

PCS for CS/HB 751

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1 A bill to be entitled
 2 An act relating to prescription drugs; amending s.
 3 456.44, F.S.; removing physiatrist; adding
 4 psychiatrist and rheumatologist; amending definition
 5 of chronic non-malignant pain; adding the American
 6 Board of Medical Specialties to recognized
 7 certification entities; amending definition of
 8 controlled substances; amending s. 458.3265, F.S.;
 9 amending definition of chronic non-malignant pain;
 10 permitting a rheumatologist to own pain clinics;
 11 adding multi-specialty practice to permitted ownership
 12 forms of pain clinics; amending s. 459.0137, F.S.;
 13 amending definition of chronic non-malignant pain;
 14 permitting a rheumatologist to own pain clinics;
 15 adding multi-specialty practice to permitted ownership
 16 forms of pain clinics; amending s. 499.003, F.S.;
 17 revising the definitions of the terms "distribute" or
 18 "distribution," "drug," "establishment," and
 19 "prescription drug"; amending s. 499.01, F.S.;
 20 deleting provisions relating to an exemption from
 21 nonresident prescription drug manufacturer permit
 22 requirements; deleting provisions relating to an
 23 exemption from out-of-state prescription drug
 24 wholesale distributor permit requirements for
 25 intracompany sale or transfer of prescription drugs;
 26 providing an exemption from permit requirements for
 27 the distribution into this state of prescription drug
 28 active pharmaceutical ingredients for incorporation

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29 | into prescription drugs in finished dosage form;
 30 | requiring a distributor claiming such exemption to
 31 | maintain a valid license, permit, or registration in
 32 | the state from which the prescription drug was
 33 | distributed; requiring compliance with certain
 34 | recordkeeping requirements; exempting compliance with
 35 | pedigree paper requirements; providing an exemption
 36 | from permit requirements for distribution into this
 37 | state of limited quantities of a prescription drug
 38 | that has not been repackaged, for research and
 39 | development or to a holder of a letter of exemption
 40 | issued by the Department of Business and Professional
 41 | Regulation for research, teaching, or testing;
 42 | granting the department authority to define "limited
 43 | quantities" by rule and limit therein the number of
 44 | transactions and amount of prescription drugs
 45 | distributed into the state; requiring a distributor
 46 | claiming such exemption to maintain a valid license,
 47 | permit, or registration in the state from which the
 48 | prescription drug was distributed; requiring all
 49 | purchasers and recipients of such prescription drugs
 50 | to ensure the products are not resold or used on
 51 | humans except in lawful clinical trials and
 52 | biostudies; requiring compliance with certain
 53 | recordkeeping requirements; exempting compliance from
 54 | pedigree paper requirements; providing labeling
 55 | requirements for active pharmaceutical ingredients
 56 | distributed within the state for teaching, testing,

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57 | research, and development; exempting from out-of-state
 58 | prescription drug wholesale distributor permit
 59 | requirements intracompany transactions or the sale of
 60 | prescription drugs from an out-of-state distributor to
 61 | a distributor in this state if both distributors
 62 | conduct wholesale distributions under the same
 63 | business name; requiring compliance with recordkeeping
 64 | and pedigree paper requirements; allowing distributors
 65 | and recipients of prescription drugs claiming
 66 | exemption from certain permitting requirements to
 67 | maintain on file their FDA registration number,
 68 | resident state distributor license or permit number,
 69 | and most recent resident state or FDA inspection
 70 | report; providing that persons claiming such
 71 | exemptions are subject to part I of chapter 499, F.S.,
 72 | the Florida Drug and Cosmetic Act; requiring persons
 73 | claiming such exemptions to make all records regarding
 74 | prescription drug distribution available to the
 75 | department, upon request, within 48 hours; requiring
 76 | submission of a report of mishandled or adulterated
 77 | prescription drugs within 14 days after receipt of
 78 | such drugs; authorizing the department to adopt rules;
 79 | providing that failure to comply with requirements or
 80 | rules governing such exemptions constitutes unlawful
 81 | purchase or receipt of a prescription drug from a
 82 | person not authorized to distribute prescription drugs
 83 | to that purchaser or recipient; providing that knowing
 84 | failure to comply with such requirements constitutes

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85 | unlawful sale, distribution, purchase, trade, holding,
 86 | or offering of a drug; providing penalties; providing
 87 | construction with respect to federal and state laws
 88 | relating to controlled substances; providing an
 89 | effective date.

90 |

91 | Be It Enacted by the Legislature of the State of Florida:

92 | Section 1. Paragraphs (a), (c) and (d) of subsection
 93 | (1), paragraph (a) of subsection (2), and paragraph (e) of
 94 | subsection (3) of section 456.44, Florida Statutes, are amended
 95 | to read:

96 | 456.44 Controlled substance prescribing.—

97 | (1) DEFINITIONS.—

98 | (a) "Addiction medicine specialist" means a board-
 99 | certified psychiatrist ~~physiatrist~~ with a subspecialty
 100 | certification in addiction medicine or who is eligible for such
 101 | subspecialty certification in addiction medicine, an addiction
 102 | medicine physician certified or eligible for certification by
 103 | the American Society of Addiction Medicine, or an osteopathic
 104 | physician who holds a certificate of added qualification in
 105 | Addiction Medicine through the American Osteopathic Association.

106 | (c) "Board-certified pain management physician" means a
 107 | physician who possesses board certification in pain medicine by
 108 | the American Board of Pain Medicine, board certification by the
 109 | American Board of Interventional Pain Physicians, or board
 110 | certification or subcertification in pain management by a
 111 | specialty board recognized by the American Association of
 112 | Physician Specialists or the American Board of Medical

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113 Specialties or an osteopathic physician who holds a certificate
 114 in Pain Management by the American Osteopathic Association.

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

119 (2) REGISTRATION.—Effective January 1, 2012, a physician
 120 licensed under chapter 458, chapter 459, chapter 461, or chapter
 121 466 who prescribes any controlled substance, listed in Schedule
 122 II, Schedule III, or Schedule IV as defined in s. 893.03, for
 123 the treatment of chronic nonmalignant pain, must:

124 (a) Designate himself or herself as a controlled substance
 125 prescribing practitioner on the physician's practitioner
 126 profile.

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

131 (e) The physician shall refer the patient as necessary for
 132 additional evaluation and treatment in order to achieve
 133 treatment objectives. Special attention shall be given to those
 134 patients who are at risk for misusing their medications and
 135 those whose living arrangements pose a risk for medication
 136 misuse or diversion. The management of pain in patients with a
 137 history of substance abuse or with a comorbid psychiatric
 138 disorder requires extra care, monitoring, and documentation and
 139 requires consultation with or referral to an addictionologist or
 140 psychiatrist ~~physiatrist~~.

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 142 This subsection does not apply to a board-certified
 143 anesthesiologist, physiatrist, rheumatologist, or neurologist,
 144 or to a board-certified physician who has surgical privileges at
 145 a hospital or ambulatory surgery center and primarily provides
 146 surgical services. This subsection does not apply to a board-
 147 certified medical specialist who has also completed a fellowship
 148 in pain medicine approved by the Accreditation Council for
 149 Graduate Medical Education or the American Osteopathic
 150 Association, or who is board certified in pain medicine by a
 151 board approved by the American Board of Medical Specialties or
 152 the American Osteopathic Association and performs interventional
 153 pain procedures of the type routinely billed using surgical
 154 codes.

155 Section 2. Paragraph (a) of subsection (1) of section
 156 458.3265, Florida Statutes, is amended to read:

157 458.3265 Pain-management clinics.—

158 (1) REGISTRATION.—

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

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

164 b. "Pain-management clinic" or "clinic" means any publicly
 165 or privately owned facility:

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

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

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169 | prescribed opioids, benzodiazepines, barbiturates, or
 170 | carisoprodol for the treatment of chronic nonmalignant pain.
 171 | 2. Each pain-management clinic must register with the
 172 | department unless:
 173 | a. That clinic is licensed as a facility pursuant to
 174 | chapter 395;
 175 | b. The majority of the physicians who provide services in
 176 | the clinic primarily provide surgical services;
 177 | c. The clinic is owned by a publicly held corporation
 178 | whose shares are traded on a national exchange or on the over-
 179 | the-counter market and whose total assets at the end of the
 180 | corporation's most recent fiscal quarter exceeded \$50 million;
 181 | d. The clinic is affiliated with an accredited medical
 182 | school at which training is provided for medical students,
 183 | residents, or fellows;
 184 | e. The clinic does not prescribe controlled substances for
 185 | the treatment of pain;
 186 | f. The clinic is owned by a corporate entity exempt from
 187 | federal taxation under 26 U.S.C. s. 501(c)(3);
 188 | g. The clinic is wholly owned and operated by one or more
 189 | board-certified anesthesiologists, physiatrists,
 190 | rheumatologists, or neurologists; or
 191 | h. The clinic is wholly owned and operated by a physician
 192 | multi-specialty practice where one or more board-certified
 193 | medical specialists who have also completed fellowships in pain
 194 | medicine approved by the Accreditation Council for Graduate
 195 | Medical Education, or who are also board-certified in pain
 196 | medicine by a board approved by the American Board of Medical

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197 Specialties and perform interventional pain procedures of the
 198 type routinely billed using surgical codes.

199 Section 3. Paragraph (a) of subsection (1) of section
 200 459.0137, Florida Statutes, is amended to read:

201 459.0137 Pain-management clinics.—

202 (1) REGISTRATION.—

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

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

208 b. "Pain-management clinic" or "clinic" means any publicly
 209 or privately owned facility:

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

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

215 2. Each pain-management clinic must register with the
 216 department unless:

217 a. That clinic is licensed as a facility pursuant to
 218 chapter 395;

219 b. The majority of the physicians who provide services in
 220 the clinic primarily provide surgical services;

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

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225 d. The clinic is affiliated with an accredited medical
 226 school at which training is provided for medical students,
 227 residents, or fellows;

228 e. The clinic does not prescribe controlled substances for
 229 the treatment of pain;

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

232 g. The clinic is wholly owned and operated by one or more
 233 board-certified anesthesiologists, physiatrists,
 234 rheumatologists, or neurologists; or

235 h. The clinic is wholly owned and operated by a physician
 236 multi-specialty practice where one or more board-certified
 237 medical specialists who have also completed fellowships in pain
 238 medicine approved by the Accreditation Council for Graduate
 239 Medical Education or the American Osteopathic Association, or
 240 who are also board-certified in pain medicine by a board
 241 approved by the American Board of Medical Specialties or the
 242 American Osteopathic Association and perform interventional pain
 243 procedures of the type routinely billed using surgical codes.

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

246 499.003 - Definitions of terms used in this part.—As used
 247 in this part, the term:

248 (17) "Distribute" or "distribution" means to sell; offer to
 249 sell; give away; transfer, whether by passage of title, physical
 250 movement, or both; deliver; or offer to deliver. The term does
 251 not mean to administer or dispense and does not include
 252 administrative billing, invoicing, and payment collection and

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253 processing activities that commonly evidence a distribution
 254 transaction.

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

256 (a) Recognized in the current edition of the United States
 257 Pharmacopoeia and National Formulary, official Homeopathic
 258 Pharmacopoeia of the United States, or any supplement to any of
 259 those publications;

260 (b) Intended for use in the diagnosis, cure, mitigation,
 261 treatment, therapy, or prevention of disease in humans or other
 262 animals;

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

265 (d) Intended for use as a component of any article
 266 specified in paragraph (a), paragraph (b), or paragraph (c), and
 267 includes active pharmaceutical ingredient, but does not include
 268 devices or their non-drug components, parts, or accessories.

269 For purposes of this paragraph, an "active pharmaceutical
 270 ingredient" includes any substance or mixture of substances
 271 intended, represented, or labeled for use in drug manufacturing
 272 that furnishes or is intended to furnish in a finished dosage
 273 form any pharmacological activity or other direct effect in the
 274 diagnosis, cure, mitigation, treatment, therapy, or prevention
 275 of disease in humans or other animals, or to affect the
 276 structure or any function of the body of humans or other
 277 animals.

278 (20) "Establishment" means a place of business at one
 279 general physical location that may extend to one or more
 280 contiguous buildings or building subdivisions, including suites,

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281 units, or floors, or to one or more buildings situated on a
 282 single controlled-access property owned or operated by a single
 283 entity or entities under common operational control. To be
 284 contiguous, buildings or building subdivisions must adjoin or
 285 share a sufficient common boundary to allow full and free access
 286 to the whole establishment without crossing a public roadway,
 287 public waterway, or similar barrier. A permit issued under this
 288 part applies only to those buildings and building subdivisions
 289 identified on the most recent application for or to renew that
 290 permit, and an establishment may not expand to include other
 291 buildings or building subdivisions without an approved change of
 292 address application under s. 499.012(6)(a).

293 (43) "Prescription drug" means a prescription, medicinal,
 294 or legend drug, including, but not limited to, finished dosage
 295 forms or active pharmaceutical ingredients subject to, defined
 296 by, or described by s. 503(b) of the Federal Food, Drug, and
 297 Cosmetic Act or s. 465.003(8), s. 499.007(13), or subsection
 298 (11), subsection (46), or subsection (53), except that an active
 299 pharmaceutical ingredient is a prescription drug only if
 300 substantially all finished dosage forms in which it may be
 301 lawfully dispensed or administered in Florida are also
 302 prescription drugs.

303 Section 5. Paragraphs (c) and (e) of subsection (2) of
 304 section 499.01, Florida Statutes, are amended, and subsections
 305 (3) and (4) of section 499.01, Florida Statutes, are created to
 306 read:

307 499.01 Permits.-

308 (2) The following permits are established:

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309 (c) Nonresident prescription drug manufacturer permit.—A
 310 nonresident prescription drug manufacturer permit is required
 311 for any person that is a manufacturer of prescription drugs,
 312 unless permitted as a third party logistics provider, located
 313 outside of this state or outside the United States and that
 314 engages in the wholesale distribution in this state of such
 315 prescription drugs. Each such manufacturer must be permitted by
 316 the department and comply with all of the provisions required of
 317 a wholesale distributor under this part, except s. 499.01212.

318 1. A person that distributes prescription drugs for which
 319 the person is not the manufacturer must also obtain an out-of-
 320 state prescription drug wholesale distributor permit or third
 321 party logistics provider permit pursuant to this section to
 322 engage in the wholesale distribution of such prescription drugs.
 323 This subparagraph does not apply to a manufacturer as defined in
 324 s. 499.003(31)(e).

325 2. Any such person must comply with the licensing or
 326 permitting requirements of the jurisdiction in which the
 327 establishment is located and the federal act, and any product
 328 wholesaled into this state must comply with this part. If a
 329 person intends to import prescription drugs from a foreign
 330 country into this state, the nonresident prescription drug
 331 manufacturer must provide to the department a list identifying
 332 each prescription drug it intends to import and document
 333 approval by the United States Food and Drug Administration for
 334 such importation.

335 ~~3. A nonresident prescription drug manufacturer permit is~~
 336 ~~not required for a manufacturer to distribute a prescription~~

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337 ~~drug active pharmaceutical ingredient that it manufactures to a~~
 338 ~~prescription drug manufacturer permitted in this state in~~
 339 ~~limited quantities intended for research and development and not~~
 340 ~~for resale, or human use other than lawful clinical trials and~~
 341 ~~biostudies authorized and regulated by federal law. A~~
 342 ~~manufacturer claiming to be exempt from the permit requirements~~
 343 ~~of this subparagraph and the prescription drug manufacturer~~
 344 ~~purchasing and receiving the active pharmaceutical ingredient~~
 345 ~~shall comply with the recordkeeping requirements of s.~~
 346 ~~499.0121(6), but not the requirements of s. 499.01212. The~~
 347 ~~prescription drug manufacturer purchasing and receiving the~~
 348 ~~active pharmaceutical ingredient shall maintain on file a record~~
 349 ~~of the FDA registration number; the out-of-state license,~~
 350 ~~permit, or registration number; and, if available, a copy of the~~
 351 ~~most current FDA inspection report, for all manufacturers from~~
 352 ~~whom they purchase active pharmaceutical ingredient under this~~
 353 ~~section. The department shall specify by rule the allowable~~
 354 ~~number of transactions within a given period of time and the~~
 355 ~~amount of active pharmaceutical ingredient that qualify as~~
 356 ~~limited quantities for purposes of this exemption. The failure~~
 357 ~~to comply with the requirements of this subparagraph, or rules~~
 358 ~~adopted by the department to administer this subparagraph, for~~
 359 ~~the purchase of prescription drug active pharmaceutical~~
 360 ~~ingredients is a violation of s. 499.005(14).~~

361 (e) Out-of-state prescription drug wholesale distributor
 362 permit.—An out-of-state prescription drug wholesale distributor
 363 is a wholesale distributor located outside this state which
 364 engages in the wholesale distribution of prescription drugs into

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365 | this state and which must be permitted by the department and
 366 | comply with all the provisions required of a wholesale
 367 | distributor under this part. An out-of-state prescription drug
 368 | wholesale distributor that applies to the department for a new
 369 | permit or the renewal of a permit must submit a bond of
 370 | \$100,000, or other equivalent means of security acceptable to
 371 | the department, such as an irrevocable letter of credit or a
 372 | deposit in a trust account or financial institution, payable to
 373 | the Florida Drug, Device, and Cosmetic Trust Fund. The purpose
 374 | of the bond is to secure payment of any administrative penalties
 375 | imposed by the department and any fees and costs incurred by the
 376 | department regarding that permit which are authorized under
 377 | state law and which the permittee fails to pay 30 days after the
 378 | fine or costs become final. The department may make a claim
 379 | against such bond or security until 1 year after the permittee's
 380 | license ceases to be valid or until 60 days after any
 381 | administrative or legal proceeding authorized in this part which
 382 | involves the permittee is concluded, including any appeal,
 383 | whichever occurs later.

384 | 1. The out-of-state prescription drug wholesale distributor
 385 | must maintain at all times a license or permit to engage in the
 386 | wholesale distribution of prescription drugs in compliance with
 387 | laws of the state in which it is a resident.

388 | ~~2. An out-of-state prescription drug wholesale distributor~~
 389 | ~~permit is not required for an intracompany sale or transfer of a~~
 390 | ~~prescription drug from an out-of-state establishment that is~~
 391 | ~~duly licensed as a prescription drug wholesale distributor, in~~
 392 | ~~its state of residence, to a licensed prescription drug~~

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393 ~~wholesale distributor in this state, if both wholesale~~
 394 ~~distributors conduct wholesale distributions of prescription~~
 395 ~~drugs under the same business name. The recordkeeping~~
 396 ~~requirements of ss. 499.0121(6) and 499.01212 must be followed~~
 397 ~~for this transaction.~~

398 (3) Exemptions.

399 (a) A nonresident prescription drug manufacturer permit is
 400 not required for a manufacturer to distribute a prescription
 401 drug active pharmaceutical ingredient that it manufactures to a
 402 prescription drug manufacturer permitted in this state in
 403 limited quantities intended for research and development and not
 404 for resale, or human use other than lawful clinical trials and
 405 biostudies authorized and regulated by federal law. A
 406 manufacturer claiming to be exempt from the permitting
 407 requirements of this part under this paragraph and the
 408 prescription drug manufacturer purchasing and receiving the
 409 active pharmaceutical ingredient shall comply with the
 410 recordkeeping requirements of s. 499.0121(6), but not the
 411 requirements of s. 499.01212. The prescription drug manufacturer
 412 purchasing and receiving the active pharmaceutical ingredient
 413 shall maintain on file a record of the FDA registration number;
 414 the out-of-state license, permit, or registration number; and,
 415 if available, a copy of the most current FDA inspection report,
 416 for all manufacturers from whom active pharmaceutical ingredient
 417 is purchased under this paragraph. The department shall define
 418 "limited quantities" by rule, and may include the allowable
 419 number of transactions within a given period of time and the
 420 amounts of prescription drugs distributed into the state for

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421 purposes of this exemption. The failure to comply with the
 422 requirements of this paragraph, or rules adopted by the
 423 department to administer this paragraph, for the purchase of
 424 prescription drug active pharmaceutical ingredients is a
 425 violation of s. 499.005(14), and a knowing failure is a
 426 violation of s. 499.0051(4).

427 (b) Subject to the requirements of paragraph (d), a permit
 428 issued under this part is not required to distribute
 429 prescription drug active pharmaceutical ingredient that has not
 430 been repackaged from an establishment located in the United
 431 States to an establishment located in this state permitted as a
 432 prescription drug manufacturer under this part for use solely by
 433 or for the recipient in preparing, deriving, processing,
 434 producing, or fabricating a prescription drug finished dosage
 435 form at the establishment in this state where the product is
 436 received under an approved and otherwise valid New Drug
 437 Application, Abbreviated New Drug Application, New Animal Drug
 438 Application, Therapeutic Biologic Application, or Biologics
 439 License Application, provided that the application, active
 440 pharmaceutical ingredient, or finished dosage form has not been
 441 withdrawn or removed from the market in this country for public
 442 health reasons.

443 (c) Subject to the requirements of paragraph (d), a permit
 444 issued under this part is not required to distribute limited
 445 quantities of a prescription drug that has not been repackaged
 446 from an establishment located in the United States to an
 447 establishment located in this state permitted as a prescription
 448 drug manufacturer under this part for research and development

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449 or to a holder of a letter of exemption issued by the department
 450 under s. 499.03(4) for research, teaching, or testing. The
 451 department shall define "limited quantities" by rule, and may
 452 include the allowable number of transactions within a given
 453 period of time and the amounts of prescription drugs distributed
 454 into the state for purposes of this exemption.

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

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

465 (d) The persons and activities described in paragraphs (b)
 466 and (c) shall comply with the following requirements, and except
 467 as provided in this subsection, the requirements of this part
 468 and rules adopted under this part:

469 1. The distributor claimed to be exempt from the permitting
 470 requirements of this part shall maintain a license, permit or
 471 registration as a manufacturer or wholesale distributor of
 472 prescription drugs under the laws of the state from which the
 473 product is distributed.

474 2. Persons purchasing or receiving prescription drugs from
 475 a distributor claimed to be exempt from the permitting
 476 requirements of this part shall maintain on file, for each such

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477 prescription drug and distributor, a record of the FDA
 478 establishment registration number where the prescription drugs
 479 were manufactured; the distributing establishment's resident
 480 state prescription drug manufacturer or wholesale distributor
 481 license, permit, or registration number; and a copy of the
 482 distributing establishment's most recent resident state or FDA
 483 inspection report, if available.

484 3. Distributors claimed to be exempt from the permitting
 485 requirements of this part, and the purchaser and recipient of
 486 the prescription drugs purchased or received from such sources,
 487 shall comply with the recordkeeping requirements of s.
 488 499.0121(6), but not the requirements of s. 499.01212.

489 (e) An out-of-state prescription drug wholesale distributor
 490 permit is not required for an intracompany sale or transfer of a
 491 prescription drug from an out-of-state establishment that is
 492 duly licensed as a prescription drug wholesale distributor, in
 493 its state of residence, to a licensed prescription drug
 494 wholesale distributor in this state, if both wholesale
 495 distributors conduct wholesale distributions of prescription
 496 drugs under the same business name. The recordkeeping
 497 requirements of ss. 499.0121(6) and 499.01212 must be followed
 498 for such transactions.

499 (f) All persons distributing prescription drugs in or into
 500 the state, regardless of any exemption from permitting
 501 requirements, are subject to this part, including ss. 499.005
 502 and 499.0051, and the rules adopted under this part, and shall
 503 make available, within 48 hours, to the department on request
 504 all records related to any prescription drugs distributed under

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505 this subsection, including those records described in s.
 506 499.051(4), regardless of the location where the records are
 507 stored.

508 (g) A person purchasing and receiving a prescription drug
 509 from a person claimed to be exempt from licensing requirements
 510 pursuant to this subsection shall report to the department in
 511 writing within 14 days of receiving any product that is
 512 misbranded or adulterated or that fails to meet minimum
 513 standards for identity, purity, potency, or sterility set forth
 514 in the official compendium or in state or federal good
 515 manufacturing practices, regardless of whether the product is
 516 thereafter rehabilitated, quarantined, returned, or destroyed.

517 (h) The department may adopt rules to administer this
 518 subsection, which rules are necessary for the protection of the
 519 public health, safety, and welfare. The failure to comply with
 520 the requirements of this subsection, or rules adopted by the
 521 department to administer this subsection, is a violation of s.
 522 499.005(14), and a knowing failure is a violation of s.
 523 499.0051(4).

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

527 (4) A prescription drug repackager permit issued under
 528 this part is not required for a restricted prescription drug
 529 distributor permit holder that is a health care entity to
 530 repackage prescription drugs in this state for its own use or
 531 for distribution to hospitals or other health care entities in

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532 the state for their own use pursuant to s. 499.003(54)(a)3.,
 533 provided:

534 (a) The prescription drug distributor notifies the
 535 department, in writing, of its intention to engage in
 536 repackaging under this exemption thirty days prior to actually
 537 engaging in the repackaging of prescription drugs at the
 538 permitted establishment;

539 (b) The prescription drug distributor is under common
 540 control with the hospitals or other health care entities to
 541 which the prescription drug distributor is distributing
 542 prescription drugs. For purposes of this subparagraph, "common
 543 control" means the power to direct or cause the direction of the
 544 management and policies of a person or an organization, whether
 545 by ownership of stock, by voting rights, by contract, or
 546 otherwise;

547 (c) The prescription drug distributor repackages the
 548 prescription drugs in accordance with current state and federal
 549 good manufacturing practices; and

550 (d) The prescription drug distributor labels the
 551 prescription drug it repackages in accordance with state and
 552 federal laws and rules.

553
 554 The prescription drug distributor is exempt from the product
 555 registration requirements of s. 499.015, with regard to the
 556 prescription drugs that it repackages and distributes under this
 557 subsection.

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