

BILL

ORIGINAL

YEAR

1                                   A bill to be entitled  
 2           An act relating to manufacturers and purchasers of  
 3           prescription drugs; amending s. 499.003, F.S.; revising  
 4           and providing definitions; amending s. 499.01, F.S.;  
 5           revising permit requirements for a prescription drug  
 6           manufacturer permit, nonresident prescription drug  
 7           manufacturer permit, and health care clinic establishment  
 8           permit; amending s. 499.0121, F.S.; specifying that a  
 9           wholesale distributor must separately maintain pedigree  
 10          papers when required by this part; providing an effective  
 11          date.

12  
 13 Be It Enacted by the Legislature of the State of Florida:

14  
 15           Section 1. Subsection (31) of section 499.003, Florida  
 16           Statutes, is amended to read:

17           499.003 Definitions of terms used in this part.--As used  
 18           in this part, the term:

19           (31) "Manufacturer" means:

20           (a) A person who prepares, derives, manufactures, or  
 21           produces a drug, device, or cosmetic.

22           (b) The holder or holders of a New Drug Application (NDA),  
 23           an Abbreviated New Drug Application (ANDA), a Biologics License  
 24           Application (BLA), or a New Animal Drug Application (NADA),  
 25           provided such application has become effective or is otherwise  
 26           approved consistent with s. 499.023.~~†~~

27           (c) A private label distributor for whom the private label  
 28           distributor's prescription drugs are originally manufactured and

BILL

ORIGINAL

YEAR

29 | ~~labeled for the distributor and have not been repackaged, or the~~  
 30 | ~~distribution point for the manufacturer, contract manufacturer,~~  
 31 | ~~or private label distributor whether the establishment is a~~  
 32 | ~~member of the manufacturer's affiliated group or is a contract~~  
 33 | ~~distribution site.~~

34 |       (d) A person registered under the federal act as a  
 35 | manufacturer who has entered into an agreement with another  
 36 | manufacturer that authorizes either manufacturer to distribute a  
 37 | prescription drug as the manufacturer of that drug consistent  
 38 | with the federal act.

39 |       (e) A person who is a member of the affiliated group of  
 40 | one of the persons identified in paragraphs (a), (b), (c), or  
 41 | (d), who only distributes prescription drugs manufactured by its  
 42 | affiliated group members. As used in this paragraph, the term  
 43 | "affiliated group" means an affiliated group as defined in 26  
 44 | U.S.C. s.1504, as amended.

45 |  
 46 | The term excludes pharmacies that are operating in compliance  
 47 | with pharmacy practice standards as defined in chapter 465 and  
 48 | rules adopted under that chapter.

49 |       Section 2. Subsection (2) of section 499.01, Florida  
 50 | Statutes, is amended to read:

51 |       499.01 Permits.--

52 |       (2) The following permits are established:

53 |       (a) Prescription drug manufacturer permit.--A prescription  
 54 | drug manufacturer permit is required for any person that is a  
 55 | manufacturer of manufactures a prescription drug and  
 56 | manufactures or distributes its prescription drugs in this

BILL

ORIGINAL

YEAR

57 | state.

58 |       1. A person that operates an establishment permitted as a  
59 | prescription drug manufacturer may engage in wholesale  
60 | distribution of prescription drugs manufactured at that  
61 | establishment and must comply with all the provisions of this  
62 | part and the rules adopted under this part that apply to a  
63 | wholesale distributor, except s. 499.01212.

64 |       2. A prescription drug manufacturer must comply with all  
65 | appropriate state and federal good manufacturing practices.

66 |       (b) Prescription drug repackager permit.—A prescription  
67 | drug repackager permit is required for any person that  
68 | repackages a prescription drug in this state.

69 |       1. A person that operates an establishment permitted as a  
70 | prescription drug repackager may engage in wholesale  
71 | distribution of prescription drugs repackaged at that  
72 | establishment and must comply with all the provisions of this  
73 | part and the rules adopted under this part that apply to a  
74 | wholesale distributor.

75 |       2. A prescription drug repackager must comply with all  
76 | appropriate state and federal good manufacturing practices.

77 |       (c) Nonresident prescription drug manufacturer permit.--A  
78 | nonresident prescription drug manufacturer permit is required  
79 | for any person that is a manufacturer of prescription drugs, ~~or~~  
80 | ~~the distribution point for a manufacturer of prescription drugs~~  
81 | ~~unless permitted as a third party logistics provider, and~~  
82 | ~~located outside of this state~~ or ~~, or that is an entity to whom~~  
83 | ~~an approved new drug application has been issued by the United~~  
84 | ~~States Food and Drug Administration, or the contracted~~

BILL

ORIGINAL

YEAR

85 ~~manufacturer of the approved new drug application holder, and~~  
 86 ~~located outside the United States, which engages in the~~  
 87 ~~wholesale distribution in this state of its ~~the~~ prescription~~  
 88 ~~drugs it manufactures or is responsible for manufacturing.~~ Each  
 89 such manufacturer or entity must be permitted by the department  
 90 and comply with all the provisions required of a wholesale  
 91 distributor under this part, except s. 499.01212.

92 1. A person that distributes prescription drugs for which  
 93 it is not the manufacturer ~~that it did not manufacture~~ must also  
 94 obtain an out-of-state prescription drug wholesale distributor  
 95 permit or third party logistics provider permit pursuant to this  
 96 section to engage in the wholesale distribution of the  
 97 prescription drugs for which it is not the manufacturer  
 98 ~~manufactured by another person and comply with the requirements~~  
 99 ~~of out-of-state prescription drug wholesale distributor.~~ This  
 100 paragraph does not apply to a manufacturer defined in s.  
 101 499.003(31)(e).

102 2. Any such person must comply with the licensing or  
 103 permitting requirements of the jurisdiction in which the  
 104 establishment is located and the federal act, and any product  
 105 wholesaled into this state must comply with this part. If a  
 106 person intends to import prescription drugs from a foreign  
 107 country into this state, the nonresident prescription drug  
 108 manufacturer must provide to the department a list identifying  
 109 each prescription drug it intends to import and document  
 110 approval by the United States Food and Drug Administration for  
 111 such importation.

112 3. A nonresident prescription drug manufacturer permit is

BILL

ORIGINAL

YEAR

113 | not required for a manufacturer to distribute a prescription  
 114 | drug active pharmaceutical ingredient that it manufactures to a  
 115 | prescription drug manufacturer permitted in this state in  
 116 | limited quantities intended for research and development and not  
 117 | for resale, or human use other than lawful clinical trials and  
 118 | biostudies authorized and regulated by federal law. A  
 119 | manufacturer claiming to be exempt from the permit requirements  
 120 | of this subparagraph and the prescription drug manufacturer  
 121 | purchasing and receiving the active pharmaceutical ingredient  
 122 | shall comply with the recordkeeping requirements of s.  
 123 | 499.0121(6), but not the requirements of s. 499.01212. The  
 124 | prescription drug manufacturer purchasing and receiving the  
 125 | active pharmaceutical ingredient shall maintain on file a record  
 126 | of the FDA registration number; the out-of-state license,  
 127 | permit, or registration number; and, if available, a copy of the  
 128 | most current FDA inspection report, for all manufacturers from  
 129 | whom they purchase active pharmaceutical ingredients under this  
 130 | section. The department shall specify by rule the allowable  
 131 | number of transactions within a given period of time and the  
 132 | amount of active pharmaceutical ingredients that qualify as  
 133 | limited quantities for purposes of this exemption. The failure  
 134 | to comply with the requirements of this subparagraph, or rules  
 135 | adopted by the department to administer this subparagraph, for  
 136 | the purchase of prescription drug active pharmaceutical  
 137 | ingredients is a violation of s. 499.005(14).

138 |       (d) Prescription drug wholesale distributor permit.--A  
 139 | prescription drug wholesale distributor is a wholesale  
 140 | distributor that may engage in the wholesale distribution of

BILL

ORIGINAL

YEAR

141 prescription drugs. A prescription drug wholesale distributor  
 142 that applies to the department for a new permit or the renewal  
 143 of a permit must submit a bond of \$100,000, or other equivalent  
 144 means of security acceptable to the department, such as an  
 145 irrevocable letter of credit or a deposit in a trust account or  
 146 financial institution, payable to the Florida Drug, Device, and  
 147 Cosmetic Trust Fund. The purpose of the bond is to secure  
 148 payment of any administrative penalties imposed by the  
 149 department and any fees and costs incurred by the department  
 150 regarding that permit which are authorized under state law and  
 151 which the permittee fails to pay 30 days after the fine or costs  
 152 become final. The department may make a claim against such bond  
 153 or security until 1 year after the permittee's license ceases to  
 154 be valid or until 60 days after any administrative or legal  
 155 proceeding authorized in this part which involves the permittee  
 156 is concluded, including any appeal, whichever occurs later. The  
 157 department may adopt rules for issuing a prescription drug  
 158 wholesale distributor-broker permit to a person who engages in  
 159 the wholesale distribution of prescription drugs and does not  
 160 take physical possession of any prescription drugs.

161 (e) Out-of-state prescription drug wholesale distributor  
 162 permit.--An out-of-state prescription drug wholesale distributor  
 163 is a wholesale distributor located outside this state which  
 164 engages in the wholesale distribution of prescription drugs into  
 165 this state and which must be permitted by the department and  
 166 comply with all the provisions required of a wholesale  
 167 distributor under this part. An out-of-state prescription drug  
 168 wholesale distributor that applies to the department for a new

BILL

ORIGINAL

YEAR

169 permit or the renewal of a permit must submit a bond of  
 170 \$100,000, or other equivalent means of security acceptable to  
 171 the department, such as an irrevocable letter of credit or a  
 172 deposit in a trust account or financial institution, payable to  
 173 the Florida Drug, Device, and Cosmetic Trust Fund. The purpose  
 174 of the bond is to secure payment of any administrative penalties  
 175 imposed by the department and any fees and costs incurred by the  
 176 department regarding that permit which are authorized under  
 177 state law and which the permittee fails to pay 30 days after the  
 178 fine or costs become final. The department may make a claim  
 179 against such bond or security until 1 year after the permittee's  
 180 license ceases to be valid or until 60 days after any  
 181 administrative or legal proceeding authorized in this part which  
 182 involves the permittee is concluded, including any appeal,  
 183 whichever occurs later.

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

188 2. An out-of-state prescription drug wholesale distributor  
 189 permit is not required for an intracompany sale or transfer of a  
 190 prescription drug from an out-of-state establishment that is  
 191 duly licensed as a prescription drug wholesale distributor, in  
 192 its state of residence, to a licensed prescription drug  
 193 wholesale distributor in this state, if both wholesale  
 194 distributors conduct wholesale distributions of prescription  
 195 drugs under the same business name. The recordkeeping  
 196 requirements of ss. 499.0121(6) and 499.01212 must be followed

BILL

ORIGINAL

YEAR

197 | for this transaction.

198 |       (f) Retail pharmacy drug wholesale distributor permit.--A  
 199 | retail pharmacy drug wholesale distributor is a retail pharmacy  
 200 | engaged in wholesale distribution of prescription drugs within  
 201 | this state under the following conditions:

202 |       1. The pharmacy must obtain a retail pharmacy drug  
 203 | wholesale distributor permit pursuant to this part and the rules  
 204 | adopted under this part.

205 |       2. The wholesale distribution activity does not exceed 30  
 206 | percent of the total annual purchases of prescription drugs. If  
 207 | the wholesale distribution activity exceeds the 30-percent  
 208 | maximum, the pharmacy must obtain a prescription drug wholesale  
 209 | distributor permit.

210 |       3. The transfer of prescription drugs that appear in any  
 211 | schedule contained in chapter 893 is subject to chapter 893 and  
 212 | the federal Comprehensive Drug Abuse Prevention and Control Act  
 213 | of 1970.

214 |       4. The transfer is between a retail pharmacy and another  
 215 | retail pharmacy, or a Modified Class II institutional pharmacy,  
 216 | or a health care practitioner licensed in this state and  
 217 | authorized by law to dispense or prescribe prescription drugs.

218 |       5. All records of sales of prescription drugs subject to  
 219 | this section must be maintained separate and distinct from other  
 220 | records and comply with the recordkeeping requirements of this  
 221 | part.

222 |       (g) Restricted prescription drug distributor permit.--A  
 223 | restricted prescription drug distributor permit is required for  
 224 | any person that engages in the distribution of a prescription



BILL

ORIGINAL

YEAR

225 drug, which distribution is not considered "wholesale  
226 distribution" under s. 499.003(53)(a).

227 1. A person who engages in the receipt or distribution of  
228 a prescription drug in this state for the purpose of processing  
229 its return or its destruction must obtain a permit as a  
230 restricted prescription drug distributor if such person is not  
231 the person initiating the return, the prescription drug  
232 wholesale supplier of the person initiating the return, or the  
233 manufacturer of the drug.

234 2. Storage, handling, and recordkeeping of these  
235 distributions must comply with the requirements for wholesale  
236 distributors under s. 499.0121, but not those set forth in s.  
237 499.01212.

238 3. A person who applies for a permit as a restricted  
239 prescription drug distributor, or for the renewal of such a  
240 permit, must provide to the department the information required  
241 under s. 499.012.

242 4. The department may adopt rules regarding the  
243 distribution of prescription drugs by hospitals, health care  
244 entities, charitable organizations, or other persons not  
245 involved in wholesale distribution, which rules are necessary  
246 for the protection of the public health, safety, and welfare.

247 (h) Complimentary drug distributor permit.--A  
248 complimentary drug distributor permit is required for any person  
249 that engages in the distribution of a complimentary drug,  
250 subject to the requirements of s. 499.028.

251 (i) Freight forwarder permit.--A freight forwarder permit  
252 is required for any person that engages in the distribution of a

BILL

ORIGINAL

YEAR

253 prescription drug as a freight forwarder unless the person is a  
 254 common carrier. The storage, handling, and recordkeeping of such  
 255 distributions must comply with the requirements for wholesale  
 256 distributors under s. 499.0121, but not those set forth in s.  
 257 499.01212. A freight forwarder must provide the source of the  
 258 prescription drugs with a validated airway bill, bill of lading,  
 259 or other appropriate documentation to evidence the exportation  
 260 of the product.

261 (j) Veterinary prescription drug retail establishment  
 262 permit.--A veterinary prescription drug retail establishment  
 263 permit is required for any person that sells veterinary  
 264 prescription drugs to the public but does not include a pharmacy  
 265 licensed under chapter 465.

266 1. The sale to the public must be based on a valid written  
 267 order from a veterinarian licensed in this state who has a valid  
 268 client-veterinarian relationship with the purchaser's animal.

269 2. Veterinary prescription drugs may not be sold in excess  
 270 of the amount clearly indicated on the order or beyond the date  
 271 indicated on the order.

272 3. An order may not be valid for more than 1 year.

273 4. A veterinary prescription drug retail establishment may  
 274 not purchase, sell, trade, or possess human prescription drugs  
 275 or any controlled substance as defined in chapter 893.

276 5. A veterinary prescription drug retail establishment  
 277 must sell a veterinary prescription drug in the original, sealed  
 278 manufacturer's container with all labeling intact and legible.  
 279 The department may adopt by rule additional labeling  
 280 requirements for the sale of a veterinary prescription drug.

BILL

ORIGINAL

YEAR

281           6. A veterinary prescription drug retail establishment  
 282 must comply with all of the wholesale distribution requirements  
 283 of s. 499.0121.

284           7. Prescription drugs sold by a veterinary prescription  
 285 drug retail establishment pursuant to a practitioner's order may  
 286 not be returned into the retail establishment's inventory.

287           (k) Veterinary prescription drug wholesale distributor  
 288 permit.--A veterinary prescription drug wholesale distributor  
 289 permit is required for any person that engages in the  
 290 distribution of veterinary prescription drugs in or into this  
 291 state. A veterinary prescription drug wholesale distributor that  
 292 also distributes prescription drugs subject to, defined by, or  
 293 described by s. 503(b) of the Federal Food, Drug, and Cosmetic  
 294 Act which it did not manufacture must obtain a permit as a  
 295 prescription drug wholesale distributor, an out-of-state  
 296 prescription drug wholesale distributor, or a limited  
 297 prescription drug veterinary wholesale distributor in lieu of  
 298 the veterinary prescription drug wholesale distributor permit. A  
 299 veterinary prescription drug wholesale distributor must comply  
 300 with the requirements for wholesale distributors under s.  
 301 499.0121, but not those set forth in s. 499.01212.

302           (1) Limited prescription drug veterinary wholesale  
 303 distributor permit.--Unless engaging in the activities of and  
 304 permitted as a prescription drug manufacturer, nonresident  
 305 prescription drug manufacturer, prescription drug wholesale  
 306 distributor, or out-of-state prescription drug wholesale  
 307 distributor, a limited prescription drug veterinary wholesale  
 308 distributor permit is required for any person that engages in

BILL

ORIGINAL

YEAR

309 | the distribution in or into this state of veterinary  
 310 | prescription drugs and prescription drugs subject to, defined  
 311 | by, or described by s. 503(b) of the Federal Food, Drug, and  
 312 | Cosmetic Act under the following conditions:  
 313 |       1. The person is engaged in the business of wholesaling  
 314 | prescription and veterinary prescription drugs to persons:  
 315 |       a. Licensed as veterinarians practicing on a full-time  
 316 | basis;  
 317 |       b. Regularly and lawfully engaged in instruction in  
 318 | veterinary medicine;  
 319 |       c. Regularly and lawfully engaged in law enforcement  
 320 | activities;  
 321 |       d. For use in research not involving clinical use; or  
 322 |       e. For use in chemical analysis or physical testing or for  
 323 | purposes of instruction in law enforcement activities, research,  
 324 | or testing.  
 325 |       2. No more than 30 percent of total annual prescription  
 326 | drug sales may be prescription drugs approved for human use  
 327 | which are subject to, defined by, or described by s. 503(b) of  
 328 | the Federal Food, Drug, and Cosmetic Act.  
 329 |       3. The person does not distribute in any jurisdiction  
 330 | prescription drugs subject to, defined by, or described by s.  
 331 | 503(b) of the Federal Food, Drug, and Cosmetic Act to any person  
 332 | who is authorized to sell, distribute, purchase, trade, or use  
 333 | these drugs on or for humans.  
 334 |       4. A limited prescription drug veterinary wholesale  
 335 | distributor that applies to the department for a new permit or  
 336 | the renewal of a permit must submit a bond of \$20,000, or other

BILL

ORIGINAL

YEAR

337 equivalent means of security acceptable to the department, such  
 338 as an irrevocable letter of credit or a deposit in a trust  
 339 account or financial institution, payable to the Florida Drug,  
 340 Device, and Cosmetic Trust Fund. The purpose of the bond is to  
 341 secure payment of any administrative penalties imposed by the  
 342 department and any fees and costs incurred by the department  
 343 regarding that permit which are authorized under state law and  
 344 which the permittee fails to pay 30 days after the fine or costs  
 345 become final. The department may make a claim against such bond  
 346 or security until 1 year after the permittee's license ceases to  
 347 be valid or until 60 days after any administrative or legal  
 348 proceeding authorized in this part which involves the permittee  
 349 is concluded, including any appeal, whichever occurs later.

350 5. A limited prescription drug veterinary wholesale  
 351 distributor must maintain at all times a license or permit to  
 352 engage in the wholesale distribution of prescription drugs in  
 353 compliance with laws of the state in which it is a resident.

354 6. A limited prescription drug veterinary wholesale  
 355 distributor must comply with the requirements for wholesale  
 356 distributors under ss. 499.0121 and 499.01212, except that a  
 357 limited prescription drug veterinary wholesale distributor is  
 358 not required to provide a pedigree paper as required by s.  
 359 499.01212 upon the wholesale distribution of a prescription drug  
 360 to a veterinarian.

361 7. A limited prescription drug veterinary wholesale  
 362 distributor may not return to inventory for subsequent wholesale  
 363 distribution any prescription drug subject to, defined by, or  
 364 described by s. 503(b) of the Federal Food, Drug, and Cosmetic

BILL

ORIGINAL

YEAR

365 Act which has been returned by a veterinarian.

366 8. A limited prescription drug veterinary wholesale  
 367 distributor permit is not required for an intracompany sale or  
 368 transfer of a prescription drug from an out-of-state  
 369 establishment that is duly licensed to engage in the wholesale  
 370 distribution of prescription drugs in its state of residence to  
 371 a licensed limited prescription drug veterinary wholesale  
 372 distributor in this state if both wholesale distributors conduct  
 373 wholesale distributions of prescription drugs under the same  
 374 business name. The recordkeeping requirements of ss. 499.0121(6)  
 375 and 499.01212 must be followed for this transaction.

376 (m) Medical oxygen retail establishment permit.--A medical  
 377 oxygen retail establishment permit is required for any person  
 378 that sells medical oxygen to patients only. The sale must be  
 379 based on an order from a practitioner authorized by law to  
 380 prescribe. The term does not include a pharmacy licensed under  
 381 chapter 465.

382 1. A medical oxygen retail establishment may not possess,  
 383 purchase, sell, or trade any prescription drug other than  
 384 medical oxygen.

385 2. A medical oxygen retail establishment may refill  
 386 medical oxygen for an individual patient based on an order from  
 387 a practitioner authorized by law to prescribe. A medical oxygen  
 388 retail establishment that refills medical oxygen must comply  
 389 with all appropriate state and federal good manufacturing  
 390 practices.

391 3. A medical oxygen retail establishment must comply with  
 392 all of the wholesale distribution requirements of s. 499.0121.

BILL

ORIGINAL

YEAR

393 4. Prescription medical oxygen sold by a medical oxygen  
 394 retail establishment pursuant to a practitioner's order may not  
 395 be returned into the retail establishment's inventory.

396 (n) Compressed medical gas wholesale distributor permit.—A  
 397 compressed medical gas wholesale distributor is a wholesale  
 398 distributor that is limited to the wholesale distribution of  
 399 compressed medical gases to other than the consumer or patient.  
 400 The compressed medical gas must be in the original sealed  
 401 container that was purchased by that wholesale distributor. A  
 402 compressed medical gas wholesale distributor may not possess or  
 403 engage in the wholesale distribution of any prescription drug  
 404 other than compressed medical gases. The department shall adopt  
 405 rules that govern the wholesale distribution of prescription  
 406 medical oxygen for emergency use. With respect to the emergency  
 407 use of prescription medical oxygen, those rules may not be  
 408 inconsistent with rules and regulations of federal agencies  
 409 unless the Legislature specifically directs otherwise.

410 (o) Compressed medical gas manufacturer permit.—A  
 411 compressed medical gas manufacturer permit is required for any  
 412 person that engages in the manufacture of compressed medical  
 413 gases or repackages compressed medical gases from one container  
 414 to another.

415 1. A compressed medical gas manufacturer may not  
 416 manufacture or possess any prescription drug other than  
 417 compressed medical gases.

418 2. A compressed medical gas manufacturer may engage in  
 419 wholesale distribution of compressed medical gases manufactured  
 420 at that establishment and must comply with all the provisions of

BILL

ORIGINAL

YEAR

421 | this part and the rules adopted under this part that apply to a  
 422 | wholesale distributor.

423 |         3. A compressed medical gas manufacturer must comply with  
 424 | all appropriate state and federal good manufacturing practices.

425 |         (p) Over-the-counter drug manufacturer permit.--An over-  
 426 | the-counter drug manufacturer permit is required for any person  
 427 | that engages in the manufacture or repackaging of an over-the-  
 428 | counter drug.

429 |         1. An over-the-counter drug manufacturer may not possess  
 430 | or purchase prescription drugs.

431 |         2. A pharmacy is exempt from obtaining an over-the-counter  
 432 | drug manufacturer permit if it is operating in compliance with  
 433 | pharmacy practice standards as defined in chapter 465 and the  
 434 | rules adopted under that chapter.

435 |         3. An over-the-counter drug manufacturer must comply with  
 436 | all appropriate state and federal good manufacturing practices.

437 |         (q) Device manufacturer permit.--A device manufacturer  
 438 | permit is required for any person that engages in the  
 439 | manufacture, repackaging, or assembly of medical devices for  
 440 | human use in this state, except that a permit is not required if  
 441 | the person is engaged only in manufacturing, repackaging, or  
 442 | assembling a medical device pursuant to a practitioner's order  
 443 | for a specific patient.

444 |         1. A manufacturer or repackager of medical devices in this  
 445 | state must comply with all appropriate state and federal good  
 446 | manufacturing practices and quality system rules.

447 |         2. The department shall adopt rules related to storage,  
 448 | handling, and recordkeeping requirements for manufacturers of



BILL

ORIGINAL

YEAR

449 | medical devices for human use.

450 |       (r) Cosmetic manufacturer permit.--A cosmetic manufacturer  
 451 | permit is required for any person that manufactures or  
 452 | repackages cosmetics in this state. A person that only labels or  
 453 | changes the labeling of a cosmetic but does not open the  
 454 | container sealed by the manufacturer of the product is exempt  
 455 | from obtaining a permit under this paragraph.

456 |       (s) Third party logistics provider permit.--A third party  
 457 | logistics provider permit is required for any person that  
 458 | contracts with a prescription drug wholesale distributor or  
 459 | prescription drug manufacturer to provide warehousing,  
 460 | distribution, or other logistics services on behalf of a  
 461 | manufacturer or wholesale distributor, but who does not take  
 462 | title to the prescription drug or have responsibility to direct  
 463 | the sale or disposition of the prescription drug. Each third  
 464 | party logistics provider permittee shall comply with the  
 465 | requirements for wholesale distributors under ss. 499.0121 and  
 466 | 499.01212, with the exception of those wholesale distributions  
 467 | described in s. 499.01212(3)(a), and other rules that the  
 468 | department requires.

469 |       (t) Health care clinic establishment permit.--Effective  
 470 | January 1, 2009, a health care clinic establishment permit is  
 471 | required for the purchase of a prescription drug by a business  
 472 | entity, as defined in s. 606.03, that operates ~~place of business~~  
 473 | at one general physical location, provides health care or  
 474 | veterinary services, and ~~owned and operated by a professional~~  
 475 | ~~corporation or professional limited liability company described~~  
 476 | ~~in chapter 621, or a corporation that employs a veterinarian as~~

BILL

ORIGINAL

YEAR

477 a qualifying practitioner. The health care clinic is not  
 478 required to obtain a permit if a qualifying practitioner  
 479 employed by the health care clinic obtains prescription drugs  
 480 under his or her license, in accordance with s. 499.03(1)(b).

481 For the purpose of this paragraph, the term "qualifying  
 482 practitioner" means a licensed health care practitioner defined  
 483 in s. 456.001 or a veterinarian licensed under chapter 474, who  
 484 is authorized under the appropriate practice act to prescribe  
 485 and administer a prescription drug.

486 1. An establishment must provide, as part of the  
 487 application required under s. 499.012, designation of a  
 488 qualifying practitioner who will be responsible for complying  
 489 with all legal and regulatory requirements related to the  
 490 purchase, recordkeeping, storage, and handling of the  
 491 prescription drugs. In addition, the designated qualifying  
 492 practitioner shall be the practitioner whose name, establishment  
 493 address, and license number is used on all distribution  
 494 documents for prescription drugs purchased or returned by the  
 495 health care clinic establishment. Upon initial appointment of a  
 496 qualifying practitioner, the qualifying practitioner and the  
 497 health care clinic establishment shall notify the department on  
 498 a form furnished by the department within 10 days after such  
 499 employment. In addition, the qualifying practitioner and health  
 500 care clinic establishment shall notify the department within 10  
 501 days after any subsequent change.

502 2. The health care clinic establishment must employ a  
 503 qualifying practitioner at each establishment.

504 3. In addition to the remedies and penalties provided in

BILL

ORIGINAL

YEAR

505 | this part, a violation of this chapter by the health care clinic  
 506 | establishment or qualifying practitioner constitutes grounds for  
 507 | discipline of the qualifying practitioner by the appropriate  
 508 | regulatory board.

509 |         4. The purchase of prescription drugs by the health care  
 510 | clinic establishment is prohibited during any period of time  
 511 | when the establishment does not comply with this paragraph.

512 |         5. A health care clinic establishment permit is not a  
 513 | pharmacy permit or otherwise subject to chapter 465. A health  
 514 | care clinic establishment that meets the criteria of a modified  
 515 | Class II institutional pharmacy under s. 465.019 is not eligible  
 516 | to be permitted under this paragraph.

517 |         6. This paragraph does not prohibit a licensed practitioner  
 518 | from obtaining prescription drugs under his or her license, in  
 519 | accordance with s. 499.03(1)(b).~~This paragraph does not prohibit~~  
 520 | ~~a qualifying practitioner from purchasing prescription drugs.~~

521 |         Section 3. Paragraph (e) of subsection (6) of section  
 522 | 499.0121, Florida Statutes, is amended to read:

523 |         499.0121 Storage and handling of prescription drugs;  
 524 | recordkeeping.--

525 |         (6) RECORDKEEPING.--The department shall adopt rules that  
 526 | require keeping such records of prescription drugs as are  
 527 | necessary for the protection of the public health.

528 |         (a) Wholesale distributors must establish and maintain  
 529 | inventories and records of all transactions regarding the  
 530 | receipt and distribution or other disposition of prescription  
 531 | drugs. These records must provide a complete audit trail from  
 532 | receipt to sale or other disposition, be readily retrievable for

BILL

ORIGINAL

YEAR

533 inspection, and include, at a minimum, the following  
 534 information:

535 1. The source of the drugs, including the name and  
 536 principal address of the seller or transferor, and the address  
 537 of the location from which the drugs were shipped;

538 2. The name, principal address, and state license permit  
 539 or registration number of the person authorized to purchase  
 540 prescription drugs;

541 3. The name, strength, dosage form, and quantity of the  
 542 drugs received and distributed or disposed of;

543 4. The dates of receipt and distribution or other  
 544 disposition of the drugs; and

545 5. Any financial documentation supporting the transaction.

546 (b) Inventories and records must be made available for  
 547 inspection and photocopying by authorized federal, state, or  
 548 local officials for a period of 2 years following disposition of  
 549 the drugs or 3 years after the creation of the records,  
 550 whichever period is longer.

551 (c) Records described in this section that are kept at the  
 552 inspection site or that can be immediately retrieved by computer  
 553 or other electronic means must be readily available for  
 554 authorized inspection during the retention period. Records that  
 555 are kept at a central location outside of this state and that  
 556 are not electronically retrievable must be made available for  
 557 inspection within 2 working days after a request by an  
 558 authorized official of a federal, state, or local law  
 559 enforcement agency. Records that are maintained at a central  
 560 location within this state must be maintained at an

BILL

ORIGINAL

YEAR

561 establishment that is permitted pursuant to this part and must  
 562 be readily available.

563 (d) Each manufacturer or repackager of medical devices,  
 564 over-the-counter drugs, or cosmetics must maintain records that  
 565 include the name and principal address of the seller or  
 566 transferor of the product, the address of the location from  
 567 which the product was shipped, the date of the transaction, the  
 568 name and quantity of the product involved, and the name and  
 569 principal address of the person who purchased the product.

570 (e) When pedigree papers are required by this part, a  
 571 wholesale distributor must maintain the pedigree papers separate  
 572 and distinct from other records required under this part~~chapter~~.

573 Section 4. This act shall take effect October 1, 2009.