manager
390 which is passed on to the health insurer or health maintenance
391 organization.

392 3. "Rebate offered to a pharmacy benefit manager" means a
393 direct payment by a prescription drug manufacturer, prescription
394 drug wholesale distributor, or pharmacy to a pharmacy benefit
395 manager for a prescription drug dispensed to an insured or
396 subscriber. Such payment serves an incentive for the pharmacy
397 benefit manager to promote use of the prescription drug, and the
398 pharmacy benefit manager may choose to keep the payment or to
399 pass it on, in full or in part, to the health insurer or health
400 maintenance organization.

401 (b)1. By July 1 of each year, a registered pharmacy
402 benefit manager shall submit a report to the office on each
403 prescription drug for which the negotiated price, during the
404 previous calendar year:

405 a. Was \$100 or more for a 30-day supply or for a course of
406 treatment lasting less than 30 days; or

407 b. Increased by at least 10 percent over the previous
408 negotiated price.

409 2. The report must include, at a minimum, the following
410 information:

411 a. The name and the negotiated price at the time of the
412 report of each prescription drug specified in subparagraph 1.
413 and the cumulative percentage negotiated price increase during
414 the previous calendar year.

415 b. The name of any generic version of the prescription drug
416 available on the market.

417 c. The total sales revenue of the pharmacy benefit manager
418 for the prescription drug during the previous calendar year.

419 d. The documentation necessary to support the information
420 reported under this paragraph.

421 3. The office may make a written request to the pharmacy
422 benefit manager for supporting documentation or additional
423 information concerning the report. The commission shall
424 prescribe by rule the timeframes for the office's request for
425 documentation or information and for the pharmacy benefit

HB 1183

2022

426 manager's response to the request. The office may extend the
427 timeframe, if necessary, for the pharmacy benefit manager's
428 response.

429 (c) A registered pharmacy benefit manager shall maintain a
430 website that provides public access to the net price of each
431 prescription drug. The registered pharmacy benefit manager shall
432 update the net price of a prescription drug on the website at
433 least 90 days before the net price of the prescription drug
434 changes.

435 (d) A registered pharmacy benefit manager violates this
436 subsection if the registered pharmacy benefit manager:

437 1. Fails to timely submit the report required under
438 paragraph (b);

439 2. Fails to provide information required under paragraph
440 (b);

441 3. Fails to timely respond to a written request by the
442 office with regard to the report required under paragraph (b);

443 4. Provides inaccurate or incomplete information in the
444 report required under paragraph (b); or

445 5. Fails to maintain a website for access to net prices of
446 prescription drugs or to update the net prices on the website,
447 as required under paragraph (c).

448 (e)1. The office may deny an application for renewal
449 registration or suspend or revoke a registration certificate of
450 a pharmacy benefit manager for violating this subsection.

451 2.a. The office may also impose an administrative fine,
 452 not to exceed \$5,000 per violation per day, for a violation of
 453 this subsection or a rule adopted to administer this subsection.
 454 Each day the violation continues constitutes a separate
 455 violation, and each such separate violation is subject to a
 456 separate fine.

457 b. In determining the amount of fine to be levied for a
 458 violation of this subsection, the office must consider the
 459 following factors:

460 (I) The severity of the violation.

461 (II) Any action taken by the pharmacy benefit manager to
 462 correct the violation or to remedy complaints.

463 (III) Any previous violation.

464 c. All fines collected under this subsection shall be
 465 deposited into the Public Medical Assistance Trust Fund
 466 administered by the Agency for Health Care Administration, to be
 467 used to help the uninsured pay for health care.

468 Section 6. Section 627.42384, Florida Statutes, is created
 469 to read:

470 627.42384 Formulary changes resulting from drug price
 471 increases.-

472 (1) A health insurer issuing a major medical individual or
 473 group policy shall submit, and update as necessary, contact
 474 information for a single point of contact for use by
 475 prescription drug manufacturers to comply with s. 499.026. The

476 office shall maintain and publish on its website a list of such
477 points of contact.

478 (2) A health insurer issuing a major medical individual or
479 group policy must provide written notice to each affected
480 insured and each prescribing health care provider at least 90
481 days before making a drug formulary change that results from a
482 prescription drug price increase reported by a drug manufacturer
483 under s. 499.026(2).

484 (3) This section applies to policies entered into or
485 renewed on or after January 1, 2023.

486 Section 7. Paragraph (b) of subsection (1) of section
487 627.64741, Florida Statutes, is redesignated as paragraph (c),
488 subsection (5) is amended, a new paragraph (b) is added to
489 subsection (1), and paragraphs (c) through (f) are added to
490 subsection (2) of that section, to read:

491 627.64741 Pharmacy benefit manager contracts.—

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

493 (b) "Net price" means the value at which a prescription
494 drug is sold by a prescription drug manufacturer, prescription
495 drug wholesale distributor, or pharmacy, under a prescription
496 drug benefits coverage administered by a pharmacy benefit
497 manager, after all taxes and other costs are added and all
498 discounts, rebates, and reductions in price are subtracted,
499 including any rebate offered to the pharmacy benefit manager
500 which is passed on to the health insurer.

501 (2) A contract between a health insurer and a pharmacy
 502 benefit manager must require that the pharmacy benefit manager:

503 (c) Maintain a website that provides public access to the
 504 net price of each covered prescription drug and update the net
 505 price of a covered prescription drug on the website at least 90
 506 days before the net price of the covered prescription drug
 507 changes.

508 (d) Provide written notice to each affected insured and
 509 each prescribing health care provider at least 90 days before
 510 making a change in the drug formulary or in the net price of a
 511 covered prescription drug, including a change that results from
 512 a price increase of a covered prescription drug reported by a
 513 drug manufacturer under s. 499.026(2).

514 (e) Inform an affected insured, in writing, of the net
 515 price of each covered prescription drug for which the insured
 516 has made a payment.

517 (f) Provide in writing to each insured and each
 518 prescribing health care provider the address of the pharmacy
 519 benefit manager's website where the list of the net prices of
 520 all prescription drugs is posted.

521 (5) This section applies to contracts entered into or
 522 renewed on or after July 1, 2022 ~~July 1, 2018~~.

523 Section 8. Paragraph (b) of subsection (1) of section
 524 627.6572, Florida Statutes, is redesignated as paragraph (c),
 525 subsection (5) is amended, a new paragraph (b) is added to

526 subsection (1), and paragraphs (c) through (f) are added to
527 subsection (2) of that section, to read:

528 627.6572 Pharmacy benefit manager contracts.—

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

530 (b) "Net price" means the value at which a prescription
531 drug is sold by a prescription drug manufacturer, prescription
532 drug wholesale distributor, or pharmacy, under a prescription
533 drug benefits coverage administered by a pharmacy benefit
534 manager, after all taxes and other costs are added and all
535 discounts, rebates, and reductions in price are subtracted,
536 including any rebate offered to the pharmacy benefit manager
537 which is passed on to the health insurer.

538 (2) A contract between a health insurer and a pharmacy
539 benefit manager must require that the pharmacy benefit manager:

540 (c) Maintain a website that provides public access to the
541 net price of each covered prescription drug and update the net
542 price of a covered prescription drug on the website at least 90
543 days before the net price of the covered prescription drug
544 changes.

545 (d) Provide written notice to each affected insured and
546 each prescribing health care provider at least 90 days before
547 making a change in the drug formulary or in the net price of a
548 covered prescription drug, including a change that results from
549 a price increase of a covered prescription drug reported by a
550 drug manufacturer under s. 499.026(2).

551 (e) Inform an insured, in writing, of the net price of
 552 each covered prescription drug for which the insured has made a
 553 payment.

554 (f) Provide in writing to each insured and each
 555 prescribing health care provider the address of the pharmacy
 556 benefit manager's website where the list of the net prices of
 557 all covered prescription drugs is posted.

558 (5) This section applies to contracts entered into or
 559 renewed on or after July 1, 2022 ~~July 1, 2018~~.

560 Section 9. Section 641.3131, Florida Statutes, is created
 561 to read:

562 641.3131 Formulary changes resulting from drug price
 563 increases.—

564 (1) A health maintenance organization issuing a major
 565 medical or other comprehensive coverage contract shall submit,
 566 and update as necessary, contact information for a single point
 567 of contact for use by prescription drug manufacturers to comply
 568 with s. 499.026. The office shall maintain and publish on its
 569 website a list of such points of contact.

570 (2) A health maintenance organization issuing a major
 571 medical or other comprehensive coverage contract must provide
 572 written notice to each affected subscriber and each prescribing
 573 health care provider at least 90 days before making a drug
 574 formulary change that results from a prescription drug price
 575 increase reported by a drug manufacturer under s. 499.026(2).

576 (3) This section applies to contracts entered into or
577 renewed on or after January 1, 2023.

578 Section 10. Paragraph (b) of subsection (1) of 641.314,
579 Florida Statutes, is redesignated as paragraph (c), subsection
580 (5) is amended, a new paragraph (b) is added to subsection (1),
581 and paragraphs (c) through (f) are added to subsection (2) of
582 that section, to read:

583 641.314 Pharmacy benefit manager contracts.—

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

585 (b) "Net price" means the value at which a prescription
586 drug is sold by a prescription drug manufacturer, prescription
587 drug wholesale distributor, or pharmacy, under a prescription
588 drug benefits coverage administered by a pharmacy benefit
589 manager, after all taxes and other costs are added and all
590 discounts, rebates, and reductions in price are subtracted,
591 including any rebate offered to the pharmacy benefit manager
592 which is passed on to the health maintenance organization.

593 (2) A contract between a health maintenance organization
594 and a pharmacy benefit manager must require that the pharmacy
595 benefit manager:

596 (c) Maintain a website that provides public access to the
597 net price of each covered prescription drug and update the net
598 price of a covered prescription drug on the website at least 90
599 days before the net price of the covered prescription drug
600 changes.

HB 1183

2022

601 (d) Provide written notice to each affected subscriber and
602 each prescribing health care provider at least 90 days before
603 making a change in the drug formulary or in the net price of a
604 covered prescription drug, including a change that results from
605 a price increase of a covered prescription drug reported by a
606 drug manufacturer under s. 499.026(2).

607 (e) Inform a subscriber in writing of the net price of
608 each covered prescription drug for which the subscriber has made
609 a payment.

610 (f) Provide in writing to each subscriber and each
611 prescribing health care provider the address of the pharmacy
612 benefit manager's website where the list of the net prices of
613 all prescription drugs is posted.

614 (5) This section applies to contracts entered into or
615 renewed on or after July 1, 2022 ~~July 1, 2018~~.

616 Section 11. Subsections (3) and (4) and paragraph (a) of
617 subsection (9) of section 110.12315, Florida Statutes, are
618 amended to read:

619 110.12315 Prescription drug program.—The state employees'
620 prescription drug program is established. This program shall be
621 administered by the Department of Management Services, according
622 to the terms and conditions of the plan as established by the
623 relevant provisions of the annual General Appropriations Act and
624 implementing legislation, subject to the following conditions:

625 (3) The department shall maintain the generic, preferred

HB 1183

2022

626 brand name, and the nonpreferred brand name lists of drugs and
627 supplies to be used in the administration of the state
628 employees' prescription drug program. These lists may not
629 include a prescription drug for which the prescription drug
630 manufacturer does not comply with the requirements of s. 499.026
631 unless the prescription drug is the most clinically appropriate,
632 clinically effective, and lowest net-cost prescription drug.

633 (4) The department shall maintain a list of maintenance
634 drugs and supplies. The list may not include a drug for which
635 the prescription drug manufacturer does not comply with the
636 requirements of s. 499.026 unless the prescription drug is the
637 most clinically appropriate, clinically effective, and lowest
638 net-cost prescription drug.

639 (a) Preferred provider organization health plan members
640 may have prescriptions for maintenance drugs and supplies filled
641 up to three times as a supply for up to 30 days through a retail
642 pharmacy; thereafter, prescriptions for the same maintenance
643 drug or supply must be filled for up to 90 days either through
644 the department's contracted mail order pharmacy or through a
645 retail pharmacy.

646 (b) Health maintenance organization health plan members
647 may have prescriptions for maintenance drugs and supplies filled
648 for up to 90 days either through a mail order pharmacy or
649 through a retail pharmacy.

650 (9) (a) Beginning with the 2020 plan year, the department

651 must implement formulary management for prescription drugs and
652 supplies. Such management practices must require prescription
653 drugs to be subject to formulary inclusion or exclusion and,
654 beginning with the 2023 plan year, must require a prescription
655 drug for which the prescription drug manufacturer does not
656 comply with the requirements of s. 499.026 to be subject to
657 formulary exclusion, but may not restrict access to the most
658 clinically appropriate, clinically effective, and lowest net-
659 cost prescription drugs and supplies. Drugs excluded from the
660 formulary must be available for inclusion if a physician,
661 advanced practice registered nurse, or physician assistant
662 prescribing a pharmaceutical clearly states on the prescription
663 that the excluded drug is medically necessary. Prescription
664 drugs and supplies first made available in the marketplace after
665 January 1, 2020, may not be covered by the prescription drug
666 program until specifically included in the list of covered
667 prescription drugs and supplies.

668 Section 12. Paragraph (n) of subsection (2) of section
669 409.815, Florida Statutes, is amended to read:

670 409.815 Health benefits coverage; limitations.—

671 (2) BENCHMARK BENEFITS.—In order for health benefits
672 coverage to qualify for premium assistance payments for an
673 eligible child under ss. 409.810-409.821, the health benefits
674 coverage, except for coverage under Medicaid and Medikids, must
675 include the following minimum benefits, as medically necessary.

676 (n) Prescribed drugs.—

677 1. Coverage shall include drugs prescribed for the
 678 treatment of illness or injury when prescribed by a licensed
 679 health practitioner acting within the scope of his or her
 680 practice.

681 2. Prescribed drugs may be limited to generics if
 682 available and brand name products if a generic substitution is
 683 not available, unless the prescribing licensed health
 684 practitioner indicates that a brand name is medically necessary.

685 3. Prescribed drugs covered under this section shall
 686 include all prescribed drugs covered under the Florida Medicaid
 687 program.

688 4. Prescribed drugs may not include a prescription drug
 689 for which the manufacturer does not comply with the requirements
 690 of s. 499.026 unless the prescription drug is the most
 691 clinically appropriate, clinically effective, and lowest net-
 692 cost prescription drug or unless a physician, advanced practice
 693 registered nurse, or physician assistant prescribing the drug
 694 clearly states on the prescription that the excluded drug is
 695 medically necessary.

696 Section 13. Subsection (8) of section 409.91195, Florida
 697 Statutes, is amended to read:

698 409.91195 Medicaid Pharmaceutical and Therapeutics
 699 Committee.—There is created a Medicaid Pharmaceutical and
 700 Therapeutics Committee within the agency for the purpose of

701 developing a Medicaid preferred drug list.

702 (8) The committee shall develop its preferred drug list
703 recommendations by considering the clinical efficacy, safety,
704 and cost-effectiveness of a product and the manufacturer's
705 prescription drug price transparency, as required under s.
706 499.012.

707 Section 14. Paragraph (a) of subsection (5) of section
708 409.912, Florida Statutes, is amended to read:

709 409.912 Cost-effective purchasing of health care.—The
710 agency shall purchase goods and services for Medicaid recipients
711 in the most cost-effective manner consistent with the delivery
712 of quality medical care. To ensure that medical services are
713 effectively utilized, the agency may, in any case, require a
714 confirmation or second physician's opinion of the correct
715 diagnosis for purposes of authorizing future services under the
716 Medicaid program. This section does not restrict access to
717 emergency services or poststabilization care services as defined
718 in 42 C.F.R. s. 438.114. Such confirmation or second opinion
719 shall be rendered in a manner approved by the agency. The agency
720 shall maximize the use of prepaid per capita and prepaid
721 aggregate fixed-sum basis services when appropriate and other
722 alternative service delivery and reimbursement methodologies,
723 including competitive bidding pursuant to s. 287.057, designed
724 to facilitate the cost-effective purchase of a case-managed
725 continuum of care. The agency shall also require providers to

726 minimize the exposure of recipients to the need for acute
727 inpatient, custodial, and other institutional care and the
728 inappropriate or unnecessary use of high-cost services. The
729 agency shall contract with a vendor to monitor and evaluate the
730 clinical practice patterns of providers in order to identify
731 trends that are outside the normal practice patterns of a
732 provider's professional peers or the national guidelines of a
733 provider's professional association. The vendor must be able to
734 provide information and counseling to a provider whose practice
735 patterns are outside the norms, in consultation with the agency,
736 to improve patient care and reduce inappropriate utilization.
737 The agency may mandate prior authorization, drug therapy
738 management, or disease management participation for certain
739 populations of Medicaid beneficiaries, certain drug classes, or
740 particular drugs to prevent fraud, abuse, overuse, and possible
741 dangerous drug interactions. The Pharmaceutical and Therapeutics
742 Committee shall make recommendations to the agency on drugs for
743 which prior authorization is required. The agency shall inform
744 the Pharmaceutical and Therapeutics Committee of its decisions
745 regarding drugs subject to prior authorization. The agency is
746 authorized to limit the entities it contracts with or enrolls as
747 Medicaid providers by developing a provider network through
748 provider credentialing. The agency may competitively bid single-
749 source-provider contracts if procurement of goods or services
750 results in demonstrated cost savings to the state without

751 limiting access to care. The agency may limit its network based
752 on the assessment of beneficiary access to care, provider
753 availability, provider quality standards, time and distance
754 standards for access to care, the cultural competence of the
755 provider network, demographic characteristics of Medicaid
756 beneficiaries, practice and provider-to-beneficiary standards,
757 appointment wait times, beneficiary use of services, provider
758 turnover, provider profiling, provider licensure history,
759 previous program integrity investigations and findings, peer
760 review, provider Medicaid policy and billing compliance records,
761 clinical and medical record audits, and other factors. Providers
762 are not entitled to enrollment in the Medicaid provider network.
763 The agency shall determine instances in which allowing Medicaid
764 beneficiaries to purchase durable medical equipment and other
765 goods is less expensive to the Medicaid program than long-term
766 rental of the equipment or goods. The agency may establish rules
767 to facilitate purchases in lieu of long-term rentals in order to
768 protect against fraud and abuse in the Medicaid program as
769 defined in s. 409.913. The agency may seek federal waivers
770 necessary to administer these policies.

771 (5)(a) The agency shall implement a Medicaid prescribed-
772 drug spending-control program that includes the following
773 components:

774 1. A Medicaid preferred drug list, which shall be a
775 listing of cost-effective therapeutic options recommended by the

HB 1183

2022

776 Medicaid Pharmacy and Therapeutics Committee established
777 pursuant to s. 409.91195 and adopted by the agency for each
778 therapeutic class on the preferred drug list. At the discretion
779 of the committee, and when feasible, the preferred drug list
780 should include at least two products in a therapeutic class. The
781 agency may post the preferred drug list and updates to the list
782 on an Internet website without following the rulemaking
783 procedures of chapter 120. Drugs for which the manufacturer does
784 not comply with the requirements of s. 499.026 are excluded from
785 the preferred list, unless the drug is the most clinically
786 appropriate, clinically effective, and lowest net-cost
787 prescription drug. Antiretroviral agents are excluded from the
788 preferred drug list. The agency shall also limit the amount of a
789 prescribed drug dispensed to no more than a 34-day supply unless
790 the drug products' smallest marketed package is greater than a
791 34-day supply, or the drug is determined by the agency to be a
792 maintenance drug in which case a 100-day maximum supply may be
793 authorized. The agency may seek any federal waivers necessary to
794 implement these cost-control programs and to continue
795 participation in the federal Medicaid rebate program, or
796 alternatively to negotiate state-only manufacturer rebates. The
797 agency may adopt rules to administer this subparagraph. The
798 agency shall continue to provide unlimited contraceptive drugs
799 and items. The agency must establish procedures to ensure that:
800 a. There is a response to a request for prior

801 authorization by telephone or other telecommunication device
802 within 24 hours after receipt of a request for prior
803 authorization; and

804 b. A 72-hour supply of the drug prescribed is provided in
805 an emergency or when the agency does not provide a response
806 within 24 hours as required by sub-subparagraph a.

807 2. A provider of prescribed drugs is reimbursed in an
808 amount not to exceed the lesser of the actual acquisition cost
809 based on the Centers for Medicare and Medicaid Services National
810 Average Drug Acquisition Cost pricing files plus a professional
811 dispensing fee, the wholesale acquisition cost plus a
812 professional dispensing fee, the state maximum allowable cost
813 plus a professional dispensing fee, or the usual and customary
814 charge billed by the provider.

815 3. The agency shall develop and implement a process for
816 managing the drug therapies of Medicaid recipients who are using
817 significant numbers of prescribed drugs each month. The
818 management process may include, but is not limited to,
819 comprehensive, physician-directed medical-record reviews, claims
820 analyses, and case evaluations to determine the medical
821 necessity and appropriateness of a patient's treatment plan and
822 drug therapies. The agency may contract with a private
823 organization to provide drug-program-management services. The
824 Medicaid drug benefit management program shall include
825 initiatives to manage drug therapies for HIV/AIDS patients,

826 patients using 20 or more unique prescriptions in a 180-day
827 period, and the top 1,000 patients in annual spending. The
828 agency shall enroll any Medicaid recipient in the drug benefit
829 management program if he or she meets the specifications of this
830 provision and is not enrolled in a Medicaid health maintenance
831 organization.

832 4. The agency may limit the size of its pharmacy network
833 based on need, competitive bidding, price negotiations,
834 credentialing, or similar criteria. The agency shall give
835 special consideration to rural areas in determining the size and
836 location of pharmacies included in the Medicaid pharmacy
837 network. A pharmacy credentialing process may include criteria
838 such as a pharmacy's full-service status, location, size,
839 patient educational programs, patient consultation, disease
840 management services, and other characteristics. The agency may
841 impose a moratorium on Medicaid pharmacy enrollment if it is
842 determined that it has a sufficient number of Medicaid-
843 participating providers. The agency must allow dispensing
844 practitioners to participate as a part of the Medicaid pharmacy
845 network regardless of the practitioner's proximity to any other
846 entity that is dispensing prescription drugs under the Medicaid
847 program. A dispensing practitioner must meet all credentialing
848 requirements applicable to his or her practice, as determined by
849 the agency.

850 5. The agency shall develop and implement a program that

851 requires Medicaid practitioners who issue written prescriptions
852 for medicinal drugs to use a counterfeit-proof prescription pad
853 for Medicaid prescriptions. The agency shall require the use of
854 standardized counterfeit-proof prescription pads by prescribers
855 who issue written prescriptions for Medicaid recipients. The
856 agency may implement the program in targeted geographic areas or
857 statewide.

858 6. The agency may enter into arrangements that require
859 manufacturers of generic drugs prescribed to Medicaid recipients
860 to provide rebates of at least 15.1 percent of the average
861 manufacturer price for the manufacturer's generic products.
862 These arrangements shall require that if a generic-drug
863 manufacturer pays federal rebates for Medicaid-reimbursed drugs
864 at a level below 15.1 percent, the manufacturer must provide a
865 supplemental rebate to the state in an amount necessary to
866 achieve a 15.1-percent rebate level.

867 7. The agency may establish a preferred drug list as
868 described in this subsection, and, pursuant to the establishment
869 of such preferred drug list, negotiate supplemental rebates from
870 manufacturers that are in addition to those required by Title
871 XIX of the Social Security Act and at no less than 14 percent of
872 the average manufacturer price as defined in 42 U.S.C. s. 1936
873 on the last day of a quarter unless the federal or supplemental
874 rebate, or both, equals or exceeds 29 percent. There is no upper
875 limit on the supplemental rebates the agency may negotiate. The

HB 1183

2022

876 agency may determine that specific products, brand-name or
877 generic, are competitive at lower rebate percentages. Agreement
878 to pay the minimum supplemental rebate percentage guarantees a
879 manufacturer that the Medicaid Pharmaceutical and Therapeutics
880 Committee will consider a product for inclusion on the preferred
881 drug list. However, a pharmaceutical manufacturer is not
882 guaranteed placement on the preferred drug list by simply paying
883 the minimum supplemental rebate. Agency decisions will be made
884 on the clinical efficacy of a drug and recommendations of the
885 Medicaid Pharmaceutical and Therapeutics Committee, as well as
886 the price of competing products minus federal and state rebates.
887 The agency may contract with an outside agency or contractor to
888 conduct negotiations for supplemental rebates. For the purposes
889 of this section, the term "supplemental rebates" means cash
890 rebates. Value-added programs as a substitution for supplemental
891 rebates are prohibited. The agency may seek any federal waivers
892 to implement this initiative.

893 8.a. The agency may implement a Medicaid behavioral drug
894 management system. The agency may contract with a vendor that
895 has experience in operating behavioral drug management systems
896 to implement this program. The agency may seek federal waivers
897 to implement this program.

898 b. The agency, in conjunction with the Department of
899 Children and Families, may implement the Medicaid behavioral
900 drug management system that is designed to improve the quality

901 of care and behavioral health prescribing practices based on
902 best practice guidelines, improve patient adherence to
903 medication plans, reduce clinical risk, and lower prescribed
904 drug costs and the rate of inappropriate spending on Medicaid
905 behavioral drugs. The program may include the following
906 elements:

907 (I) Provide for the development and adoption of best
908 practice guidelines for behavioral health-related drugs such as
909 antipsychotics, antidepressants, and medications for treating
910 bipolar disorders and other behavioral conditions; translate
911 them into practice; review behavioral health prescribers and
912 compare their prescribing patterns to a number of indicators
913 that are based on national standards; and determine deviations
914 from best practice guidelines.

915 (II) Implement processes for providing feedback to and
916 educating prescribers using best practice educational materials
917 and peer-to-peer consultation.

918 (III) Assess Medicaid beneficiaries who are outliers in
919 their use of behavioral health drugs with regard to the numbers
920 and types of drugs taken, drug dosages, combination drug
921 therapies, and other indicators of improper use of behavioral
922 health drugs.

923 (IV) Alert prescribers to patients who fail to refill
924 prescriptions in a timely fashion, are prescribed multiple same-
925 class behavioral health drugs, and may have other potential

926 medication problems.

927 (V) Track spending trends for behavioral health drugs and
928 deviation from best practice guidelines.

929 (VI) Use educational and technological approaches to
930 promote best practices, educate consumers, and train prescribers
931 in the use of practice guidelines.

932 (VII) Disseminate electronic and published materials.

933 (VIII) Hold statewide and regional conferences.

934 (IX) Implement a disease management program with a model
935 quality-based medication component for severely mentally ill
936 individuals and emotionally disturbed children who are high
937 users of care.

938 9. The agency shall implement a Medicaid prescription drug
939 management system.

940 a. The agency may contract with a vendor that has
941 experience in operating prescription drug management systems in
942 order to implement this system. Any management system that is
943 implemented in accordance with this subparagraph must rely on
944 cooperation between physicians and pharmacists to determine
945 appropriate practice patterns and clinical guidelines to improve
946 the prescribing, dispensing, and use of drugs in the Medicaid
947 program. The agency may seek federal waivers to implement this
948 program.

949 b. The drug management system must be designed to improve
950 the quality of care and prescribing practices based on best

951 practice guidelines, improve patient adherence to medication
952 plans, reduce clinical risk, and lower prescribed drug costs and
953 the rate of inappropriate spending on Medicaid prescription
954 drugs. The program must:

955 (I) Provide for the adoption of best practice guidelines
956 for the prescribing and use of drugs in the Medicaid program,
957 including translating best practice guidelines into practice;
958 reviewing prescriber patterns and comparing them to indicators
959 that are based on national standards and practice patterns of
960 clinical peers in their community, statewide, and nationally;
961 and determine deviations from best practice guidelines.

962 (II) Implement processes for providing feedback to and
963 educating prescribers using best practice educational materials
964 and peer-to-peer consultation.

965 (III) Assess Medicaid recipients who are outliers in their
966 use of a single or multiple prescription drugs with regard to
967 the numbers and types of drugs taken, drug dosages, combination
968 drug therapies, and other indicators of improper use of
969 prescription drugs.

970 (IV) Alert prescribers to recipients who fail to refill
971 prescriptions in a timely fashion, are prescribed multiple drugs
972 that may be redundant or contraindicated, or may have other
973 potential medication problems.

974 10. The agency may contract for drug rebate
975 administration, including, but not limited to, calculating

976 rebate amounts, invoicing manufacturers, negotiating disputes
 977 with manufacturers, and maintaining a database of rebate
 978 collections.

979 11. The agency may specify the preferred daily dosing form
 980 or strength for the purpose of promoting best practices with
 981 regard to the prescribing of certain drugs as specified in the
 982 General Appropriations Act and ensuring cost-effective
 983 prescribing practices.

984 12. The agency may require prior authorization for
 985 Medicaid-covered prescribed drugs. The agency may prior-
 986 authorize the use of a product:

- 987 a. For an indication not approved in labeling;
- 988 b. To comply with certain clinical guidelines; or
- 989 c. If the product has the potential for overuse, misuse,
 990 or abuse.

991
 992 The agency may require the prescribing professional to provide
 993 information about the rationale and supporting medical evidence
 994 for the use of a drug. The agency shall post prior
 995 authorization, step-edit criteria and protocol, and updates to
 996 the list of drugs that are subject to prior authorization on the
 997 agency's Internet website within 21 days after the prior
 998 authorization and step-edit criteria and protocol and updates
 999 are approved by the agency. For purposes of this subparagraph,
 1000 the term "step-edit" means an automatic electronic review of

HB 1183

2022

1001 certain medications subject to prior authorization.

1002 13. The agency, in conjunction with the Pharmaceutical and
1003 Therapeutics Committee, may require age-related prior
1004 authorizations for certain prescribed drugs. The agency may
1005 preauthorize the use of a drug for a recipient who may not meet
1006 the age requirement or may exceed the length of therapy for use
1007 of this product as recommended by the manufacturer and approved
1008 by the Food and Drug Administration. Prior authorization may
1009 require the prescribing professional to provide information
1010 about the rationale and supporting medical evidence for the use
1011 of a drug.

1012 14. The agency shall implement a step-therapy prior
1013 authorization approval process for medications excluded from the
1014 preferred drug list. Medications listed on the preferred drug
1015 list must be used within the previous 12 months before the
1016 alternative medications that are not listed. The step-therapy
1017 prior authorization may require the prescriber to use the
1018 medications of a similar drug class or for a similar medical
1019 indication unless contraindicated in the Food and Drug
1020 Administration labeling. The trial period between the specified
1021 steps may vary according to the medical indication. The step-
1022 therapy approval process shall be developed in accordance with
1023 the committee as stated in s. 409.91195(7) and (8). A drug
1024 product may be approved without meeting the step-therapy prior
1025 authorization criteria if the prescribing physician provides the

HB 1183

2022

1026 agency with additional written medical or clinical documentation
1027 that the product is medically necessary because:

1028 a. There is not a drug on the preferred drug list to treat
1029 the disease or medical condition which is an acceptable clinical
1030 alternative;

1031 b. The alternatives have been ineffective in the treatment
1032 of the beneficiary's disease; or

1033 c. Based on historic evidence and known characteristics of
1034 the patient and the drug, the drug is likely to be ineffective,
1035 or the number of doses have been ineffective.

1036

1037 The agency shall work with the physician to determine the best
1038 alternative for the patient. The agency may adopt rules waiving
1039 the requirements for written clinical documentation for specific
1040 drugs in limited clinical situations.

1041 15. The agency shall implement a return and reuse program
1042 for drugs dispensed by pharmacies to institutional recipients,
1043 which includes payment of a \$5 restocking fee for the
1044 implementation and operation of the program. The return and
1045 reuse program shall be implemented electronically and in a
1046 manner that promotes efficiency. The program must permit a
1047 pharmacy to exclude drugs from the program if it is not
1048 practical or cost-effective for the drug to be included and must
1049 provide for the return to inventory of drugs that cannot be
1050 credited or returned in a cost-effective manner. The agency

HB 1183

2022

1051 shall determine if the program has reduced the amount of
1052 Medicaid prescription drugs which are destroyed on an annual
1053 basis and if there are additional ways to ensure more
1054 prescription drugs are not destroyed which could safely be
1055 reused.

1056 Section 15. Subsection (9) of section 499.067, Florida
1057 Statutes, is amended to read:

1058 499.067 Denial, suspension, or revocation of permit,
1059 certification, or registration.—

1060 (9)(a) The department may deny, suspend, or revoke a
1061 permit under this part if it finds the permittee has not
1062 complied with the reporting requirements of, or knowingly made a
1063 false statement in a report required by, s. 499.0121(14).

1064 (b) The department may deny an application for a renewal
1065 permit or suspend or revoke a permit if it finds the permittee
1066 has not complied with the reporting requirements of, or
1067 knowingly made a false statement in a report required by, s.
1068 499.0121(16).

1069 (c) The department may deny an application for a renewal
1070 permit or suspend or revoke a permit if it finds the permittee
1071 has not complied with the notification or reporting requirements
1072 of, or knowingly made a false statement in a notice or report
1073 required by, s. 499.026(2) or (3), respectively.

1074 Section 16. This act shall take effect July 1, 2022.