

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

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

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

85 humans except in lawful clinical trials and
86 biostudies; requiring compliance with certain
87 recordkeeping requirements; exempting compliance from
88 pedigree paper requirements; providing labeling
89 requirements for active pharmaceutical ingredients
90 distributed within the state for teaching, testing,
91 research, and development; exempting from out-of-state
92 prescription drug wholesale distributor permit
93 requirements intracompany transactions or the sale of
94 prescription drugs from an out-of-state distributor to
95 a distributor in this state if both distributors
96 conduct wholesale distributions under the same
97 business name; requiring compliance with recordkeeping
98 and pedigree paper requirements; allowing distributors
99 and recipients of prescription drugs claiming
100 exemption from certain permitting requirements to
101 maintain on file their FDA registration number,
102 resident state distributor license or permit number,
103 and most recent resident state or FDA inspection
104 report; providing that persons claiming such
105 exemptions are subject to part I of chapter 499, F.S.,
106 the Florida Drug and Cosmetic Act; requiring persons
107 claiming such exemptions to make all records regarding
108 prescription drug distribution available to the
109 department, upon request, within 48 hours; requiring
110 submission of a report of mishandled or adulterated
111 prescription drugs within 14 days after receipt of
112 such drugs; authorizing the department to adopt rules;

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

127
 128 Be It Enacted by the Legislature of the State of Florida:

129
 130 Section 1. Paragraphs (a), (c), and (d) of subsection (1),
 131 paragraph (a) of subsection (2), and paragraph (e) of subsection
 132 (3) of section 456.44, Florida Statutes, are amended to read:

133 456.44 Controlled substance prescribing.—

134 (1) DEFINITIONS.—

135 (a) "Addiction medicine specialist" means a board-
 136 certified psychiatrist ~~psychiatrist~~ with a subspecialty
 137 certification in addiction medicine or who is eligible for such
 138 subspecialty certification in addiction medicine, an addiction
 139 medicine physician certified or eligible for certification by
 140 the American Society of Addiction Medicine, or an osteopathic

141 physician who holds a certificate of added qualification in
 142 Addiction Medicine through the American Osteopathic Association.

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

152 (d) "Chronic nonmalignant pain" means pain unrelated to
 153 cancer ~~or rheumatoid arthritis~~ which persists beyond the usual
 154 course of disease or the injury that is the cause of the pain or
 155 more than 90 days after surgery.

156 (2) REGISTRATION.—Effective January 1, 2012, a physician
 157 licensed under chapter 458, chapter 459, chapter 461, or chapter
 158 466 who prescribes any controlled substance, listed in Schedule
 159 II, Schedule III, or Schedule IV as defined in s. 893.03, for
 160 the treatment of chronic nonmalignant pain, must:

161 (a) Designate himself or herself as a controlled substance
 162 prescribing practitioner on the physician's practitioner
 163 profile.

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

168 (e) The physician shall refer the patient as necessary for

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169 additional evaluation and treatment in order to achieve
170 treatment objectives. Special attention shall be given to those
171 patients who are at risk for misusing their medications and
172 those whose living arrangements pose a risk for medication
173 misuse or diversion. The management of pain in patients with a
174 history of substance abuse or with a comorbid psychiatric
175 disorder requires extra care, monitoring, and documentation and
176 requires consultation with or referral to an addictionologist or
177 psychiatrist ~~physiatrist~~.

178
179 This subsection does not apply to a board-eligible or board-
180 certified anesthesiologist, physiatrist, rheumatologist, or
181 neurologist, or to a board-certified physician who has surgical
182 privileges at a hospital or ambulatory surgery center and
183 primarily provides surgical services. This subsection does not
184 apply to a board-eligible or board-certified medical specialist
185 who has also completed a fellowship in pain medicine approved by
186 the Accreditation Council for Graduate Medical Education or the
187 American Osteopathic Association, or who is board eligible or
188 board certified in pain medicine by the American Board of Pain
189 Medicine or a board approved by the American Board of Medical
190 Specialties or the American Osteopathic Association and performs
191 interventional pain procedures of the type routinely billed
192 using surgical codes.

193 Section 2. Paragraph (a) of subsection (1) of section
194 458.3265, Florida Statutes, is amended to read:

195 458.3265 Pain-management clinics.—

196 (1) REGISTRATION.—

197 (a)1. As used in this section, the term:
 198 a. "Chronic nonmalignant pain" means pain unrelated to
 199 cancer ~~or rheumatoid arthritis~~ which persists beyond the usual
 200 course of disease or the injury that is the cause of the pain or
 201 more than 90 days after surgery.
 202 b. "Pain-management clinic" or "clinic" means any publicly
 203 or privately owned facility:
 204 (I) That advertises in any medium for any type of pain-
 205 management services; or
 206 (II) Where in any month a majority of patients are
 207 prescribed opioids, benzodiazepines, barbiturates, or
 208 carisoprodol for the treatment of chronic nonmalignant pain.
 209 2. Each pain-management clinic must register with the
 210 department unless:
 211 a. That clinic is licensed as a facility pursuant to
 212 chapter 395;
 213 b. The majority of the physicians who provide services in
 214 the clinic primarily provide surgical services;
 215 c. The clinic is owned by a publicly held corporation
 216 whose shares are traded on a national exchange or on the over-
 217 the-counter market and whose total assets at the end of the
 218 corporation's most recent fiscal quarter exceeded \$50 million;
 219 d. The clinic is affiliated with an accredited medical
 220 school at which training is provided for medical students,
 221 residents, or fellows;
 222 e. The clinic does not prescribe controlled substances for
 223 the treatment of pain;
 224 f. The clinic is owned by a corporate entity exempt from

225 federal taxation under 26 U.S.C. s. 501(c)(3);

226 g. The clinic is wholly owned and operated by one or more
 227 board-eligible or board-certified anesthesiologists,
 228 physiatrists, rheumatologists, or neurologists; or

229 h. The clinic is wholly owned and operated by a physician
 230 multispecialty practice where one or more board-eligible or
 231 board-certified medical specialists who have also completed
 232 fellowships in pain medicine approved by the Accreditation
 233 Council for Graduate Medical Education, or who are also board-
 234 certified in pain medicine by the American Board of Pain or a
 235 board approved by the American Board of Medical Specialties, the
 236 American Association of Physician Specialists, or the American
 237 Osteopathic Association and perform interventional pain
 238 procedures of the type routinely billed using surgical codes.

239 Section 3. Paragraph (a) of subsection (1) of section
 240 459.0137, Florida Statutes, is amended to read:

241 459.0137 Pain-management clinics.—

242 (1) REGISTRATION.—

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

244 a. "Chronic nonmalignant pain" means pain unrelated to
 245 ~~cancer or rheumatoid arthritis~~ which persists beyond the usual
 246 course of disease or the injury that is the cause of the pain or
 247 more than 90 days after surgery.

248 b. "Pain-management clinic" or "clinic" means any publicly
 249 or privately owned facility:

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

252 (II) Where in any month a majority of patients are

253 | prescribed opioids, benzodiazepines, barbiturates, or
 254 | carisoprodol for the treatment of chronic nonmalignant pain.

255 | 2. Each pain-management clinic must register with the
 256 | department unless:

257 | a. That clinic is licensed as a facility pursuant to
 258 | chapter 395;

259 | b. The majority of the physicians who provide services in
 260 | the clinic primarily provide surgical services;

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

265 | d. The clinic is affiliated with an accredited medical
 266 | school at which training is provided for medical students,
 267 | residents, or fellows;

268 | e. The clinic does not prescribe controlled substances for
 269 | the treatment of pain;

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

272 | g. The clinic is wholly owned and operated by one or more
 273 | board-eligible or board-certified anesthesiologists,
 274 | physiatrists, rheumatologists, or neurologists; or

275 | h. The clinic is wholly owned and operated by a physician
 276 | multispecialty practice where one or more board-eligible or
 277 | board-certified medical specialists who have also completed
 278 | fellowships in pain medicine approved by the Accreditation
 279 | Council for Graduate Medical Education or the American
 280 | Osteopathic Association, or who are also board-certified in pain

281 medicine by the American Board of Pain Medicine or a board
282 approved by the American Board of Medical Specialties, the
283 American Association of Physician Specialties, or the American
284 Osteopathic Association and perform interventional pain
285 procedures of the type routinely billed using surgical codes.

286 Section 4. Subsections (17), (19), (20), and (43) of
287 section 499.003, Florida Statutes, are amended to read:

288 499.003 Definitions of terms used in this part.—As used in
289 this part, the term:

290 (17) "Distribute" or "distribution" means to sell; offer
291 to sell; give away; transfer, whether by passage of title,
292 physical movement, or both; deliver; or offer to deliver. The
293 term does not mean to administer or dispense and does not
294 include administrative billing, invoicing, and payment
295 collection and processing activities that commonly evidence a
296 distribution transaction.

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

298 (a) Recognized in the current edition of the United States
299 Pharmacopoeia and National Formulary, official Homeopathic
300 Pharmacopoeia of the United States, or any supplement to any of
301 those publications;

302 (b) Intended for use in the diagnosis, cure, mitigation,
303 treatment, therapy, or prevention of disease in humans or other
304 animals;

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

307 (d) Intended for use as a component of any article
308 specified in paragraph (a), paragraph (b), or paragraph (c), and

309 includes active pharmaceutical ingredient, but does not include
310 devices or their nondrug components, parts, or accessories. For
311 purposes of this paragraph, an "active pharmaceutical
312 ingredient" includes any substance or mixture of substances
313 intended, represented, or labeled for use in drug manufacturing
314 that furnishes or is intended to furnish in a finished dosage
315 form any pharmacological activity or other direct effect in the
316 diagnosis, cure, mitigation, treatment, therapy, or prevention
317 of disease in humans or other animals, or to affect the
318 structure or any function of the body of humans or other
319 animals.

320 (20) "Establishment" means a place of business at one
321 general physical location that may extend to one or more
322 contiguous buildings or building subdivisions, including suites,
323 units, or floors, or to one or more buildings situated on a
324 single controlled-access property owned or operated by a single
325 entity or entities under common operational control. To be
326 contiguous, buildings or building subdivisions must adjoin or
327 share a sufficient common boundary to allow full and free access
328 to the whole establishment without crossing a public roadway,
329 public waterway, or similar barrier. A permit issued under this
330 part applies only to those buildings and building subdivisions
331 identified on the most recent application for or to renew that
332 permit, and an establishment may not expand to include other
333 buildings or building subdivisions without an approved change of
334 address application under s. 499.012(6)(a).

335 (43) "Prescription drug" means a prescription, medicinal,
336 or legend drug, including, but not limited to, finished dosage

337 forms or active pharmaceutical ingredients subject to, defined
 338 by, or described by s. 503(b) of the Federal Food, Drug, and
 339 Cosmetic Act or s. 465.003(8), s. 499.007(13), or subsection
 340 (11), subsection (46), or subsection (53), except that an active
 341 pharmaceutical ingredient is a prescription drug only if
 342 substantially all finished dosage forms in which it may be
 343 lawfully dispensed or administered in Florida are also
 344 prescription drugs.

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

348 499.01 Permits.—

349 (2) The following permits are established:

350 (c) Nonresident prescription drug manufacturer permit.—A
 351 nonresident prescription drug manufacturer permit is required
 352 for any person that is a manufacturer of prescription drugs,
 353 unless permitted as a third party logistics provider, located
 354 outside of this state or outside the United States and that
 355 engages in the wholesale distribution in this state of such
 356 prescription drugs. Each such manufacturer must be permitted by
 357 the department and comply with all of the provisions required of
 358 a wholesale distributor under this part, except s. 499.01212.

359 1. A person that distributes prescription drugs for which
 360 the person is not the manufacturer must also obtain an out-of-
 361 state prescription drug wholesale distributor permit or third
 362 party logistics provider permit pursuant to this section to
 363 engage in the wholesale distribution of such prescription drugs.
 364 This subparagraph does not apply to a manufacturer as defined in

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365 s. 499.003(31)(e).

366 2. Any such person must comply with the licensing or
367 permitting requirements of the jurisdiction in which the
368 establishment is located and the federal act, and any product
369 wholesaled into this state must comply with this part. If a
370 person intends to import prescription drugs from a foreign
371 country into this state, the nonresident prescription drug
372 manufacturer must provide to the department a list identifying
373 each prescription drug it intends to import and document
374 approval by the United States Food and Drug Administration for
375 such importation.

376 ~~3. A nonresident prescription drug manufacturer permit is~~
377 ~~not required for a manufacturer to distribute a prescription~~
378 ~~drug active pharmaceutical ingredient that it manufactures to a~~
379 ~~prescription drug manufacturer permitted in this state in~~
380 ~~limited quantities intended for research and development and not~~
381 ~~for resale, or human use other than lawful clinical trials and~~
382 ~~biostudies authorized and regulated by federal law. A~~
383 ~~manufacturer claiming to be exempt from the permit requirements~~
384 ~~of this subparagraph and the prescription drug manufacturer~~
385 ~~purchasing and receiving the active pharmaceutical ingredient~~
386 ~~shall comply with the recordkeeping requirements of s.~~
387 ~~499.0121(6), but not the requirements of s. 499.01212. The~~
388 ~~prescription drug manufacturer purchasing and receiving the~~
389 ~~active pharmaceutical ingredient shall maintain on file a record~~
390 ~~of the FDA registration number; the out-of-state license,~~
391 ~~permit, or registration number; and, if available, a copy of the~~
392 ~~most current FDA inspection report, for all manufacturers from~~

393 ~~whom they purchase active pharmaceutical ingredients under this~~
394 ~~section. The department shall specify by rule the allowable~~
395 ~~number of transactions within a given period of time and the~~
396 ~~amount of active pharmaceutical ingredients that qualify as~~
397 ~~limited quantities for purposes of this exemption. The failure~~
398 ~~to comply with the requirements of this subparagraph, or rules~~
399 ~~adopted by the department to administer this subparagraph, for~~
400 ~~the purchase of prescription drug active pharmaceutical~~
401 ~~ingredients is a violation of s. 499.005(14).~~

402 (e) Out-of-state prescription drug wholesale distributor
403 permit.—An out-of-state prescription drug wholesale distributor
404 is a wholesale distributor located outside this state which
405 engages in the wholesale distribution of prescription drugs into
406 this state and which must be permitted by the department and
407 comply with all the provisions required of a wholesale
408 distributor under this part. An out-of-state prescription drug
409 wholesale distributor that applies to the department for a new
410 permit or the renewal of a permit must submit a bond of
411 \$100,000, or other equivalent means of security acceptable to
412 the department, such as an irrevocable letter of credit or a
413 deposit in a trust account or financial institution, payable to
414 the Florida Drug, Device, and Cosmetic Trust Fund. The purpose
415 of the bond is to secure payment of any administrative penalties
416 imposed by the department and any fees and costs incurred by the
417 department regarding that permit which are authorized under
418 state law and which the permittee fails to pay 30 days after the
419 fine or costs become final. The department may make a claim
420 against such bond or security until 1 year after the permittee's

421 license ceases to be valid or until 60 days after any
 422 administrative or legal proceeding authorized in this part which
 423 involves the permittee is concluded, including any appeal,
 424 whichever occurs later.

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

429 ~~2. An out-of-state prescription drug wholesale distributor~~
 430 ~~permit is not required for an intracompany sale or transfer of a~~
 431 ~~prescription drug from an out-of-state establishment that is~~
 432 ~~duly licensed as a prescription drug wholesale distributor, in~~
 433 ~~its state of residence, to a licensed prescription drug~~
 434 ~~wholesale distributor in this state, if both wholesale~~
 435 ~~distributors conduct wholesale distributions of prescription~~
 436 ~~drugs under the same business name. The recordkeeping~~
 437 ~~requirements of ss. 499.0121(6) and 499.01212 must be followed~~
 438 ~~for this transaction.~~

439 (3) A nonresident prescription drug manufacturer permit is
 440 not required for a manufacturer to distribute a prescription
 441 drug active pharmaceutical ingredient that it manufactures to a
 442 prescription drug manufacturer permitted in this state in
 443 limited quantities intended for research and development and not
 444 for resale, or human use other than lawful clinical trials and
 445 biostudies authorized and regulated by federal law. A
 446 manufacturer claiming to be exempt from the permitting
 447 requirements of this part under this paragraph and the
 448 prescription drug manufacturer purchasing and receiving the

449 active pharmaceutical ingredient shall comply with the
450 recordkeeping requirements of s. 499.0121(6), but not the
451 requirements of s. 499.01212. The prescription drug manufacturer
452 purchasing and receiving the active pharmaceutical ingredient
453 shall maintain on file a record of the FDA registration number;
454 the out-of-state license, permit, or registration number; and,
455 if available, a copy of the most current FDA inspection report,
456 for all manufacturers from whom active pharmaceutical ingredient
457 is purchased under this paragraph. The department shall define
458 "limited quantities" by rule, and may include the allowable
459 number of transactions within a given period of time and the
460 amounts of prescription drugs distributed into the state for
461 purposes of this exemption. The failure to comply with the
462 requirements of this paragraph, or rules adopted by the
463 department to administer this paragraph, for the purchase of
464 prescription drug active pharmaceutical ingredients is a
465 violation of s. 499.005(14), and a knowing failure is a
466 violation of s. 499.0051(4).

467 (b) Subject to the requirements of paragraph (d), a permit
468 issued under this part is not required to distribute
469 prescription drug active pharmaceutical ingredient from an
470 establishment located in the United States to an establishment
471 located in this state permitted as a prescription drug
472 manufacturer under this part for use solely by or for the
473 recipient in preparing, deriving, processing, producing, or
474 fabricating a prescription drug finished dosage form at the
475 establishment in this state where the product is received under
476 an approved and otherwise valid New Drug Application,

477 Abbreviated New Drug Application, New Animal Drug Application,
478 Therapeutic Biologic Application, or Biologics License
479 Application, provided that the application, active
480 pharmaceutical ingredient, or finished dosage form has not been
481 withdrawn or removed from the market in this country for public
482 health reasons.

483 (c) Subject to the requirements of paragraph (d), a permit
484 issued under this part is not required to distribute limited
485 quantities of a prescription drug that has not been repackaged
486 from an establishment located in the United States to an
487 establishment located in this state permitted as a prescription
488 drug manufacturer under this part for research and development
489 or to a holder of a letter of exemption issued by the department
490 under s. 499.03(4) for research, teaching, or testing. The
491 department shall define "limited quantities" by rule, and may
492 include the allowable number of transactions within a given
493 period of time and the amounts of prescription drugs distributed
494 into the state for purposes of this exemption.

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

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

505 (d) The persons and activities described in paragraphs (b)
506 and (c) shall comply with the following requirements, and except
507 as provided in this subsection, the requirements of this part
508 and rules adopted under this part:

509 1. The distributor claimed to be exempt from the
510 permitting requirements of this part shall maintain a license,
511 permit or registration as a manufacturer or wholesale
512 distributor of prescription drugs under the laws of the state
513 from which the product is distributed.

514 2. Persons purchasing or receiving prescription drugs from
515 a distributor claimed to be exempt from the permitting
516 requirements of this part shall maintain on file, for each such
517 prescription drug and distributor, a record of the FDA
518 establishment registration number where the prescription drugs
519 were manufactured; the distributing establishment's resident
520 state prescription drug manufacturer or wholesale distributor
521 license, permit, or registration number; and a copy of the
522 distributing establishment's most recent resident state or FDA
523 inspection report, if available.

524 3. Distributors claimed to be exempt from the permitting
525 requirements of this part, and the purchaser and recipient of
526 the prescription drugs purchased or received from such sources,
527 shall comply with the recordkeeping requirements of s.
528 499.0121(6), but not the requirements of s. 499.01212.

529 (e) An out-of-state prescription drug wholesale
530 distributor permit is not required for an intracompany sale or
531 transfer of a prescription drug from an out-of-state
532 establishment that is duly licensed as a prescription drug

533 wholesale distributor, in its state of residence, to a licensed
534 prescription drug wholesale distributor in this state, if both
535 wholesale distributors conduct wholesale distributions of
536 prescription drugs under the same business name. The
537 recordkeeping requirements of ss. 499.0121(6) and 499.01212 must
538 be followed for such transactions.

539 (f) All persons distributing prescription drugs in or into
540 the state, regardless of any exemption from permitting
541 requirements, are subject to this part, including ss. 499.005
542 and 499.0051, and the rules adopted under this part, and shall
543 make available, within 48 hours, to the department on request
544 all records related to any prescription drugs distributed under
545 this subsection, including those records described in s.
546 499.051(4), regardless of the location where the records are
547 stored.

548 (g) A person purchasing and receiving a prescription drug
549 from a person claimed to be exempt from licensing requirements
550 pursuant to this subsection shall report to the department in
551 writing within 14 days after receiving any product that is
552 misbranded or adulterated or that fails to meet minimum
553 standards for identity, purity, potency, or sterility set forth
554 in the official compendium or in state or federal good
555 manufacturing practices, regardless of whether the product is
556 thereafter rehabilitated, quarantined, returned, or destroyed.

557 (h) The department may adopt rules to administer this
558 subsection, which rules are necessary for the protection of the
559 public health, safety, and welfare. The failure to comply with
560 the requirements of this subsection, or rules adopted by the

561 department to administer this subsection, is a violation of s.
562 499.005(14), and a knowing failure is a violation of s.
563 499.0051(4).

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

567 (4) A prescription drug repackager permit issued under
568 this part is not required for a restricted prescription drug
569 distributor permitholder that is a health care entity to
570 repackage prescription drugs in this state for its own use or
571 for distribution to hospitals or other health care entities in
572 the state for their own use pursuant to s. 499.003(54)(a)3.,
573 provided:

574 (a) The prescription drug distributor notifies the
575 department, in writing, of its intention to engage in
576 repackaging under this exemption 30 days prior to actually
577 engaging in the repackaging of prescription drugs at the
578 permitted establishment;

579 (b) The prescription drug distributor is under common
580 control with the hospitals or other health care entities to
581 which the prescription drug distributor is distributing
582 prescription drugs. For purposes of this subparagraph, the term
583 "common control" means the power to direct or cause the
584 direction of the management and policies of a person or an
585 organization, whether by ownership of stock, by voting rights,
586 by contract, or otherwise;

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587 (c) The prescription drug distributor repackages the
588 prescription drugs in accordance with current state and federal
589 good manufacturing practices; and

590 (d) The prescription drug distributor labels the
591 prescription drug it repackages in accordance with state and
592 federal laws and rules.

593
594 The prescription drug distributor is exempt from the product
595 registration requirements of s. 499.015 with regard to the
596 prescription drugs that it repackages and distributes under this
597 subsection.

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