



231424

588-02257A-09

Proposed Committee Substitute by the Committee on Health
Regulation

1 A bill to be entitled
2 An act relating to the purchase of prescription drugs;
3 amending s. 499.003, F.S.; defining the term
4 "qualifying practitioner" as it relates to the Florida
5 Drug and Cosmetic Act; amending s. 499.01, F.S.;
6 deleting provisions requiring a health care clinic
7 establishment permit for the purchase of certain
8 prescription drugs; conforming a cross-reference;
9 amending s. 499.01211, F.S.; conforming a cross-
10 reference; amending s. 499.03, F.S.; authorizing
11 certain establishments to possess prescription drugs;
12 creating s. 499.031, F.S.; establishing criteria for
13 certain business entities to purchase and possess
14 prescription drugs; requiring a qualifying
15 practitioner at the establishment; requiring the
16 registration of certain qualifying practitioners;
17 assigning duties and responsibilities to a qualifying
18 practitioner and business entity; requiring the
19 Department of Health to establish an online
20 registration system and post certain information
21 related to qualifying practitioners on its website;
22 providing additional grounds for discipline of a
23 qualifying practitioner; providing recordkeeping
24 requirements; amending s. 499.041, F.S.; deleting
25 provisions requiring a fee for a health care clinic
26 establishment permit to conform to changes made by the
27 act; requiring a fee to register as a qualifying



231424

588-02257A-09

28 practitioner; authorizing a nonrefundable application
29 fee for withdrawn applications or applications that
30 become void; amending s. 499.05, F.S.; conforming
31 cross-references; amending s. 400.9935, F.S.;
32 assigning responsibilities to a medical director who
33 acts as the qualifying practitioner of a licensed
34 health care clinic; amending ss. 409.9201 and
35 465.0265, F.S.; conforming cross-references; providing
36 an effective date.

37

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

39

40 Section 1. Present subsections (48) through (54) of section
41 499.003, Florida Statutes, are renumbered as subsections (49)
42 through (55), respectively, and a new subsection (48) is added
43 to that section, to read:

44 499.003 Definitions of terms used in this part.—As used in
45 this part, the term:

46 (48) "Qualifying practitioner" means a licensed health care
47 practitioner as defined in s. 456.001, or a veterinarian
48 licensed under chapter 474, who is authorized under the
49 appropriate practice act to prescribe and administer a
50 prescription drug.

51 Section 2. Subsection (1) and paragraphs (g) and (t) of
52 subsection (2) of section 499.01, Florida Statutes, are amended
53 to read:

54 499.01 Permits.—

55 (1) Prior to operating, a permit is required for each
56 person and establishment that intends to operate as:



231424

588-02257A-09

- 57 (a) A prescription drug manufacturer;
- 58 (b) A prescription drug repackager;
- 59 (c) A nonresident prescription drug manufacturer;
- 60 (d) A prescription drug wholesale distributor;
- 61 (e) An out-of-state prescription drug wholesale
- 62 distributor;
- 63 (f) A retail pharmacy drug wholesale distributor;
- 64 (g) A restricted prescription drug distributor;
- 65 (h) A complimentary drug distributor;
- 66 (i) A freight forwarder;
- 67 (j) A veterinary prescription drug retail establishment;
- 68 (k) A veterinary prescription drug wholesale distributor;
- 69 (l) A limited prescription drug veterinary wholesale
- 70 distributor;
- 71 (m) A medical oxygen retail establishment;
- 72 (n) A compressed medical gas wholesale distributor;
- 73 (o) A compressed medical gas manufacturer;
- 74 (p) An over-the-counter drug manufacturer;
- 75 (q) A device manufacturer;
- 76 (r) A cosmetic manufacturer; or
- 77 (s) A third party logistics provider. ~~or~~
- 78 ~~(t) A health care clinic establishment.~~
- 79 (2) The following permits are established:
- 80 (g) *Restricted prescription drug distributor permit.*—A
- 81 restricted prescription drug distributor permit is required for
- 82 any person that engages in the distribution of a prescription
- 83 drug, which distribution is not considered “wholesale
- 84 distribution” under s. 499.003(54)(a) ~~s. 499.003(53)(a)~~.
- 85 1. A person who engages in the receipt or distribution of a



231424

588-02257A-09

86 prescription drug in this state for the purpose of processing
87 its return or its destruction must obtain a permit as a
88 restricted prescription drug distributor if such person is not
89 the person initiating the return, the prescription drug
90 wholesale supplier of the person initiating the return, or the
91 manufacturer of the drug.

92 2. Storage, handling, and recordkeeping of these
93 distributions must comply with the requirements for wholesale
94 distributors under s. 499.0121, but not those set forth in s.
95 499.01212.

96 3. A person who applies for a permit as a restricted
97 prescription drug distributor, or for the renewal of such a
98 permit, must provide to the department the information required
99 under s. 499.012.

100 4. The department may adopt rules regarding the
101 distribution of prescription drugs by hospitals, health care
102 entities, charitable organizations, or other persons not
103 involved in wholesale distribution, which rules are necessary
104 for the protection of the public health, safety, and welfare.

105 ~~(t) Health care clinic establishment permit. Effective~~
106 ~~January 1, 2009, a health care clinic establishment permit is~~
107 ~~required for the purchase of a prescription drug by a place of~~
108 ~~business at one general physical location owned and operated by~~
109 ~~a professional corporation or professional limited liability~~
110 ~~company described in chapter 621, or a corporation that employs~~
111 ~~a veterinarian as a qualifying practitioner. For the purpose of~~
112 ~~this paragraph, the term "qualifying practitioner" means a~~
113 ~~licensed health care practitioner defined in s. 456.001 or a~~
114 ~~veterinarian licensed under chapter 474, who is authorized under~~



231424

588-02257A-09

115 ~~the appropriate practice act to prescribe and administer a~~
116 ~~prescription drug.~~

117 ~~1. An establishment must provide, as part of the~~
118 ~~application required under s. 499.012, designation of a~~
119 ~~qualifying practitioner who will be responsible for complying~~
120 ~~with all legal and regulatory requirements related to the~~
121 ~~purchase, recordkeeping, storage, and handling of the~~
122 ~~prescription drugs. In addition, the designated qualifying~~
123 ~~practitioner shall be the practitioner whose name, establishment~~
124 ~~address, and license number is used on all distribution~~
125 ~~documents for prescription drugs purchased or returned by the~~
126 ~~health care clinic establishment. Upon initial appointment of a~~
127 ~~qualifying practitioner, the qualifying practitioner and the~~
128 ~~health care clinic establishment shall notify the department on~~
129 ~~a form furnished by the department within 10 days after such~~
130 ~~employment. In addition, the qualifying practitioner and health~~
131 ~~care clinic establishment shall notify the department within 10~~
132 ~~days after any subsequent change.~~

133 ~~2. The health care clinic establishment must employ a~~
134 ~~qualifying practitioner at each establishment.~~

135 ~~3. In addition to the remedies and penalties provided in~~
136 ~~this part, a violation of this chapter by the health care clinic~~
137 ~~establishment or qualifying practitioner constitutes grounds for~~
138 ~~discipline of the qualifying practitioner by the appropriate~~
139 ~~regulatory board.~~

140 ~~4. The purchase of prescription drugs by the health care~~
141 ~~clinic establishment is prohibited during any period of time~~
142 ~~when the establishment does not comply with this paragraph.~~

143 ~~5. A health care clinic establishment permit is not a~~



231424

588-02257A-09

144 ~~pharmacy permit or otherwise subject to chapter 465. A health~~
145 ~~care clinic establishment that meets the criteria of a modified~~
146 ~~Class II institutional pharmacy under s. 465.019 is not eligible~~
147 ~~to be permitted under this paragraph.~~

148 ~~6. This paragraph does not prohibit a qualifying~~
149 ~~practitioner from purchasing prescription drugs.~~

150 Section 3. Paragraph (b) of subsection (2) of section
151 499.01211, Florida Statutes, is amended to read:

152 499.01211 Drug Wholesale Distributor Advisory Council.—

153 (2) The State Surgeon General, or his or her designee, and
154 the Secretary of Health Care Administration, or her or his
155 designee, shall be members of the council. The State Surgeon
156 General shall appoint nine additional members to the council who
157 shall be appointed to a term of 4 years each, as follows:

158 (b) One person employed by a prescription drug wholesale
159 distributor licensed under this part which is a secondary
160 wholesale distributor, as defined in s. 499.003(52) ~~s.~~
161 ~~499.003(51)~~.

162 Section 4. Subsection (1) of section 499.03, Florida
163 Statutes, is amended to read:

164 499.03 Possession of certain drugs without prescriptions
165 unlawful; exemptions and exceptions.—

166 (1) A person may not possess, or possess with intent to
167 sell, dispense, or deliver, any habit-forming, toxic, harmful,
168 or new drug subject to s. 499.003(32), or prescription drug as
169 defined in s. 499.003(42), unless the possession of the drug has
170 been obtained by a valid prescription of a practitioner licensed
171 by law to prescribe the drug. However, this section does not
172 apply to the delivery of such drugs to persons included in any



231424

588-02257A-09

173 of the classes named in this subsection, or to the agents or
174 employees of such persons, for use in the usual course of their
175 businesses or practices or in the performance of their official
176 duties, as the case may be; nor does this section apply to the
177 possession of such drugs by those persons or their agents or
178 employees for such use:

179 (a) A licensed pharmacist or any person under the licensed
180 pharmacist's supervision while acting within the scope of the
181 licensed pharmacist's practice;

182 (b) A licensed practitioner authorized by law to prescribe
183 prescription drugs or any person under the licensed
184 practitioner's supervision while acting within the scope of the
185 licensed practitioner's practice;

186 (c) A qualified person who uses prescription drugs for
187 lawful research, teaching, or testing, and not for resale;

188 (d) A licensed hospital or other institution that procures
189 such drugs for lawful administration or dispensing by
190 practitioners;

191 (e) An officer or employee of a federal, state, or local
192 government; ~~or~~

193 (f) A person that holds a valid permit issued by the
194 department pursuant to this part which authorizes that person to
195 possess prescription drugs; or

196 (g) An establishment of a legal business entity at which
197 qualifying practitioners practice their profession under state
198 law if the establishment complies with s. 499.031.

199 Section 5. Section 499.031, Florida Statutes, is created to
200 read:

201 499.031 Medical and veterinary clinics; purchase and



231424

588-02257A-09

202 possession of prescription drugs; registration and duties of
203 qualifying practitioners.-

204 (1) An establishment of a legal business entity that has
205 been issued a federal tax identification number and through
206 which qualifying practitioners practice their profession under
207 state law and that:

208 (a) Has a qualifying practitioner registered with the
209 department who is an owner or member of the entity or an
210 employee of the entity at that establishment; or

211 (b) Is a health care clinic licensed under part X of
212 chapter 400 which has included in the medical director's written
213 agreement the responsibility to serve as the qualifying
214 practitioner for the clinic,

215
216 may purchase and possess prescription drugs in the name of the
217 business entity in accordance with this section.

218 (2) A health care clinic licensed under part X of chapter
219 400 which does not have a medical director as provided in
220 subsection (1) for more than 10 days must register a qualifying
221 practitioner who meets the requirements of paragraph (1)(a) with
222 the department in order to purchase and possess prescription
223 drugs.

224 (3) A qualifying practitioner who is registered with the
225 department for an establishment and the business entity must
226 each notify the department, and any person from whom the
227 business entity has purchased prescription drugs for that
228 establishment in the previous 6 months, within 10 days after the
229 qualifying practitioner ceases serving as the qualifying
230 practitioner for that establishment. An establishment that is



231424

588-02257A-09

231 required to have a qualifying practitioner registered with the
232 department must have a new qualifying practitioner registered
233 with the department within 10 days after a registered qualifying
234 practitioner ceases serving in that capacity.

235 (4) The business entity may purchase only prescription
236 drugs that the registered qualifying practitioner or medical
237 director serving as the qualifying practitioner of the
238 establishment is authorized to prescribe. The authorization to
239 purchase prescription drugs under this section is not a permit
240 that authorizes the purchase and possession of controlled
241 substances, and the business entity and establishment must
242 comply with chapter 893 and applicable federal law related to
243 controlled substances.

244 (5) The qualifying practitioner is responsible for
245 complying with all legal and regulatory requirements related to
246 the purchase, recordkeeping, storage, and handling of the
247 prescription drugs purchased by the business entity of the
248 establishment for which the health care practitioner or
249 veterinarian is the qualifying practitioner. A qualifying
250 practitioner must ensure that there are policies and procedures
251 for handling prescription drugs at an establishment which
252 protect the integrity of the drugs at the establishment and the
253 public health upon the termination of the qualifying
254 practitioner from serving in that capacity at the establishment.

255 (6) A qualifying practitioner at an establishment for which
256 a business entity wishes to purchase prescription drugs, other
257 than the medical director of a health care clinic as described
258 in paragraph (1) (b), must:

259 (a) Register with the department his or her name and



231424

588-02257A-09

260 practitioner license number, the name of the business entity
261 that will be purchasing prescription drugs, and the address of
262 the establishment for which he or she is the qualifying
263 practitioner;

264 (b) Certify acceptance of the responsibilities of a
265 qualifying practitioner; and

266 (c) Pay the registration fee required in s. 499.041(10).

267 (7) A registration under this section does not expire as
268 long as the qualifying practitioner maintains his or her
269 professional license and does not cease serving as the
270 qualifying practitioner for the business entity at that
271 establishment.

272 (8) The department shall establish an online system for the
273 registration of qualifying practitioners. Until the online
274 system is operational, the department must accept any written
275 document that provides the information required in subsection
276 (6), along with the registration fee. The name of the purchasing
277 business entity; the address of the establishment; and the name,
278 license number, and registration number of the qualifying
279 practitioner must be published on the department's website.

280 (9) In addition to the remedies and penalties provided in
281 this part, a violation of this part constitutes grounds for
282 discipline against the qualifying practitioner by the
283 appropriate regulatory board.

284 (10) In addition to other recordkeeping requirements,
285 distribution documents for prescription drugs purchased or
286 returned by:

287 (a) An establishment that has a registered qualifying
288 practitioner must include the registration number of the



231424

588-02257A-09

289 qualifying practitioner; or

290 (b) A health care clinic that has a medical director
291 serving as the qualifying practitioner must include the health
292 care clinic license number.

293 (11) This section does not prohibit a licensed practitioner
294 whose professional license authorizes the practitioner to
295 prescribe prescription drugs from purchasing prescription drugs
296 under his or her practice license.

297 Section 6. Section 499.041, Florida Statutes, is amended to
298 read:

299 499.041 Schedule of fees for drug, device, and cosmetic
300 applications and permits, product registrations, and free-sale
301 certificates.—

302 (1) The department shall assess applicants requiring a
303 manufacturing permit an annual fee within the ranges established
304 in this section for the specific type of manufacturer.

305 (a) The fee for a prescription drug manufacturer permit may
306 not be less than \$500 or more than \$750 annually.

307 (b) The fee for a device manufacturer permit may not be
308 less than \$500 or more than \$600 annually.

309 (c) The fee for a cosmetic manufacturer permit may not be
310 less than \$250 or more than \$400 annually.

311 (d) The fee for an over-the-counter drug manufacturer
312 permit may not be less than \$300 or more than \$400 annually.

313 (e) The fee for a compressed medical gas manufacturer
314 permit may not be less than \$400 or more than \$500 annually.

315 (f) The fee for a prescription drug repackager permit may
316 not be less than \$500 or more than \$750 annually.

317 (g) A manufacturer may not be required to pay more than one



231424

588-02257A-09

318 fee per establishment to obtain an additional manufacturing
319 permit, but each manufacturer must pay the highest fee
320 applicable to his or her operation in each establishment.

321 (2) The department shall assess an applicant that is
322 required to have a wholesaling permit an annual fee within the
323 ranges established in this section for the specific type of
324 wholesaling.

325 (a) The fee for a prescription drug wholesale distributor
326 permit may not be less than \$300 or more than \$800 annually.

327 (b) The fee for a compressed medical gas wholesale
328 distributor permit may not be less than \$200 or more than \$300
329 annually.

330 (c) The fee for an out-of-state prescription drug wholesale
331 distributor permit may not be less than \$300 or more than \$800
332 annually.

333 (d) The fee for a nonresident prescription drug
334 manufacturer permit may not be less than \$300 or more than \$500
335 annually.

336 (e) The fee for a retail pharmacy drug wholesale
337 distributor permit may not be less than \$35 or more than \$50
338 annually.

339 (f) The fee for a freight forwarder permit may not be less
340 than \$200 or more than \$300 annually.

341 (g) The fee for a veterinary prescription drug wholesale
342 distributor permit may not be less than \$300 or more than \$500
343 annually.

344 (h) The fee for a limited prescription drug veterinary
345 wholesale distributor permit may not be less than \$300 or more
346 than \$500 annually.



231424

588-02257A-09

347 (i) The fee for a third party logistics provider permit may
348 not be less than \$200 or more than \$300 annually.

349 (3) The department shall assess an applicant that is
350 required to have a retail establishment permit an annual fee
351 within the ranges established in this section for the specific
352 type of retail establishment.

353 (a) The fee for a veterinary prescription drug retail
354 establishment permit may not be less than \$200 or more than \$300
355 annually.

356 (b) The fee for a medical oxygen retail establishment
357 permit may not be less than \$200 or more than \$300 annually.

358 ~~(c) The fee for a health care clinic establishment permit~~
359 ~~may not be less than \$125 or more than \$250 annually.~~

360 (4) The department shall assess an applicant that is
361 required to have a restricted prescription drug distributor
362 permit an annual fee of not less than \$200 or more than \$300.

363 (5) In addition to the fee charged for a permit required by
364 this part, the department shall assess applicants an initial
365 application fee of \$150 for each new permit issued by the
366 department which requires an onsite inspection.

367 (6) A person that is required to register drugs, devices,
368 or cosmetic products under s. 499.015 shall pay an annual
369 product registration fee of not less than \$5 or more than \$15
370 for each separate and distinct product in package form. The
371 registration fee is in addition to the fee charged for a free-
372 sale certificate.

373 (7) The department shall assess an applicant that requests
374 a free-sale certificate a fee of \$25. A fee of \$2 will be
375 charged for each signature copy of a free-sale certificate that



231424

588-02257A-09

376 is obtained at the same time the free-sale certificate is
377 issued.

378 (8) The department shall assess an out-of-state
379 prescription drug wholesale distributor applicant or permittee
380 an onsite inspection fee of not less than \$1,000 or more than
381 \$3,000 annually, to be based on the actual cost of the
382 inspection if an onsite inspection is performed by agents of the
383 department.

384 (9) The department shall assess each person applying for
385 certification as a designated representative a fee of \$150, plus
386 the cost of processing the criminal history record check.

387 (10) The department shall assess a person registering as a
388 qualifying practitioner for an establishment under s. 499.031 a
389 fee of \$25 for each establishment.

390 (11) The department shall assess each person applying for a
391 permit or certification as a designated representative a
392 nonrefundable application fee of \$150 or 50 percent of the
393 permit or certification fee, whichever is less, if the
394 application is withdrawn or it becomes void.

395 (12)~~(10)~~ The department shall assess other fees as provided
396 in this part.

397 Section 7. Paragraphs (i) and (m) of subsection (1) of
398 section 499.05, Florida Statutes, are amended to read:

399 499.05 Rules.—

400 (1) The department shall adopt rules to implement and
401 enforce this part with respect to:

402 (i) Additional conditions that qualify as an emergency
403 medical reason under s. 499.003(54)(b)2. ~~s. 499.003(53)(b)2.~~

404 (m) The recordkeeping, storage, and handling with respect



231424

588-02257A-09

405 to each of the distributions of prescription drugs specified in
406 s. 499.003(54)(a)-(d) ~~s. 499.003(53)(a)-(d)~~.

407 Section 8. Paragraph (i) is added to subsection (1) of
408 section 400.9935, Florida Statutes, to read:

409 400.9935 Clinic responsibilities.—

410 (1) Each clinic shall appoint a medical director or clinic
411 director who shall agree in writing to accept legal
412 responsibility for the following activities on behalf of the
413 clinic. The medical director or the clinic director shall:

414 (i) Be responsible for complying with all legal and
415 regulatory requirements related to the purchase, recordkeeping,
416 storage, and handling of prescription drugs that have been sold
417 to the clinic using the medical director as the qualifying
418 practitioner under ss. 499.03 and 499.031.

419 Section 9. Paragraph (a) of subsection (1) of section
420 409.9201, Florida Statutes, is amended to read:

421 409.9201 Medicaid fraud.—

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

423 (a) "Prescription drug" means any drug, including, but not
424 limited to, finished dosage forms or active ingredients that are
425 subject to, defined by, or described by s. 503(b) of the Federal
426 Food, Drug, and Cosmetic Act or by s. 465.003(8), s. 499.003(45)
427 or (53) ~~(52)~~, or s. 499.007(13).

428
429 The value of individual items of the legend drugs or goods or
430 services involved in distinct transactions committed during a
431 single scheme or course of conduct, whether involving a single
432 person or several persons, may be aggregated when determining
433 the punishment for the offense.



231424

588-02257A-09

434 Section 10. Subsection (3) of section 465.0265, Florida
435 Statutes, is amended to read:

436 465.0265 Centralized prescription filling.—

437 (3) The filling, delivery, and return of a prescription by
438 one pharmacy for another pursuant to this section shall not be
439 construed as the filling of a transferred prescription as set
440 forth in s. 465.026 or as a wholesale distribution as set forth
441 in s. 499.003(54) ~~s. 499.003(53)~~.

442 Section 11. This act shall take effect July 1, 2009.