

1 A bill to be entitled
 2 An act relating to drugs, cosmetics, and certain devices;
 3 amending s. 499.01, F.S.; requiring the Department of
 4 Health to notify an applicant for a prescription drug
 5 wholesale distributor permit or an out-of-state
 6 prescription drug wholesale distributor permit of the
 7 status of its permit application within a specified period
 8 after receipt of all required documentation; deleting
 9 provisions relating to the submission of a bond or certain
 10 other security; amending s. 499.012, F.S.; revising permit
 11 application requirements to apply those requirements to
 12 all applicants and delete provisions specific to certain
 13 applicants; amending ss. 499.003, 499.0121, and 499.067,
 14 F.S.; conforming provisions; providing an effective date.

15
 16 Be It Enacted by the Legislature of the State of Florida:

17
 18 Section 1. Paragraphs (d) and (e) of subsection (2) of
 19 section 499.01, Florida Statutes, are amended to read:

20 499.01 Permits.—

21 (2) The following permits are established:

22 (d) Prescription drug wholesale distributor permit.—A
 23 prescription drug wholesale distributor is a wholesale
 24 distributor that may engage in the wholesale distribution of
 25 prescription drugs. ~~A prescription drug wholesale distributor~~
 26 ~~that applies to the department for a new permit or the renewal~~
 27 ~~of a permit must submit a bond of \$100,000, or other equivalent~~
 28 ~~means of security acceptable to the department, such as an~~

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29 ~~irrevocable letter of credit or a deposit in a trust account or~~
30 ~~financial institution, payable to the Florida Drug, Device, and~~
31 ~~Cosmetic Trust Fund. The purpose of the bond is to secure~~
32 ~~payment of any administrative penalties imposed by the~~
33 ~~department and any fees and costs incurred by the department~~
34 ~~regarding that permit which are authorized under state law and~~
35 ~~which the permittee fails to pay 30 days after the fine or costs~~
36 ~~become final. The department may make a claim against such bond~~
37 ~~or security until 1 year after the permittee's license ceases to~~
38 ~~be valid or until 60 days after any administrative or legal~~
39 ~~proceeding authorized in this part which involves the permittee~~
40 ~~is concluded, including any appeal, whichever occurs later. The~~
41 ~~department may adopt rules for issuing a prescription drug~~
42 ~~wholesale distributor ~~distributor-broker~~ permit to a person who~~
43 ~~engages in the wholesale distribution of prescription drugs and~~
44 ~~does not take physical possession of any prescription drugs. The~~
45 ~~department shall notify a prescription drug wholesale~~
46 ~~distributor that applies for a permit the status of its permit~~
47 ~~within 60 days after receipt of all documentation required by~~
48 ~~the application.~~

49 (e) Out-of-state prescription drug wholesale distributor
50 permit.—An out-of-state prescription drug wholesale distributor
51 is a wholesale distributor located outside this state which
52 engages in the wholesale distribution of prescription drugs into
53 this state and which must be permitted by the department and
54 comply with all the provisions required of a wholesale
55 distributor under this part. ~~An out-of-state prescription drug~~
56 ~~wholesale distributor that applies to the department for a new~~

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57 ~~permit or the renewal of a permit must submit a bond of~~
58 ~~\$100,000, or other equivalent means of security acceptable to~~
59 ~~the department, such as an irrevocable letter of credit or a~~
60 ~~deposit in a trust account or financial institution, payable to~~
61 ~~the Florida Drug, Device, and Cosmetic Trust Fund. The purpose~~
62 ~~of the bond is to secure payment of any administrative penalties~~
63 ~~imposed by the department and any fees and costs incurred by the~~
64 ~~department regarding that permit which are authorized under~~
65 ~~state law and which the permittee fails to pay 30 days after the~~
66 ~~fine or costs become final. The department may make a claim~~
67 ~~against such bond or security until 1 year after the permittee's~~
68 ~~license ceases to be valid or until 60 days after any~~
69 ~~administrative or legal proceeding authorized in this part which~~
70 ~~involves the permittee is concluded, including any appeal,~~
71 ~~whichever occurs later.~~

72 1. The out-of-state prescription drug wholesale
73 distributor must maintain at all times a license or permit to
74 engage in the wholesale distribution of prescription drugs in
75 compliance with laws of the state in which it is a resident.

76 2. The department shall notify an out-of-state
77 prescription drug wholesale distributor that applies for a
78 permit the status of its permit within 60 days after receipt of
79 all documentation required by the application.

80 ~~3.2.~~ An out-of-state prescription drug wholesale
81 distributor permit is not required for an intracompany sale or
82 transfer of a prescription drug from an out-of-state
83 establishment that is duly licensed as a prescription drug
84 wholesale distributor, in its state of residence, to a licensed

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85 prescription drug wholesale distributor in this state, if both
86 wholesale distributors conduct wholesale distributions of
87 prescription drugs under the same business name. The
88 recordkeeping requirements of ss. 499.0121(6) and 499.01212 must
89 be followed for this transaction.

90 Section 2. Section 499.012, Florida Statutes, is amended
91 to read:

92 499.012 Permit application requirements.—

93 (1) (a) A permit issued pursuant to this part may be issued
94 only to a natural person who is at least 18 years of age or to
95 an applicant that is not a natural person if each person who,
96 directly or indirectly, manages, controls, or oversees the
97 operation of that applicant is at least 18 years of age.

98 (b) An establishment that is a place of residence may not
99 receive a permit and may not operate under this part.

100 (c) A person that applies for or renews a permit to
101 manufacture or distribute prescription drugs may not use a name
102 identical to the name used by any other establishment or
103 licensed person authorized to purchase prescription drugs in
104 this state, except that a restricted drug distributor permit
105 issued to a health care entity will be issued in the name in
106 which the institutional pharmacy permit is issued and a retail
107 pharmacy drug wholesale distributor will be issued a permit in
108 the name of its retail pharmacy permit.

109 (d) A permit for a prescription drug manufacturer,
110 prescription drug repackager, prescription drug wholesale
111 distributor, limited prescription drug veterinary wholesale
112 distributor, or retail pharmacy drug wholesale distributor may

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113 not be issued to the address of a health care entity or to a
114 pharmacy licensed under chapter 465, except as provided in this
115 paragraph. The department may issue a prescription drug
116 manufacturer permit to an applicant at the same address as a
117 licensed nuclear pharmacy, which is a health care entity, for
118 the purpose of manufacturing prescription drugs used in positron
119 emission tomography or other radiopharmaceuticals, as listed in
120 a rule adopted by the department pursuant to this paragraph. The
121 purpose of this exemption is to assure availability of state-of-
122 the-art pharmaceuticals that would pose a significant danger to
123 the public health if manufactured at a separate establishment
124 address from the nuclear pharmacy from which the prescription
125 drugs are dispensed. The department may also issue a retail
126 pharmacy drug wholesale distributor permit to the address of a
127 community pharmacy licensed under chapter 465 which does not
128 meet the definition of a closed pharmacy in s. 499.003.

129 (e) A county or municipality may not issue an occupational
130 license for any licensing period beginning on or after October
131 1, 2003, for any establishment that requires a permit pursuant
132 to this part, unless the establishment exhibits a current permit
133 issued by the department for the establishment. Upon
134 presentation of the requisite permit issued by the department,
135 an occupational license may be issued by the municipality or
136 county in which application is made. The department shall
137 furnish to local agencies responsible for issuing occupational
138 licenses a current list of all establishments licensed pursuant
139 to this part.

140 (2) Notwithstanding subsection (6), a permitted person in

141 good standing may change the type of permit issued to that
 142 person by completing a new application for the requested permit,
 143 paying the amount of the difference in the permit fees if the
 144 fee for the new permit is more than the fee for the original
 145 permit, and meeting the applicable permitting conditions for the
 146 new permit type. The new permit expires on the expiration date
 147 of the original permit being changed; however, a new permit for
 148 a prescription drug wholesale distributor, an out-of-state
 149 prescription drug wholesale distributor, or a retail pharmacy
 150 drug wholesale distributor shall expire on the expiration date
 151 of the original permit or 1 year after the date of issuance of
 152 the new permit, whichever is earlier. A refund may not be issued
 153 if the fee for the new permit is less than the fee that was paid
 154 for the original permit.

155 (3) A written application for a permit or to renew a
 156 permit must be filed with the department on forms furnished by
 157 the department. The department shall establish, by rule, the
 158 form and content of the application to obtain or renew a permit.
 159 The applicant must submit to the department with the application
 160 a statement that swears or affirms that the information is true
 161 and correct.

162 (4) (a) ~~Except for a permit for a prescription drug~~
 163 ~~wholesale distributor or an out-of-state prescription drug~~
 164 ~~wholesale distributor,~~ An application for a permit must include:

- 165 1. The name, full business address, and telephone number
- 166 of the applicant;
- 167 2. All trade or business names used by the applicant;
- 168 3. The address, telephone numbers, and the names of

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169 | contact persons for each facility used by the applicant for the
170 | storage, handling, and distribution of prescription drugs;

171 | 4. The type of ownership or operation, such as a
172 | partnership, corporation, or sole proprietorship; and

173 | 5. The names of the owner and the operator of the
174 | establishment, including:

175 | a. If an individual, the name of the individual;

176 | b. If a partnership, the name of each partner and the name
177 | of the partnership;

178 | c. If a corporation, the name and title of each corporate
179 | officer and director, the corporate names, and the name of the
180 | state of incorporation;

181 | d. If a sole proprietorship, the full name of the sole
182 | proprietor and the name of the business entity;

183 | e. If a limited liability company, the name of each
184 | member, the name of each manager, the name of the limited
185 | liability company, and the name of the state in which the
186 | limited liability company was organized; and

187 | f. Any other relevant information that the department
188 | requires.

189 | (b) Upon approval of the application by the department and
190 | payment of the required fee, the department shall issue a permit
191 | to the applicant, if the applicant meets the requirements of
192 | this part and rules adopted under this part.

193 | (c) Any change in information required under paragraph (a)
194 | must be submitted to the department before the change occurs.

195 | (d) The department shall consider, at a minimum, the
196 | following factors in reviewing the qualifications of persons to

197 | be permitted under this part:

198 | 1. The applicant's having been found guilty, regardless of
 199 | adjudication, in a court of this state or other jurisdiction, of
 200 | a violation of a law that directly relates to a drug, device, or
 201 | cosmetic. A plea of nolo contendere constitutes a finding of
 202 | guilt for purposes of this subparagraph.

203 | 2. The applicant's having been disciplined by a regulatory
 204 | agency in any state for any offense that would constitute a
 205 | violation of this part.

206 | 3. Any felony conviction of the applicant under a federal,
 207 | state, or local law;

208 | 4. The applicant's past experience in manufacturing or
 209 | distributing drugs, devices, or cosmetics;

210 | 5. The furnishing by the applicant of false or fraudulent
 211 | material in any application made in connection with
 212 | manufacturing or distributing drugs, devices, or cosmetics;

213 | 6. Suspension or revocation by a federal, state, or local
 214 | government of any permit currently or previously held by the
 215 | applicant for the manufacture or distribution of any drugs,
 216 | devices, or cosmetics;

217 | 7. Compliance with permitting requirements under any
 218 | previously granted permits;

219 | 8. Compliance with requirements to maintain or make
 220 | available to the state permitting authority or to federal,
 221 | state, or local law enforcement officials those records required
 222 | under this section; and

223 | 9. Any other factors or qualifications the department
 224 | considers relevant to and consistent with the public health and

225 safety.

226 (5) ~~Except for a permit for a prescription drug wholesale~~
 227 ~~distributor or an out-of-state prescription drug wholesale~~
 228 ~~distributor:~~

229 (a) The department shall adopt rules for the biennial
 230 renewal of permits.

231 (b) The department shall renew a permit upon receipt of
 232 the renewal application and renewal fee if the applicant meets
 233 the requirements established under this part and the rules
 234 adopted under this part.

235 (c) A permit, unless sooner suspended or revoked,
 236 automatically expires 2 years after the last day of the
 237 anniversary month in which the permit was originally issued. A
 238 permit issued under this part may be renewed by making
 239 application for renewal on forms furnished by the department and
 240 paying the appropriate fees. If a renewal application and fee
 241 are submitted and postmarked after the expiration date of the
 242 permit, the permit may be renewed only upon payment of a late
 243 renewal delinquent fee of \$100, plus the required renewal fee,
 244 not later than 60 days after the expiration date.

245 (d) Failure to renew a permit in accordance with this
 246 section precludes any future renewal of that permit. If a permit
 247 issued pursuant to this part has expired and cannot be renewed,
 248 before an establishment may engage in activities that require a
 249 permit under this part, the establishment must submit an
 250 application for a new permit, pay the applicable application
 251 fee, the initial permit fee, and all applicable penalties, and
 252 be issued a new permit by the department.

253 (6) A permit issued by the department is nontransferable.
 254 Each permit is valid only for the person or governmental unit to
 255 which it is issued and is not subject to sale, assignment, or
 256 other transfer, voluntarily or involuntarily; nor is a permit
 257 valid for any establishment other than the establishment for
 258 which it was originally issued.

259 (a) A person permitted under this part must notify the
 260 department before making a change of address. The department
 261 shall set a change of location fee not to exceed \$100.

262 (b)1. An application for a new permit is required when a
 263 majority of the ownership or controlling interest of a permitted
 264 establishment is transferred or assigned or when a lessee agrees
 265 to undertake or provide services to the extent that legal
 266 liability for operation of the establishment will rest with the
 267 lessee. The application for the new permit must be made before
 268 the date of the sale, transfer, assignment, or lease.

269 2. A permittee that is authorized to distribute
 270 prescription drugs may transfer such drugs to the new owner or
 271 lessee under subparagraph 1. only after the new owner or lessee
 272 has been approved for a permit to distribute prescription drugs.

273 (c) If an establishment permitted under this part closes,
 274 the owner must notify the department in writing before the
 275 effective date of closure and must:

- 276 1. Return the permit to the department;
- 277 2. If the permittee is authorized to distribute
- 278 prescription drugs, indicate the disposition of such drugs,
- 279 including the name, address, and inventory, and provide the name
- 280 and address of a person to contact regarding access to records

281 that are required to be maintained under this part. Transfer of
 282 ownership of prescription drugs may be made only to persons
 283 authorized to possess prescription drugs under this part.

284
 285 The department may revoke the permit of any person that fails to
 286 comply with the requirements of this subsection.

287 (7) A permit must be posted in a conspicuous place on the
 288 licensed premises.

289 ~~(8) An application for a permit or to renew a permit for a~~
 290 ~~prescription drug wholesale distributor or an out-of-state~~
 291 ~~prescription drug wholesale distributor submitted to the~~
 292 ~~department must include:~~

293 ~~(a) The name, full business address, and telephone number~~
 294 ~~of the applicant.~~

295 ~~(b) All trade or business names used by the applicant.~~

296 ~~(c) The address, telephone numbers, and the names of~~
 297 ~~contact persons for each facility used by the applicant for the~~
 298 ~~storage, handling, and distribution of prescription drugs.~~

299 ~~(d) The type of ownership or operation, such as a~~
 300 ~~partnership, corporation, or sole proprietorship.~~

301 ~~(e) The names of the owner and the operator of the~~
 302 ~~establishment, including:~~

303 ~~1. If an individual, the name of the individual.~~

304 ~~2. If a partnership, the name of each partner and the name~~
 305 ~~of the partnership.~~

306 ~~3. If a corporation:~~

307 ~~a. The name, address, and title of each corporate officer~~
 308 ~~and director.~~

309 ~~b. The name and address of the corporation, resident agent~~
 310 ~~of the corporation, the resident agent's address, and the~~
 311 ~~corporation's state of incorporation.~~

312 ~~e. The name and address of each shareholder of the~~
 313 ~~corporation that owns 5 percent or more of the outstanding stock~~
 314 ~~of the corporation.~~

315 ~~4. If a sole proprietorship, the full name of the sole~~
 316 ~~proprietor and the name of the business entity.~~

317 ~~5. If a limited liability company:~~

318 ~~a. The name and address of each member.~~

319 ~~b. The name and address of each manager.~~

320 ~~e. The name and address of the limited liability company,~~
 321 ~~the resident agent of the limited liability company, and the~~
 322 ~~name of the state in which the limited liability company was~~
 323 ~~organized.~~

324 ~~(f) If applicable, the name and address of each member of~~
 325 ~~the affiliated group of which the applicant is a member.~~

326 ~~(g)1. For an application for a new permit, the estimated~~
 327 ~~annual dollar volume of prescription drug sales of the~~
 328 ~~applicant, the estimated annual percentage of the applicant's~~
 329 ~~total company sales that are prescription drugs, the applicant's~~
 330 ~~estimated annual total dollar volume of purchases of~~
 331 ~~prescription drugs, and the applicant's estimated annual total~~
 332 ~~dollar volume of prescription drug purchases directly from~~
 333 ~~manufacturers.~~

334 ~~2. For an application to renew a permit, the total dollar~~
 335 ~~volume of prescription drug sales in the previous year, the~~
 336 ~~total dollar volume of prescription drug sales made in the~~

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337 ~~previous 6 months, the percentage of total company sales that~~
338 ~~were prescription drugs in the previous year, the total dollar~~
339 ~~volume of purchases of prescription drugs in the previous year,~~
340 ~~and the total dollar volume of prescription drug purchases~~
341 ~~directly from manufacturers in the previous year.~~

342

343 ~~Such portions of the information required pursuant to this~~
344 ~~paragraph which are a trade secret, as defined in s. 812.081,~~
345 ~~shall be maintained by the department as trade secret~~
346 ~~information is required to be maintained under s. 499.051.~~

347 ~~(h) The tax year of the applicant.~~

348 ~~(i) A copy of the deed for the property on which~~
349 ~~applicant's establishment is located, if the establishment is~~
350 ~~owned by the applicant, or a copy of the applicant's lease for~~
351 ~~the property on which applicant's establishment is located that~~
352 ~~has an original term of not less than 1 calendar year, if the~~
353 ~~establishment is not owned by the applicant.~~

354 ~~(j) A list of all licenses and permits issued to the~~
355 ~~applicant by any other state which authorize the applicant to~~
356 ~~purchase or possess prescription drugs.~~

357 ~~(k) The name of the manager of the establishment that is~~
358 ~~applying for the permit or to renew the permit, the next four~~
359 ~~highest ranking employees responsible for prescription drug~~
360 ~~wholesale operations for the establishment, and the name of all~~
361 ~~affiliated parties for the establishment, together with the~~
362 ~~personal information statement and fingerprints required~~
363 ~~pursuant to subsection (9) for each of such persons.~~

364 ~~(l) The name of each of the applicant's designated~~

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365 ~~representatives as required by subsection (16), together with~~
366 ~~the personal information statement and fingerprints required~~
367 ~~pursuant to subsection (9) for each such person.~~

368 ~~(m) For an applicant that is a secondary wholesale~~
369 ~~distributor, each of the following:~~

370 ~~1. A personal background information statement containing~~
371 ~~the background information and fingerprints required pursuant to~~
372 ~~subsection (9) for each person named in the applicant's response~~
373 ~~to paragraphs (k) and (l) and for each affiliated party of the~~
374 ~~applicant.~~

375 ~~2. If any of the five largest shareholders of the~~
376 ~~corporation seeking the permit is a corporation, the name,~~
377 ~~address, and title of each corporate officer and director of~~
378 ~~each such corporation; the name and address of such corporation;~~
379 ~~the name of such corporation's resident agent, such~~
380 ~~corporation's resident agent's address, and such corporation's~~
381 ~~state of its incorporation; and the name and address of each~~
382 ~~shareholder of such corporation that owns 5 percent or more of~~
383 ~~the stock of such corporation.~~

384 ~~3. The name and address of all financial institutions in~~
385 ~~which the applicant has an account which is used to pay for the~~
386 ~~operation of the establishment or to pay for drugs purchased for~~
387 ~~the establishment, together with the names of all persons that~~
388 ~~are authorized signatories on such accounts. The portions of the~~
389 ~~information required pursuant to this subparagraph which are a~~
390 ~~trade secret, as defined in s. 812.081, shall be maintained by~~
391 ~~the department as trade secret information is required to be~~
392 ~~maintained under s. 499.051.~~

393 ~~4. The sources of all funds and the amounts of such funds~~
 394 ~~used to purchase or finance purchases of prescription drugs or~~
 395 ~~to finance the premises on which the establishment is to be~~
 396 ~~located.~~

397 ~~5. If any of the funds identified in subparagraph 4. were~~
 398 ~~borrowed, copies of all promissory notes or loans used to obtain~~
 399 ~~such funds.~~

400 ~~(n) Any other relevant information that the department~~
 401 ~~requires, including, but not limited to, any information related~~
 402 ~~to whether the applicant satisfies the definition of a primary~~
 403 ~~wholesale distributor or a secondary wholesale distributor.~~

404 ~~(9)(a) Each person required by subsection (8) to provide a~~
 405 ~~personal information statement and fingerprints shall provide~~
 406 ~~the following information to the department on forms prescribed~~
 407 ~~by the department:~~

408 ~~1. The person's places of residence for the past 7 years.~~

409 ~~2. The person's date and place of birth.~~

410 ~~3. The person's occupations, positions of employment, and~~
 411 ~~offices held during the past 7 years.~~

412 ~~4. The principal business and address of any business,~~
 413 ~~corporation, or other organization in which each such office of~~
 414 ~~the person was held or in which each such occupation or position~~
 415 ~~of employment was carried on.~~

416 ~~5. Whether the person has been, during the past 7 years,~~
 417 ~~the subject of any proceeding for the revocation of any license~~
 418 ~~and, if so, the nature of the proceeding and the disposition of~~
 419 ~~the proceeding.~~

420 ~~6. Whether, during the past 7 years, the person has been~~

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421 ~~enjoined, temporarily or permanently, by a court of competent~~
422 ~~jurisdiction from violating any federal or state law regulating~~
423 ~~the possession, control, or distribution of prescription drugs,~~
424 ~~together with details concerning any such event.~~

425 ~~7. A description of any involvement by the person with any~~
426 ~~business, including any investments, other than the ownership of~~
427 ~~stock in a publicly traded company or mutual fund, during the~~
428 ~~past 7 years, which manufactured, administered, prescribed,~~
429 ~~distributed, or stored pharmaceutical products and any lawsuits~~
430 ~~in which such businesses were named as a party.~~

431 ~~8. A description of any felony criminal offense of which~~
432 ~~the person, as an adult, was found guilty, regardless of whether~~
433 ~~adjudication of guilt was withheld or whether the person pled~~
434 ~~guilty or nolo contendere. A criminal offense committed in~~
435 ~~another jurisdiction which would have been a felony in this~~
436 ~~state must be reported. If the person indicates that a criminal~~
437 ~~conviction is under appeal and submits a copy of the notice of~~
438 ~~appeal of that criminal offense, the applicant must, within 15~~
439 ~~days after the disposition of the appeal, submit to the~~
440 ~~department a copy of the final written order of disposition.~~

441 ~~9. A photograph of the person taken in the previous 30~~
442 ~~days.~~

443 ~~10. A set of fingerprints for the person on a form and~~
444 ~~under procedures specified by the department, together with~~
445 ~~payment of an amount equal to the costs incurred by the~~
446 ~~department for the criminal record check of the person.~~

447 ~~11. The name, address, occupation, and date and place of~~
448 ~~birth for each member of the person's immediate family who is 18~~

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449 ~~years of age or older. As used in this subparagraph, the term~~
450 ~~"member of the person's immediate family" includes the person's~~
451 ~~spouse, children, parents, siblings, the spouses of the person's~~
452 ~~children, and the spouses of the person's siblings.~~

453 ~~12. Any other relevant information that the department~~
454 ~~requires.~~

455 ~~(b) The information required pursuant to paragraph (a)~~
456 ~~shall be provided under oath.~~

457 ~~(c) The department shall submit the fingerprints provided~~
458 ~~by a person for initial licensure to the Department of Law~~
459 ~~Enforcement for a statewide criminal record check and for~~
460 ~~forwarding to the Federal Bureau of Investigation for a national~~
461 ~~criminal record check of the person. The department shall submit~~
462 ~~the fingerprints provided by a person as a part of a renewal~~
463 ~~application to the Department of Law Enforcement for a statewide~~
464 ~~criminal record check, and for forwarding to the Federal Bureau~~
465 ~~of Investigation for a national criminal record check, for the~~
466 ~~initial renewal of a permit after January 1, 2004; for any~~
467 ~~subsequent renewal of a permit, the department shall submit the~~
468 ~~required information for a statewide and national criminal~~
469 ~~record check of the person. Any person who as a part of an~~
470 ~~initial permit application or initial permit renewal after~~
471 ~~January 1, 2004, submits to the department a set of fingerprints~~
472 ~~required for the criminal record check required in this~~
473 ~~paragraph shall not be required to provide a subsequent set of~~
474 ~~fingerprints for a criminal record check to the department, if~~
475 ~~the person has undergone a criminal record check as a condition~~
476 ~~of the issuance of an initial permit or the initial renewal of a~~

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477 ~~permit of an applicant after January 1, 2004.~~

478 ~~(10) The department may deny an application for a permit~~
479 ~~or refuse to renew a permit for a prescription drug wholesale~~
480 ~~distributor or an out-of-state prescription drug wholesale~~
481 ~~distributor if:~~

482 ~~(a) The applicant has not met the requirements for the~~
483 ~~permit.~~

484 ~~(b) The management, officers, or directors of the~~
485 ~~applicant or any affiliated party are found by the department to~~
486 ~~be incompetent or untrustworthy.~~

487 ~~(c) The applicant is so lacking in experience in managing~~
488 ~~a wholesale distributor as to make the issuance of the proposed~~
489 ~~permit hazardous to the public health.~~

490 ~~(d) The applicant is so lacking in experience in managing~~
491 ~~a wholesale distributor as to jeopardize the reasonable promise~~
492 ~~of successful operation of the wholesale distributor.~~

493 ~~(e) The applicant is lacking in experience in the~~
494 ~~distribution of prescription drugs.~~

495 ~~(f) The applicant's past experience in manufacturing or~~
496 ~~distributing prescription drugs indicates that the applicant~~
497 ~~poses a public health risk.~~

498 ~~(g) The applicant is affiliated directly or indirectly~~
499 ~~through ownership, control, or other business relations, with~~
500 ~~any person or persons whose business operations are or have been~~
501 ~~detrimental to the public health.~~

502 ~~(h) The applicant, or any affiliated party, has been found~~
503 ~~guilty of or has pleaded guilty or nolo contendere to any felony~~
504 ~~or crime punishable by imprisonment for 1 year or more under the~~

505 ~~laws of the United States, any state, or any other country,~~
 506 ~~regardless of whether adjudication of guilt was withheld.~~

507 ~~(i) The applicant or any affiliated party has been charged~~
 508 ~~with a felony in a state or federal court and the disposition of~~
 509 ~~that charge is pending during the application review or renewal~~
 510 ~~review period.~~

511 ~~(j) The applicant has furnished false or fraudulent~~
 512 ~~information or material in any application made in this state or~~
 513 ~~any other state in connection with obtaining a permit or license~~
 514 ~~to manufacture or distribute drugs, devices, or cosmetics.~~

515 ~~(k) That a federal, state, or local government permit~~
 516 ~~currently or previously held by the applicant, or any affiliated~~
 517 ~~party, for the manufacture or distribution of any drugs,~~
 518 ~~devices, or cosmetics has been disciplined, suspended, or~~
 519 ~~revoked and has not been reinstated.~~

520 ~~(l) The applicant does not possess the financial or~~
 521 ~~physical resources to operate in compliance with the permit~~
 522 ~~being sought, this chapter, and the rules adopted under this~~
 523 ~~chapter.~~

524 ~~(m) The applicant or any affiliated party receives,~~
 525 ~~directly or indirectly, financial support and assistance from a~~
 526 ~~person who was an affiliated party of a permittee whose permit~~
 527 ~~was subject to discipline or was suspended or revoked, other~~
 528 ~~than through the ownership of stock in a publicly traded company~~
 529 ~~or a mutual fund.~~

530 ~~(n) The applicant or any affiliated party receives,~~
 531 ~~directly or indirectly, financial support and assistance from a~~
 532 ~~person who has been found guilty of any violation of this part~~

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533 ~~or chapter 465, chapter 501, or chapter 893, any rules adopted~~
534 ~~under this part or those chapters, any federal or state drug~~
535 ~~law, or any felony where the underlying facts related to drugs,~~
536 ~~regardless of whether the person has been pardoned, had her or~~
537 ~~his civil rights restored, or had adjudication withheld, other~~
538 ~~than through the ownership of stock in a publicly traded company~~
539 ~~or a mutual fund.~~

540 ~~(e) The applicant for renewal of a permit under s.~~
541 ~~499.01(2)(d) or (e) has not actively engaged in the wholesale~~
542 ~~distribution of prescription drugs, as demonstrated by the~~
543 ~~regular and systematic distribution of prescription drugs~~
544 ~~throughout the year as evidenced by not fewer than 12 wholesale~~
545 ~~distributions in the previous year and not fewer than three~~
546 ~~wholesale distributions in the previous 6 months.~~

547 ~~(p) Information obtained in response to s. 499.01(2)(d) or~~
548 ~~(e) demonstrates it would not be in the best interest of the~~
549 ~~public health, safety, and welfare to issue a permit.~~

550 ~~(q) The applicant does not possess the financial standing~~
551 ~~and business experience for the successful operation of the~~
552 ~~applicant.~~

553 ~~(r) The applicant or any affiliated party has failed to~~
554 ~~comply with the requirements for manufacturing or distributing~~
555 ~~prescription drugs under this part, similar federal laws,~~
556 ~~similar laws in other states, or the rules adopted under such~~
557 ~~laws.~~

558 ~~(11) Upon approval of the application by the department~~
559 ~~and payment of the required fee, the department shall issue or~~
560 ~~renew a prescription drug wholesale distributor or an out-of-~~

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561 ~~state prescription drug wholesale distributor permit to the~~
562 ~~applicant.~~

563 ~~(12) For a permit for a prescription drug wholesale~~
564 ~~distributor or an out-of-state prescription drug wholesale~~
565 ~~distributor:~~

566 ~~(a) The department shall adopt rules for the annual~~
567 ~~renewal of permits. At least 90 days before the expiration of a~~
568 ~~permit, the department shall forward a permit renewal~~
569 ~~notification and renewal application to the prescription drug~~
570 ~~wholesale distributor or out-of-state prescription drug~~
571 ~~wholesale distributor at the mailing address of the permitted~~
572 ~~establishment on file with the department. The permit renewal~~
573 ~~notification must state conspicuously the date on which the~~
574 ~~permit for the establishment will expire and that the~~
575 ~~establishment may not operate unless the permit for the~~
576 ~~establishment is renewed timely.~~

577 ~~(b) A permit, unless sooner suspended or revoked,~~
578 ~~automatically expires 1 year after the last day of the~~
579 ~~anniversary month in which the permit was originally issued. A~~
580 ~~permit may be renewed by making application for renewal on forms~~
581 ~~furnished by the department and paying the appropriate fees. If~~
582 ~~a renewal application and fee are submitted and postmarked after~~
583 ~~45 days prior to the expiration date of the permit, the permit~~
584 ~~may be renewed only upon payment of a late renewal fee of \$100,~~
585 ~~plus the required renewal fee. A permittee that has submitted a~~
586 ~~renewal application in accordance with this paragraph may~~
587 ~~continue to operate under its permit, unless the permit is~~
588 ~~suspended or revoked, until final disposition of the renewal~~

589 application.

590 ~~(c) Failure to renew a permit in accordance with this~~
 591 ~~section precludes any future renewal of that permit. If a permit~~
 592 ~~issued pursuant to this section has expired and cannot be~~
 593 ~~renewed, before an establishment may engage in activities that~~
 594 ~~require a permit under this part, the establishment must submit~~
 595 ~~an application for a new permit; pay the applicable application~~
 596 ~~fee, initial permit fee, and all applicable penalties; and be~~
 597 ~~issued a new permit by the department.~~

598 ~~(13) A person that engages in wholesale distribution of~~
 599 ~~prescription drugs in this state must have a wholesale~~
 600 ~~distributor's permit issued by the department, except as noted~~
 601 ~~in this section. Each establishment must be separately permitted~~
 602 ~~except as noted in this subsection.~~

603 ~~(a) A separate establishment permit is not required when a~~
 604 ~~permitted prescription drug wholesale distributor consigns a~~
 605 ~~prescription drug to a pharmacy that is permitted under chapter~~
 606 ~~465 and located in this state, provided that:~~

607 ~~1. The consignor wholesale distributor notifies the~~
 608 ~~department in writing of the contract to consign prescription~~
 609 ~~drugs to a pharmacy along with the identity and location of each~~
 610 ~~consignee pharmacy;~~

611 ~~2. The pharmacy maintains its permit under chapter 465;~~

612 ~~3. The consignor wholesale distributor, which has no legal~~
 613 ~~authority to dispense prescription drugs, complies with all~~
 614 ~~wholesale distribution requirements of ss. 499.0121 and~~
 615 ~~499.01212 with respect to the consigned drugs and maintains~~
 616 ~~records documenting the transfer of title or other completion of~~

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617 ~~the wholesale distribution of the consigned prescription drugs;~~

618 ~~4. The distribution of the prescription drug is otherwise~~
619 ~~lawful under this chapter and other applicable law;~~

620 ~~5. Open packages containing prescription drugs within a~~
621 ~~pharmacy are the responsibility of the pharmacy, regardless of~~
622 ~~how the drugs are titled; and~~

623 ~~6. The pharmacy dispenses the consigned prescription drug~~
624 ~~in accordance with the limitations of its permit under chapter~~
625 ~~465 or returns the consigned prescription drug to the consignor~~
626 ~~wholesale distributor. In addition, a person who holds title to~~
627 ~~prescription drugs may transfer the drugs to a person permitted~~
628 ~~or licensed to handle the reverse distribution or destruction of~~
629 ~~drugs. Any other distribution by and means of the consigned~~
630 ~~prescription drug by any person, not limited to the consignor~~
631 ~~wholesale distributor or consignee pharmacy, to any other person~~
632 ~~is prohibited.~~

633 ~~(b) A wholesale distributor's permit is not required for~~
634 ~~the one-time transfer of title of a pharmacy's lawfully acquired~~
635 ~~prescription drug inventory by a pharmacy with a valid permit~~
636 ~~issued under chapter 465 to a consignor prescription drug~~
637 ~~wholesale distributor, permitted under this chapter, in~~
638 ~~accordance with a written consignment agreement between the~~
639 ~~pharmacy and that wholesale distributor if the permitted~~
640 ~~pharmacy and the permitted prescription drug wholesale~~
641 ~~distributor comply with all of the provisions of paragraph (a)~~
642 ~~and the prescription drugs continue to be within the permitted~~
643 ~~pharmacy's inventory for dispensing in accordance with the~~
644 ~~limitations of the pharmacy permit under chapter 465. A~~

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645 ~~consignor drug wholesale distributor may not use the pharmacy as~~
646 ~~a wholesale distributor through which it distributes the~~
647 ~~prescription drugs to other pharmacies. Nothing in this section~~
648 ~~is intended to prevent a wholesale distributor from obtaining~~
649 ~~this inventory in the event of nonpayment by the pharmacy.~~

650 ~~(c) A separate establishment permit is not required when a~~
651 ~~permitted prescription drug wholesale distributor operates~~
652 ~~temporary transit storage facilities for the sole purpose of~~
653 ~~storage, for up to 16 hours, of a delivery of prescription drugs~~
654 ~~when the wholesale distributor was temporarily unable to~~
655 ~~complete the delivery to the recipient.~~

656 ~~(d) The department shall require information from each~~
657 ~~wholesale distributor as part of the permit and renewal of such~~
658 ~~permit, as required under this section.~~

659 ~~(14) Personnel employed in wholesale distribution must~~
660 ~~have appropriate education and experience to enable them to~~
661 ~~perform their duties in compliance with state permitting~~
662 ~~requirements.~~

663 ~~(15) The name of a permittee or establishment on a~~
664 ~~prescription drug wholesale distributor permit or an out-of-~~
665 ~~state prescription drug wholesale distributor permit may not~~
666 ~~include any indicia of attainment of any educational degree, any~~
667 ~~indicia that the permittee or establishment possesses a~~
668 ~~professional license, or any name or abbreviation that the~~
669 ~~department determines is likely to cause confusion or mistake or~~
670 ~~that the department determines is deceptive, including that of~~
671 ~~any other entity authorized to purchase prescription drugs.~~

672 ~~(16) (a) Each establishment that is issued an initial or~~

673 ~~renewal permit as a prescription drug wholesale distributor or~~
 674 ~~an out-of-state prescription drug wholesale distributor must~~
 675 ~~designate in writing to the department at least one natural~~
 676 ~~person to serve as the designated representative of the~~
 677 ~~wholesale distributor. Such person must have an active~~
 678 ~~certification as a designated representative from the~~
 679 ~~department.~~

680 ~~(b) To be certified as a designated representative, a~~
 681 ~~natural person must:~~

- 682 ~~1. Submit an application on a form furnished by the~~
 683 ~~department and pay the appropriate fees;~~
- 684 ~~2. Be at least 18 years of age;~~
- 685 ~~3. Have not less than 2 years of verifiable full-time work~~
 686 ~~experience in a pharmacy licensed in this state or another~~
 687 ~~state, where the person's responsibilities included, but were~~
 688 ~~not limited to, recordkeeping for prescription drugs, or have~~
 689 ~~not less than 2 years of verifiable full-time managerial~~
 690 ~~experience with a prescription drug wholesale distributor~~
 691 ~~licensed in this state or in another state;~~
- 692 ~~4. Receive a passing score of at least 75 percent on an~~
 693 ~~examination given by the department regarding federal laws~~
 694 ~~governing distribution of prescription drugs and this part and~~
 695 ~~the rules adopted by the department governing the wholesale~~
 696 ~~distribution of prescription drugs. This requirement shall be~~
 697 ~~effective 1 year after the results of the initial examination~~
 698 ~~are mailed to the persons that took the examination. The~~
 699 ~~department shall offer such examinations at least four times~~
 700 ~~each calendar year; and~~

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701 ~~5. Provide the department with a personal information~~
702 ~~statement and fingerprints pursuant to subsection (9).~~

703 ~~(c) The department may deny an application for~~
704 ~~certification as a designated representative or may suspend or~~
705 ~~revoke a certification of a designated representative pursuant~~
706 ~~to s. 499.067.~~

707 ~~(d) A designated representative:~~

708 ~~1. Must be actively involved in and aware of the actual~~
709 ~~daily operation of the wholesale distributor.~~

710 ~~2. Must be employed full time in a managerial position by~~
711 ~~the wholesale distributor.~~

712 ~~3. Must be physically present at the establishment during~~
713 ~~normal business hours, except for time periods when absent due~~
714 ~~to illness, family illness or death, scheduled vacation, or~~
715 ~~other authorized absence.~~

716 ~~4. May serve as a designated representative for only one~~
717 ~~wholesale distributor at any one time.~~

718 ~~(e) A wholesale distributor must notify the department~~
719 ~~when a designated representative leaves the employ of the~~
720 ~~wholesale distributor. Such notice must be provided to the~~
721 ~~department within 10 business days after the last day of~~
722 ~~designated representative's employment with the wholesale~~
723 ~~distributor.~~

724 ~~(f) A wholesale distributor may not operate under a~~
725 ~~prescription drug wholesale distributor permit or an out-of-~~
726 ~~state prescription drug wholesale distributor permit for more~~
727 ~~than 10 business days after the designated representative leaves~~
728 ~~the employ of the wholesale distributor, unless the wholesale~~

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729 ~~distributor employs another designated representative and~~
730 ~~notifies the department within 10 business days of the identity~~
731 ~~of the new designated representative.~~

732 Section 3. Subsection (3) of section 499.003, Florida
733 Statutes, is amended to read:

734 499.003 Definitions of terms used in this part.—As used in
735 this part, the term:

736 (3) "Affiliated party" means:

737 (a) A director, officer, trustee, partner, or committee
738 member of a permittee or applicant or a subsidiary or service
739 corporation of the permittee or applicant;

740 (b) A person who, directly or indirectly, manages,
741 controls, or oversees the operation of a permittee or applicant,
742 regardless of whether such person is a partner, shareholder,
743 manager, member, officer, director, independent contractor, or
744 employee of the permittee or applicant;

745 ~~(c) A person who has filed or is required to file a~~
746 ~~personal information statement pursuant to s. 499.012(9) or is~~
747 ~~required to be identified in an application for a permit or to~~
748 ~~renew a permit pursuant to s. 499.012(8); or~~

749 (c) ~~(d)~~ The five largest natural shareholders that own at
750 least 5 percent of the permittee or applicant.

751 Section 4. Paragraph (b) of subsection (13) of section
752 499.0121, Florida Statutes, is amended to read:

753 499.0121 Storage and handling of prescription drugs;
754 recordkeeping.—The department shall adopt rules to implement
755 this section as necessary to protect the public health, safety,
756 and welfare. Such rules shall include, but not be limited to,

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757 requirements for the storage and handling of prescription drugs
758 and for the establishment and maintenance of prescription drug
759 distribution records.

760 (13) DUE DILIGENCE OF SUPPLIERS.—Prior to purchasing any
761 prescription drugs from another wholesale distributor, a
762 prescription drug wholesale distributor, an out-of-state
763 prescription drug wholesale distributor, or a prescription drug
764 repackager must:

765 (b) Determine that the selling wholesale distributor has
766 insurance coverage of not less than the greater of 1 percent of
767 the amount of the total dollar volume of the prescription drug
768 sales in the previous year ~~reported to the department under s.~~
769 ~~499.012(8)(g)~~ or \$500,000; however, the coverage need not exceed
770 \$2 million.

771 Section 5. Paragraph (b) of subsection (1) of section
772 499.067, Florida Statutes, is amended to read:

773 499.067 Denial, suspension, or revocation of permit,
774 certification, or registration.—

775 (1)

776 (b) The department may deny an application for a permit or
777 certification, or suspend or revoke a permit or certification,
778 if the department finds that:

779 1. The applicant is not of good moral character or that it
780 would be a danger or not in the best interest of the public
781 health, safety, and welfare if the applicant were issued a
782 permit or certification.

783 2. The applicant has not met the requirements for the
784 permit or certification.

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785 3. The applicant is not eligible for a permit or
786 certification for any of the reasons enumerated in s. 499.012.

787 ~~4. The applicant, permittee, or person certified under s.~~
788 ~~499.012(16) demonstrates any of the conditions enumerated in s.~~
789 ~~499.012.~~

790 ~~5. The applicant, permittee, or person certified under s.~~
791 ~~499.012(16) has committed any violation of ss. 499.005-499.0054.~~

792 Section 6. This act shall take effect July 1, 2011.