

1 A bill to be entitled
2 An act relating to prescription drugs; amending s.
3 456.44, F.S.; revising the definition of the term
4 "addiction medicine specialist" to include board-
5 certified psychiatrists; defining the term "board
6 eligible"; excluding a board-certified physiatrist as
7 an addiction medicine specialist; including the
8 American Board of Medical Specialties as a recognized
9 certification entity; revising the definition of the
10 term "chronic nonmalignant pain" to exclude reference
11 to rheumatoid arthritis; exempting specified board-
12 eligible health care providers from application of
13 certain provisions; adding the American Board of Pain
14 Medicine as a recognized board-certification entity
15 for purposes of exemption from application of certain
16 provisions; amending s. 458.3265, F.S.; defining the
17 term "board eligible"; revising the definition of the
18 term "chronic nonmalignant pain" to exclude reference
19 to rheumatoid arthritis; permitting specified board-
20 eligible physicians to own a pain-management clinic
21 without registering the clinic; permitting a
22 rheumatologist to own a pain-management clinic without
23 registering the clinic; including a physician
24 multispecialty practice to permitted ownership forms
25 of pain-management clinics; requiring at least one
26 specialist in multispecialty practice to be board-
27 eligible; recognizing the American Board of Pain
28 Medicine, the American Association of Physician

29 Specialists, and the American Osteopathic Association
30 as board-certification organizations for purposes of
31 determining a board-certified pain medicine specialist
32 as an owner of a pain-management clinic; amending s.
33 459.0137, F.S.; defining the term "board eligible";
34 revising the definition of the term "chronic
35 nonmalignant pain" to exclude reference to rheumatoid
36 arthritis; permitting a board-eligible rheumatologist
37 to own a pain-management clinic; including a physician
38 multispecialty practice to permitted ownership forms
39 of pain-management clinics; permitting specified
40 board-eligible physicians to own a pain-management
41 clinic without registering the clinic; permitting a
42 rheumatologist to own a pain-management clinic without
43 registering the clinic; adding multispecialty practice
44 to permitted ownership forms of pain-management
45 clinics; requiring at least one specialist in
46 multispecialty practice to be board-eligible;
47 recognizing the American Board of Pain Medicine and
48 the American Association of Physician Specialists as
49 board-certification organizations for purposes of
50 determining a board-certified pain medicine specialist
51 as owner of a pain-management clinic; amending s.
52 499.003, F.S.; revising the definitions of the terms
53 "distribute" or "distribution," "drug,"
54 "establishment," "prescription drug," and "wholesale
55 distribution"; amending s. 499.01, F.S.; deleting
56 provisions relating to an exemption from nonresident

57 | prescription drug manufacturer permit requirements;
58 | deleting provisions relating to an exemption from out-
59 | of-state prescription drug wholesale distributor
60 | permit requirements for intracompany sale or transfer
61 | of prescription drugs; providing an exemption from
62 | permit requirements for the distribution into this
63 | state of prescription drug active pharmaceutical
64 | ingredients for incorporation into prescription drugs
65 | in finished dosage form; requiring a distributor
66 | claiming such exemption to maintain a valid license,
67 | permit, or registration in the state from which the
68 | prescription drug was distributed; requiring
69 | compliance with certain recordkeeping requirements;
70 | exempting compliance with pedigree paper requirements;
71 | providing an exemption from permit requirements for
72 | distribution into this state of limited quantities of
73 | a prescription drug that has not been repackaged, for
74 | research and development or to a holder of a letter of
75 | exemption issued by the Department of Business and
76 | Professional Regulation for research, teaching, or
77 | testing; granting the department authority to define
78 | "limited quantities" by rule and limit therein the
79 | number of transactions and amount of prescription
80 | drugs distributed into the state; requiring a
81 | distributor claiming such exemption to maintain a
82 | valid license, permit, or registration in the state
83 | from which the prescription drug was distributed;
84 | requiring all purchasers and recipients of such

85 prescription drugs to ensure the products are not
86 resold or used on humans except in lawful clinical
87 trials and biostudies; requiring compliance with
88 certain recordkeeping requirements; exempting
89 compliance from pedigree paper requirements; providing
90 labeling requirements for active pharmaceutical
91 ingredients distributed within the state for teaching,
92 testing, research, and development; exempting from
93 out-of-state prescription drug wholesale distributor
94 permit requirements intracompany transactions or the
95 sale of prescription drugs from an out-of-state
96 distributor to a distributor in this state if both
97 distributors conduct wholesale distributions under the
98 same business name; requiring compliance with
99 recordkeeping and pedigree paper requirements;
100 allowing distributors and recipients of prescription
101 drugs claiming exemption from certain permitting
102 requirements to maintain on file their FDA
103 registration number, resident state distributor
104 license or permit number, and most recent resident
105 state or FDA inspection report; providing that persons
106 claiming such exemptions are subject to part I of
107 chapter 499, F.S., the Florida Drug and Cosmetic Act;
108 requiring persons claiming such exemptions to make all
109 records regarding prescription drug distribution
110 available to the department, upon request, within 48
111 hours; requiring submission of a report of mishandled
112 or adulterated prescription drugs within 14 days after

113 receipt of such drugs; authorizing the department to
 114 adopt rules; providing that failure to comply with
 115 requirements or rules governing such exemptions
 116 constitutes unlawful purchase or receipt of a
 117 prescription drug from a person not authorized to
 118 distribute prescription drugs to that purchaser or
 119 recipient; providing that knowing failure to comply
 120 with such requirements constitutes unlawful sale,
 121 distribution, purchase, trade, holding, or offering of
 122 a drug; providing penalties; providing construction
 123 with respect to federal and state laws relating to
 124 controlled substances; providing conditions for
 125 exemption from a prescription drug repackager permit
 126 with respect to certain restricted prescription drug
 127 distributor permitholders; providing an effective
 128 date.

129

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

131

132 Section 1. Present paragraphs (a), (c), and (d) of
 133 subsection (1), paragraph (a) of subsection (2), and paragraph
 134 (e) of subsection (3) of section 456.44, Florida Statutes, are
 135 amended, and a new paragraph (d) is added to subsection (1) of
 136 that section, to read:

137 456.44 Controlled substance prescribing.—

138 (1) DEFINITIONS.—

139 (a) "Addiction medicine specialist" means a board-
 140 certified psychiatrist ~~physiatrist~~ with a subspecialty

141 certification in addiction medicine or who is eligible for such
 142 subspecialty certification in addiction medicine, an addiction
 143 medicine physician certified or eligible for certification by
 144 the American Society of Addiction Medicine, or an osteopathic
 145 physician who holds a certificate of added qualification in
 146 Addiction Medicine through the American Osteopathic Association.

147 (c) "Board-certified pain management physician" means a
 148 physician who possesses board certification in pain medicine by
 149 the American Board of Pain Medicine, board certification by the
 150 American Board of Interventional Pain Physicians, or board
 151 certification or subcertification in pain management by a
 152 specialty board recognized by the American Association of
 153 Physician Specialists or the American Board of Medical
 154 Specialties or an osteopathic physician who holds a certificate
 155 in Pain Management by the American Osteopathic Association.

156 (d) "Board eligible" means successful completion of an
 157 anesthesia, physical medicine and rehabilitation, rheumatology,
 158 or neurology residency program approved by the Accreditation
 159 Council for Graduate Medical Education or the American
 160 Osteopathic Association for a period of six years from
 161 successful completion of such residency program.

162 (e) ~~(d)~~ "Chronic nonmalignant pain" means pain unrelated to
 163 cancer ~~or rheumatoid arthritis~~ which persists beyond the usual
 164 course of disease or the injury that is the cause of the pain or
 165 more than 90 days after surgery.

166 (2) REGISTRATION.—Effective January 1, 2012, a physician
 167 licensed under chapter 458, chapter 459, chapter 461, or chapter
 168 466 who prescribes any controlled substance, listed in Schedule

169 II, Schedule III, or Schedule IV as defined in s. 893.03, for
170 the treatment of chronic nonmalignant pain, must:

171 (a) Designate himself or herself as a controlled substance
172 prescribing practitioner on the physician's practitioner
173 profile.

174 (3) STANDARDS OF PRACTICE.—The standards of practice in
175 this section do not supersede the level of care, skill, and
176 treatment recognized in general law related to health care
177 licensure.

178 (e) The physician shall refer the patient as necessary for
179 additional evaluation and treatment in order to achieve
180 treatment objectives. Special attention shall be given to those
181 patients who are at risk for misusing their medications and
182 those whose living arrangements pose a risk for medication
183 misuse or diversion. The management of pain in patients with a
184 history of substance abuse or with a comorbid psychiatric
185 disorder requires extra care, monitoring, and documentation and
186 requires consultation with or referral to an addictionologist or
187 psychiatrist ~~physiatrist~~.

188

189 This subsection does not apply to a board-eligible or board-
190 certified anesthesiologist, physiatrist, rheumatologist, or
191 neurologist, or to a board-certified physician who has surgical
192 privileges at a hospital or ambulatory surgery center and
193 primarily provides surgical services. This subsection does not
194 apply to a board-eligible or board-certified medical specialist
195 who has also completed a fellowship in pain medicine approved by
196 the Accreditation Council for Graduate Medical Education or the

197 American Osteopathic Association, or who is board eligible or
 198 board certified in pain medicine by the American Board of Pain
 199 Medicine or a board approved by the American Board of Medical
 200 Specialties or the American Osteopathic Association and performs
 201 interventional pain procedures of the type routinely billed
 202 using surgical codes.

203 Section 2. Paragraph (a) of subsection (1) of section
 204 458.3265, Florida Statutes, is amended to read:

205 458.3265 Pain-management clinics.—

206 (1) REGISTRATION.—

207 (a)1. As used in this section, the term:

208 a. "Board eligible" means successful completion of an
 209 anesthesia, physical medicine and rehabilitation, rheumatology,
 210 or neurology residency program approved by the Accreditation
 211 Council for Graduate Medical Education or the American
 212 Osteopathic Association for a period of six years from
 213 successful completion of such residency program.

214 ~~b.a.~~ "Chronic nonmalignant pain" means pain unrelated to
 215 cancer ~~or rheumatoid arthritis~~ which persists beyond the usual
 216 course of disease or the injury that is the cause of the pain or
 217 more than 90 days after surgery.

218 ~~c.b.~~ "Pain-management clinic" or "clinic" means any
 219 publicly or privately owned facility:

220 (I) That advertises in any medium for any type of pain-
 221 management services; or

222 (II) Where in any month a majority of patients are
 223 prescribed opioids, benzodiazepines, barbiturates, or
 224 carisoprodol for the treatment of chronic nonmalignant pain.

225 2. Each pain-management clinic must register with the
 226 department unless:

227 a. That clinic is licensed as a facility pursuant to
 228 chapter 395;

229 b. The majority of the physicians who provide services in
 230 the clinic primarily provide surgical services;

231 c. The clinic is owned by a publicly held corporation
 232 whose shares are traded on a national exchange or on the over-
 233 the-counter market and whose total assets at the end of the
 234 corporation's most recent fiscal quarter exceeded \$50 million;

235 d. The clinic is affiliated with an accredited medical
 236 school at which training is provided for medical students,
 237 residents, or fellows;

238 e. The clinic does not prescribe controlled substances for
 239 the treatment of pain;

240 f. The clinic is owned by a corporate entity exempt from
 241 federal taxation under 26 U.S.C. s. 501(c)(3);

242 g. The clinic is wholly owned and operated by one or more
 243 board-eligible or board-certified anesthesiologists,
 244 physiatrists, rheumatologists, or neurologists; or

245 h. The clinic is wholly owned and operated by a physician
 246 multispecialty practice where one or more board-eligible or
 247 board-certified medical specialists who have also completed
 248 fellowships in pain medicine approved by the Accreditation
 249 Council for Graduate Medical Education, or who are also board-
 250 certified in pain medicine by the American Board of Pain
 251 Medicine or a board approved by the American Board of Medical
 252 Specialties, the American Association of Physician Specialists,

253 | or the American Osteopathic Association and perform
 254 | interventional pain procedures of the type routinely billed
 255 | using surgical codes.

256 | Section 3. Paragraph (a) of subsection (1) of section
 257 | 459.0137, Florida Statutes, is amended to read:

258 | 459.0137 Pain-management clinics.—

259 | (1) REGISTRATION.—

260 | (a)1. As used in this section, the term:

261 | a. "Board eligible" means successful completion of an
 262 | anesthesia, physical medicine and rehabilitation, rheumatology,
 263 | or neurology residency program approved by the Accreditation
 264 | Council for Graduate Medical Education or the American
 265 | Osteopathic Association for a period of six years from
 266 | successful completion of such residency program.

267 | ~~b.a.~~ "Chronic nonmalignant pain" means pain unrelated to
 268 | cancer ~~or rheumatoid arthritis~~ which persists beyond the usual
 269 | course of disease or the injury that is the cause of the pain or
 270 | more than 90 days after surgery.

271 | ~~c.b.~~ "Pain-management clinic" or "clinic" means any
 272 | publicly or privately owned facility:

273 | (I) That advertises in any medium for any type of pain-
 274 | management services; or

275 | (II) Where in any month a majority of patients are
 276 | prescribed opioids, benzodiazepines, barbiturates, or
 277 | carisoprodol for the treatment of chronic nonmalignant pain.

278 | 2. Each pain-management clinic must register with the
 279 | department unless:

280 | a. That clinic is licensed as a facility pursuant to

281 chapter 395;

282 b. The majority of the physicians who provide services in
283 the clinic primarily provide surgical services;

284 c. The clinic is owned by a publicly held corporation
285 whose shares are traded on a national exchange or on the over-
286 the-counter market and whose total assets at the end of the
287 corporation's most recent fiscal quarter exceeded \$50 million;

288 d. The clinic is affiliated with an accredited medical
289 school at which training is provided for medical students,
290 residents, or fellows;

291 e. The clinic does not prescribe controlled substances for
292 the treatment of pain;

293 f. The clinic is owned by a corporate entity exempt from
294 federal taxation under 26 U.S.C. s. 501(c)(3);

295 g. The clinic is wholly owned and operated by one or more
296 board-eligible or board-certified anesthesiologists,
297 physiatrists, rheumatologists, or neurologists; or

298 h. The clinic is wholly owned and operated by a physician
299 multispecialty practice where one or more board-eligible or
300 board-certified medical specialists who have also completed
301 fellowships in pain medicine approved by the Accreditation
302 Council for Graduate Medical Education or the American
303 Osteopathic Association, or who are also board-certified in pain
304 medicine by the American Board of Pain Medicine or a board
305 approved by the American Board of Medical Specialties, the
306 American Association of Physician Specialties, or the American
307 Osteopathic Association and perform interventional pain
308 procedures of the type routinely billed using surgical codes.

309 Section 4. Subsections (17), (19), (20), and (43) and
 310 paragraph (a) of subsection (54) of section 499.003, Florida
 311 Statutes, are amended to read:

312 499.003 Definitions of terms used in this part.—As used in
 313 this part, the term:

314 (17) "Distribute" or "distribution" means to sell; offer
 315 to sell; give away; transfer, whether by passage of title,
 316 physical movement, or both; deliver; or offer to deliver. The
 317 term does not mean to administer or dispense and does not
 318 include administrative billing, invoicing, and payment
 319 collection and processing activities that commonly evidence a
 320 distribution transaction.

321 (19) "Drug" means an article that is:

322 (a) Recognized in the current edition of the United States
 323 Pharmacopoeia and National Formulary, official Homeopathic
 324 Pharmacopoeia of the United States, or any supplement to any of
 325 those publications;

326 (b) Intended for use in the diagnosis, cure, mitigation,
 327 treatment, therapy, or prevention of disease in humans or other
 328 animals;

329 (c) Intended to affect the structure or any function of
 330 the body of humans or other animals; or

331 (d) Intended for use as a component of any article
 332 specified in paragraph (a), paragraph (b), or paragraph (c), and
 333 includes active pharmaceutical ingredient, but does not include
 334 devices or their nondrug components, parts, or accessories. For
 335 purposes of this paragraph, an "active pharmaceutical
 336 ingredient" includes any substance or mixture of substances

337 intended, represented, or labeled for use in drug manufacturing
338 that furnishes or is intended to furnish in a finished dosage
339 form any pharmacological activity or other direct effect in the
340 diagnosis, cure, mitigation, treatment, therapy, or prevention
341 of disease in humans or other animals, or to affect the
342 structure or any function of the body of humans or other
343 animals.

344 (20) "Establishment" means a place of business at one
345 general physical location that may extend to one or more
346 contiguous buildings or building subdivisions, including suites,
347 units, or floors, or to one or more buildings situated on a
348 single controlled-access property owned or operated by a single
349 entity or entities under common operational control. To be
350 contiguous, buildings or building subdivisions must adjoin or
351 share a sufficient common boundary to allow full and free access
352 to the whole establishment without crossing a public roadway,
353 public waterway, or similar barrier. A permit issued under this
354 part applies only to those buildings and building subdivisions
355 identified on the most recent application for or to renew that
356 permit, and an establishment may not expand to include other
357 buildings or building subdivisions without an approved change of
358 address application under s. 499.012(6)(a).

359 (43) "Prescription drug" means a prescription, medicinal,
360 or legend drug, including, but not limited to, finished dosage
361 forms or active pharmaceutical ingredients subject to, defined
362 by, or described by s. 503(b) of the Federal Food, Drug, and
363 Cosmetic Act or s. 465.003(8), s. 499.007(13), or subsection
364 (11), subsection (46), or subsection (53), except that an active

365 pharmaceutical ingredient is a prescription drug only if
366 substantially all finished dosage forms in which it may be
367 lawfully dispensed or administered in Florida are also
368 prescription drugs.

369 (54) "Wholesale distribution" means distribution of
370 prescription drugs to persons other than a consumer or patient,
371 but does not include:

372 (a) Any of the following activities, which is not a
373 violation of s. 499.005(21) if such activity is conducted in
374 accordance with s. 499.01(2)(g):

375 1. The purchase or other acquisition by a hospital or
376 other health care entity that is a member of a group purchasing
377 organization of a prescription drug for its own use from the
378 group purchasing organization or from other hospitals or health
379 care entities that are members of that organization.

380 2. The sale, purchase, or trade of a prescription drug or
381 an offer to sell, purchase, or trade a prescription drug by a
382 charitable organization described in s. 501(c)(3) of the
383 Internal Revenue Code of 1986, as amended and revised, to a
384 nonprofit affiliate of the organization to the extent otherwise
385 permitted by law.

386 3. The sale, purchase, or trade of a prescription drug or
387 an offer to sell, purchase, or trade a prescription drug among
388 hospitals or other health care entities that are under common
389 control. For purposes of this subparagraph, "common control"
390 means the power to direct or cause the direction of the
391 management and policies of a person or an organization, whether

392 by ownership of stock, by voting rights, by contract, or
 393 otherwise.

394 4. The sale, purchase, trade, or other transfer of a
 395 prescription drug from or for any federal, state, or local
 396 government agency or any entity eligible to purchase
 397 prescription drugs at public health services prices pursuant to
 398 Pub. L. No. 102-585, s. 602 to a contract provider or its
 399 subcontractor for eligible patients of the agency or entity
 400 under the following conditions:

401 a. The agency or entity must obtain written authorization
 402 for the sale, purchase, trade, or other transfer of a
 403 prescription drug under this subparagraph from the State Surgeon
 404 General or his or her designee.

405 b. The contract provider or subcontractor must be
 406 authorized by law to administer or dispense prescription drugs.

407 c. In the case of a subcontractor, the agency or entity
 408 must be a party to and execute the subcontract.

409 ~~d. A contract provider or subcontractor must maintain~~
 410 ~~separate and apart from other prescription drug inventory any~~
 411 ~~prescription drugs of the agency or entity in its possession.~~

412 d.e. The contract provider and subcontractor must maintain
 413 and produce immediately for inspection all records of movement
 414 or transfer of all the prescription drugs belonging to the
 415 agency or entity, including, but not limited to, the records of
 416 receipt and disposition of prescription drugs. Each contractor
 417 and subcontractor dispensing or administering these drugs must
 418 maintain and produce records documenting the dispensing or
 419 administration. Records that are required to be maintained

420 include, but are not limited to, a perpetual inventory itemizing
421 drugs received and drugs dispensed by prescription number or
422 administered by patient identifier, which must be submitted to
423 the agency or entity quarterly.

424 ~~e.f.~~ The contract provider or subcontractor may administer
425 or dispense the prescription drugs only to the eligible patients
426 of the agency or entity or must return the prescription drugs
427 for or to the agency or entity. The contract provider or
428 subcontractor must require proof from each person seeking to
429 fill a prescription or obtain treatment that the person is an
430 eligible patient of the agency or entity and must, at a minimum,
431 maintain a copy of this proof as part of the records of the
432 contractor or subcontractor required under sub-subparagraph d e.

433 ~~f.g.~~ In addition to the departmental inspection authority
434 set forth in s. 499.051, the establishment of the contract
435 provider and subcontractor and all records pertaining to
436 prescription drugs subject to this subparagraph shall be subject
437 to inspection by the agency or entity. All records relating to
438 prescription drugs of a manufacturer under this subparagraph
439 shall be subject to audit by the manufacturer of those drugs,
440 without identifying individual patient information.

441 Section 5. Paragraphs (c) and (e) of subsection (2) of
442 section 499.01, Florida Statutes, are amended, and subsections
443 (3) and (4) are added to that section, to read:

444 499.01 Permits.—

445 (2) The following permits are established:

446 (c) Nonresident prescription drug manufacturer permit.—A
447 nonresident prescription drug manufacturer permit is required

448 for any person that is a manufacturer of prescription drugs,
 449 unless permitted as a third party logistics provider, located
 450 outside of this state or outside the United States and that
 451 engages in the wholesale distribution in this state of such
 452 prescription drugs. Each such manufacturer must be permitted by
 453 the department and comply with all of the provisions required of
 454 a wholesale distributor under this part, except s. 499.01212.

455 1. A person that distributes prescription drugs for which
 456 the person is not the manufacturer must also obtain an out-of-
 457 state prescription drug wholesale distributor permit or third
 458 party logistics provider permit pursuant to this section to
 459 engage in the wholesale distribution of such prescription drugs.
 460 This subparagraph does not apply to a manufacturer as defined in
 461 s. 499.003(31)(e).

462 2. Any such person must comply with the licensing or
 463 permitting requirements of the jurisdiction in which the
 464 establishment is located and the federal act, and any product
 465 wholesaled into this state must comply with this part. If a
 466 person intends to import prescription drugs from a foreign
 467 country into this state, the nonresident prescription drug
 468 manufacturer must provide to the department a list identifying
 469 each prescription drug it intends to import and document
 470 approval by the United States Food and Drug Administration for
 471 such importation.

472 ~~3. A nonresident prescription drug manufacturer permit is~~
 473 ~~not required for a manufacturer to distribute a prescription~~
 474 ~~drug active pharmaceutical ingredient that it manufactures to a~~
 475 ~~prescription drug manufacturer permitted in this state in~~

476 ~~limited quantities intended for research and development and not~~
477 ~~for resale, or human use other than lawful clinical trials and~~
478 ~~biostudies authorized and regulated by federal law. A~~
479 ~~manufacturer claiming to be exempt from the permit requirements~~
480 ~~of this subparagraph and the prescription drug manufacturer~~
481 ~~purchasing and receiving the active pharmaceutical ingredient~~
482 ~~shall comply with the recordkeeping requirements of s.~~
483 ~~499.0121(6), but not the requirements of s. 499.01212. The~~
484 ~~prescription drug manufacturer purchasing and receiving the~~
485 ~~active pharmaceutical ingredient shall maintain on file a record~~
486 ~~of the FDA registration number; the out-of-state license,~~
487 ~~permit, or registration number; and, if available, a copy of the~~
488 ~~most current FDA inspection report, for all manufacturers from~~
489 ~~whom they purchase active pharmaceutical ingredients under this~~
490 ~~section. The department shall specify by rule the allowable~~
491 ~~number of transactions within a given period of time and the~~
492 ~~amount of active pharmaceutical ingredients that qualify as~~
493 ~~limited quantities for purposes of this exemption. The failure~~
494 ~~to comply with the requirements of this subparagraph, or rules~~
495 ~~adopted by the department to administer this subparagraph, for~~
496 ~~the purchase of prescription drug active pharmaceutical~~
497 ~~ingredients is a violation of s. 499.005(14).~~

498 (e) Out-of-state prescription drug wholesale distributor
499 permit.—An out-of-state prescription drug wholesale distributor
500 is a wholesale distributor located outside this state which
501 engages in the wholesale distribution of prescription drugs into
502 this state and which must be permitted by the department and
503 comply with all the provisions required of a wholesale

504 distributor under this part. An out-of-state prescription drug
505 wholesale distributor that applies to the department for a new
506 permit or the renewal of a permit must submit a bond of
507 \$100,000, or other equivalent means of security acceptable to
508 the department, such as an irrevocable letter of credit or a
509 deposit in a trust account or financial institution, payable to
510 the Florida Drug, Device, and Cosmetic Trust Fund. The purpose
511 of the bond is to secure payment of any administrative penalties
512 imposed by the department and any fees and costs incurred by the
513 department regarding that permit which are authorized under
514 state law and which the permittee fails to pay 30 days after the
515 fine or costs become final. The department may make a claim
516 against such bond or security until 1 year after the permittee's
517 license ceases to be valid or until 60 days after any
518 administrative or legal proceeding authorized in this part which
519 involves the permittee is concluded, including any appeal,
520 whichever occurs later.

521 ~~1.~~ The out-of-state prescription drug wholesale
522 distributor must maintain at all times a license or permit to
523 engage in the wholesale distribution of prescription drugs in
524 compliance with laws of the state in which it is a resident.

525 ~~2. An out-of-state prescription drug wholesale distributor~~
526 ~~permit is not required for an intracompany sale or transfer of a~~
527 ~~prescription drug from an out-of-state establishment that is~~
528 ~~duly licensed as a prescription drug wholesale distributor, in~~
529 ~~its state of residence, to a licensed prescription drug~~
530 ~~wholesale distributor in this state, if both wholesale~~
531 ~~distributors conduct wholesale distributions of prescription~~

532 ~~drugs under the same business name. The recordkeeping~~
533 ~~requirements of ss. 499.0121(6) and 499.01212 must be followed~~
534 ~~for this transaction.~~

535 (3) A nonresident prescription drug manufacturer permit is
536 not required for a manufacturer to distribute a prescription
537 drug active pharmaceutical ingredient that it manufactures to a
538 prescription drug manufacturer permitted in this state in
539 limited quantities intended for research and development and not
540 for resale, or human use other than lawful clinical trials and
541 biostudies authorized and regulated by federal law. A
542 manufacturer claiming to be exempt from the permitting
543 requirements of this part under this paragraph and the
544 prescription drug manufacturer purchasing and receiving the
545 active pharmaceutical ingredient shall comply with the
546 recordkeeping requirements of s. 499.0121(6), but not the
547 requirements of s. 499.01212. The prescription drug manufacturer
548 purchasing and receiving the active pharmaceutical ingredient
549 shall maintain on file a record of the FDA registration number;
550 the out-of-state license, permit, or registration number; and,
551 if available, a copy of the most current FDA inspection report,
552 for all manufacturers from whom active pharmaceutical ingredient
553 is purchased under this paragraph. The department shall define
554 "limited quantities" by rule, and may include the allowable
555 number of transactions within a given period of time and the
556 amounts of prescription drugs distributed into the state for
557 purposes of this exemption. The failure to comply with the
558 requirements of this paragraph, or rules adopted by the
559 department to administer this paragraph, for the purchase of

560 prescription drug active pharmaceutical ingredients is a
561 violation of s. 499.005(14), and a knowing failure is a
562 violation of s. 499.0051(4).

563 (b) Subject to the requirements of paragraph (d), a permit
564 issued under this part is not required to distribute
565 prescription drug active pharmaceutical ingredient from an
566 establishment located in the United States to an establishment
567 located in this state permitted as a prescription drug
568 manufacturer under this part for use solely by or for the
569 recipient in preparing, deriving, processing, producing, or
570 fabricating a prescription drug finished dosage form at the
571 establishment in this state where the product is received under
572 an approved and otherwise valid New Drug Application,
573 Abbreviated New Drug Application, New Animal Drug Application,
574 Therapeutic Biologic Application, or Biologics License
575 Application, provided that the application, active
576 pharmaceutical ingredient, or finished dosage form has not been
577 withdrawn or removed from the market in this country for public
578 health reasons.

579 (c) Subject to the requirements of paragraph (d), a permit
580 issued under this part is not required to distribute limited
581 quantities of a prescription drug that has not been repackaged
582 from an establishment located in the United States to an
583 establishment located in this state permitted as a prescription
584 drug manufacturer under this part for research and development
585 or to a holder of a letter of exemption issued by the department
586 under s. 499.03(4) for research, teaching, or testing. The
587 department shall define "limited quantities" by rule, and may

588 include the allowable number of transactions within a given
589 period of time and the amounts of prescription drugs distributed
590 into the state for purposes of this exemption.

591 1. All purchasers and recipients of any prescription drugs
592 distributed pursuant to this paragraph shall ensure that the
593 products are not resold or used, directly or indirectly, on
594 humans except in lawful clinical trials and biostudies
595 authorized and regulated by federal law.

596 2. The immediate package or container of any prescription
597 drug distributed into the state intended for teaching, testing,
598 research, or development shall bear a label prominently
599 displaying the statement "Caution: Research, Teaching, or
600 Testing Only - Not for Commercial Use, Distribution, or Resale."

601 (d) The persons and activities described in paragraphs (b)
602 and (c) shall comply with the following requirements, and except
603 as provided in this subsection, the requirements of this part
604 and rules adopted under this part:

605 1. The distributor claimed to be exempt from the
606 permitting requirements of this part shall maintain a license,
607 permit or registration as a manufacturer or wholesale
608 distributor of prescription drugs under the laws of the state
609 from which the product is distributed.

610 2. Persons purchasing or receiving prescription drugs from
611 a distributor claimed to be exempt from the permitting
612 requirements of this part shall maintain on file, for each such
613 prescription drug and distributor, a record of the FDA
614 establishment registration number where the prescription drugs
615 were manufactured; the distributing establishment's resident

616 state prescription drug manufacturer or wholesale distributor
617 license, permit, or registration number; and a copy of the
618 distributing establishment's most recent resident state or FDA
619 inspection report, if available.

620 3. Distributors claimed to be exempt from the permitting
621 requirements of this part, and the purchaser and recipient of
622 the prescription drugs purchased or received from such sources,
623 shall comply with the recordkeeping requirements of s.
624 499.0121(6), but not the requirements of s. 499.01212.

625 (e) An out-of-state prescription drug wholesale
626 distributor permit is not required for an intracompany sale or
627 transfer of a prescription drug from an out-of-state
628 establishment that is duly licensed as a prescription drug
629 wholesale distributor, in its state of residence, to a licensed
630 prescription drug wholesale distributor in this state, if both
631 wholesale distributors conduct wholesale distributions of
632 prescription drugs under the same business name. The
633 recordkeeping requirements of ss. 499.0121(6) and 499.01212 must
634 be followed for such transactions.

635 (f) All persons distributing prescription drugs in or into
636 the state, regardless of any exemption from permitting
637 requirements, are subject to this part, including ss. 499.005
638 and 499.0051, and the rules adopted under this part, and shall
639 make available, within 48 hours, to the department on request
640 all records related to any prescription drugs distributed under
641 this subsection, including those records described in s.
642 499.051(4), regardless of the location where the records are
643 stored.

644 (g) A person purchasing and receiving a prescription drug
645 from a person claimed to be exempt from licensing requirements
646 pursuant to this subsection shall report to the department in
647 writing within 14 days after receiving any product that is
648 misbranded or adulterated or that fails to meet minimum
649 standards for identity, purity, potency, or sterility set forth
650 in the official compendium or in state or federal good
651 manufacturing practices, regardless of whether the product is
652 thereafter rehabilitated, quarantined, returned, or destroyed.

653 (h) The department may adopt rules to administer this
654 subsection, which rules are necessary for the protection of the
655 public health, safety, and welfare. The failure to comply with
656 the requirements of this subsection, or rules adopted by the
657 department to administer this subsection, is a violation of s.
658 499.005(14), and a knowing failure is a violation of s.
659 499.0051(4).

660 (i) This subsection does not relieve any person from any
661 requirement prescribed by law with respect to controlled
662 substances as defined in the applicable federal and state laws.

663 (4) A prescription drug repackager permit issued under
664 this part is not required for a restricted prescription drug
665 distributor permit holder that is a health care entity to
666 repackage prescription drugs in this state for its own use or
667 for distribution to hospitals or other health care entities in
668 the state for their own use pursuant to s. 499.003(54)(a)3.,
669 provided:

670 (a) The prescription drug distributor notifies the
671 department, in writing, of its intention to engage in

672 repackaging under this exemption 30 days prior to actually
673 engaging in the repackaging of prescription drugs at the
674 permitted establishment;

675 (b) The prescription drug distributor is under common
676 control with the hospitals or other health care entities to
677 which the prescription drug distributor is distributing
678 prescription drugs. For purposes of this subparagraph, the term
679 "common control" means the power to direct or cause the
680 direction of the management and policies of a person or an
681 organization, whether by ownership of stock, by voting rights,
682 by contract, or otherwise;

683 (c) The prescription drug distributor repackages the
684 prescription drugs in accordance with current state and federal
685 good manufacturing practices; and

686 (d) The prescription drug distributor labels the
687 prescription drug it repackages in accordance with state and
688 federal laws and rules.

689
690 The prescription drug distributor is exempt from the product
691 registration requirements of s. 499.015 with regard to the
692 prescription drugs that it repackages and distributes under this
693 subsection.

694 Section 6. This act shall take effect July 1, 2012.