

By the Committee on Health Policy; and Senator Grimsley

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1                                   A bill to be entitled  
2           An act relating to the provision of health care with  
3           controlled substances; creating ss. 400.996 and  
4           408.833, F.S.; providing that regulation of the  
5           licensure, activity, and operation of clinics and  
6           health care facilities is preempted to the state;  
7           prohibiting a local government or political  
8           subdivision of the state from enacting or enforcing an  
9           ordinance that imposes a levy, charge, or fee upon, or  
10          that otherwise regulates, clinics and health care  
11          facilities, except for ordinances regarding local  
12          business taxes and land development; amending s.  
13          456.44, F.S.; limiting the application of requirements  
14          for prescribing controlled substances; requiring a  
15          physician to consult the prescription drug monitoring  
16          program database before prescribing certain controlled  
17          substances; authorizing the board to adopt a penalty  
18          for failure to consult the database; exempting nursing  
19          home residents and certain physicians from  
20          requirements regarding prescriptions of controlled  
21          substances; amending s. 458.326, F.S.; requiring a  
22          physician to consult the prescription drug monitoring  
23          program database or designate an agent to consult the  
24          database before prescribing certain controlled  
25          substances; authorizing the board to adopt a penalty  
26          for failure to consult the database; amending ss.  
27          458.3265 and 459.0137, F.S.; requiring that owners of  
28          pain-management clinics be licensed physicians;  
29          removing language regarding nonphysician-owned pain-

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30 management clinics; providing that regulation of the  
31 licensure and activity of certain physicians and  
32 osteopathic physicians is preempted to the state;  
33 prohibiting a local government or political  
34 subdivision of the state from enacting or enforcing an  
35 ordinance that imposes a levy, charge, or fee upon, or  
36 that otherwise regulates, physicians and osteopathic  
37 physicians, except for ordinances regarding local  
38 business taxes and land development; amending s.  
39 465.003, F.S.; defining a term; conforming a cross-  
40 reference; creating s. 465.0065, F.S.; providing  
41 notice requirements for inspection of a pharmacy;  
42 amending s. 465.016, F.S.; providing additional  
43 grounds for disciplinary action; conforming a cross-  
44 reference; amending s. 465.022, F.S.; conforming a  
45 cross-reference; requiring a pharmacy permittee to  
46 commence operations within 180 days after permit  
47 issuance or show good cause why operations were not  
48 commenced; requiring the board to establish rules;  
49 requiring a pharmacy permittee to be supervised by a  
50 prescription department manager or consultant  
51 pharmacist of record; amending s. 465.023, F.S.;  
52 providing additional grounds for disciplinary action;  
53 conforming a cross-reference; creating s. 465.1902,  
54 F.S.; providing that regulation of the licensure,  
55 activity, and operation of pharmacies and pharmacists  
56 is preempted to the state; prohibiting a local  
57 government or political subdivision of the state from  
58 enacting or enforcing an ordinance that imposes a

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59       levy, charge, or fee upon, or that otherwise  
60       regulates, pharmacies and pharmacists, except for  
61       ordinances regarding local business taxes and land  
62       development; amending s. 893.055, F.S.; deleting an  
63       obsolete provision; authorizing the prescription drug  
64       monitoring program to be funded by state funds and  
65       pharmaceutical company donations; amending ss.  
66       409.9201, 458.331, 459.015, 465.014, 465.015,  
67       465.0156, 465.0197, 465.1901, 499.003, and 893.02,  
68       F.S.; conforming cross-references; providing an  
69       effective date.

70

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

72

73       Section 1. Section 400.996, Florida Statutes, is created to  
74       read:

75       400.996 Preemption.—This chapter preempts to the state all  
76       regulation of the licensure, activity, and operation of clinics  
77       under part X of chapter 400, excluding registration and  
78       licensing for pain-management clinics. A local government or  
79       political subdivision of the state may not enact or enforce an  
80       ordinance that imposes a levy, charge, or fee upon, or that  
81       otherwise regulates, clinics under part X of chapter 400,  
82       including services provided within such facilities, except that  
83       this preemption does not prohibit a local government or  
84       political subdivision from enacting an ordinance regarding the  
85       following:

86       (1) Local business taxes adopted pursuant to chapter 205.

87       (2) Land use development regulations adopted pursuant to

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88 chapter 163, which include regulation of any aspect of  
89 development, including a subdivision, building construction,  
90 sign regulation, and any other regulation concerning the  
91 development of land, landscaping, or tree protection, and which  
92 do not include restrictions on pain-management services, health  
93 care services, or the prescribing of controlled substances.  
94 However, a clinic that treats pain or provides pain-management  
95 services is a permissible use in a land use or zoning category  
96 that permits hospitals, other health care facilities, or clinics  
97 as defined in chapter 395, s. 408.07, or part X of chapter 400.

98 Section 2. Section 408.833, Florida Statutes, is created to  
99 read:

100 408.833 Preemption.—This chapter preempts to the state all  
101 regulation of the licensure, activity, and operation of health  
102 care facilities as defined in s. 408.07. A local government or  
103 political subdivision of the state may not enact or enforce an  
104 ordinance that imposes a levy, charge, or fee upon, or that  
105 otherwise regulates health care facilities as defined in s.  
106 408.07, including services provided within such facilities,  
107 except that this preemption does not prohibit a local government  
108 or political subdivision from enacting an ordinance regarding  
109 the following:

110 (1) Local business taxes adopted pursuant to chapter 205.

111 (2) Land use development regulations adopted pursuant to  
112 chapter 163, which include regulation of any aspect of  
113 development, including a subdivision, building construction,  
114 sign regulation, and any other regulation concerning the  
115 development of land, landscaping, or tree protection, and which  
116 do not include restrictions on pain-management services, health

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117 care services, or the prescribing of controlled substances.  
118 However, a health care facility or clinic that treats pain or  
119 provides pain-management services is a permissible use in a land  
120 use or zoning category that permits hospitals, other health care  
121 facilities, or clinics as defined in chapter 395, s. 408.07, or  
122 part X of chapter 400.

123 Section 3. Subsections (2) and (3) of section 456.44,  
124 Florida Statutes, are amended to read:

125 456.44 Controlled substance prescribing.—

126 (2) REGISTRATION.—~~Effective January 1, 2012,~~ A physician  
127 licensed under chapter 458, chapter 459, chapter 461, or chapter  
128 466 who prescribes more than a 30-day supply of any controlled  
129 substance, listed in Schedule II, Schedule III, or Schedule IV  
130 as defined in s. 893.03, over a 6-month period to any one  
131 patient for the treatment of chronic nonmalignant pain, must:

132 (a) Designate himself or herself as a controlled substance  
133 prescribing practitioner on the physician's practitioner  
134 profile.

135 (b) Comply with the requirements of this section and  
136 applicable board rules.

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

141 (a) A complete medical history and a physical examination  
142 must be conducted before beginning any treatment and must be  
143 documented in the medical record. The exact components of the  
144 physical examination shall be left to the judgment of the  
145 clinician who is expected to perform a physical examination

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146 proportionate to the diagnosis that justifies a treatment. The  
147 medical record must, at a minimum, document the nature and  
148 intensity of the pain, current and past treatments for pain,  
149 underlying or coexisting diseases or conditions, the effect of  
150 the pain on physical and psychological function, a review of  
151 previous medical records, previous diagnostic studies, and  
152 history of alcohol and substance abuse. The medical record shall  
153 also document the presence of one or more recognized medical  
154 indications for the use of a controlled substance. Each  
155 registrant must develop a written plan for assessing each  
156 patient's risk of aberrant drug-related behavior, which may  
157 include patient drug testing. Registrants must assess each  
158 patient's risk for aberrant drug-related behavior and monitor  
159 that risk on an ongoing basis in accordance with the plan.

160 (b) Before or during a new patient's visit for pain-  
161 treatment services at a pain-management clinic registered under  
162 s. 458.3265 or s. 459.0137, a physician shall consult the  
163 prescription drug monitoring program database provided under s.  
164 893.055(2) (a) before prescribing a controlled substance listed  
165 in Schedule II or Schedule III in s. 893.03. The physician may  
166 designate an agent under his or her supervision to consult the  
167 database. The board shall adopt rules to establish a penalty for  
168 a physician who does not comply with this subsection.

169 (c) ~~(b)~~ Each registrant must develop a written  
170 individualized treatment plan for each patient. The treatment  
171 plan shall state objectives that will be used to determine  
172 treatment success, such as pain relief and improved physical and  
173 psychosocial function, and shall indicate if any further  
174 diagnostic evaluations or other treatments are planned. After

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175 treatment begins, the physician shall adjust drug therapy to the  
176 individual medical needs of each patient. Other treatment  
177 modalities, including a rehabilitation program, shall be  
178 considered depending on the etiology of the pain and the extent  
179 to which the pain is associated with physical and psychosocial  
180 impairment. The interdisciplinary nature of the treatment plan  
181 shall be documented.

182 (d)~~(e)~~ The physician shall discuss the risks and benefits  
183 of the use of controlled substances, including the risks of  
184 abuse and addiction, as well as physical dependence and its  
185 consequences, with the patient, persons designated by the  
186 patient, or the patient's surrogate or guardian if the patient  
187 is incompetent. The physician shall use a written controlled  
188 substance agreement between the physician and the patient  
189 outlining the patient's responsibilities, including, but not  
190 limited to:

191 1. Number and frequency of controlled substance  
192 prescriptions and refills.

193 2. Patient compliance and reasons for which drug therapy  
194 may be discontinued, such as a violation of the agreement.

195 3. An agreement that controlled substances for the  
196 treatment of chronic nonmalignant pain shall be prescribed by a  
197 single treating physician unless otherwise authorized by the  
198 treating physician and documented in the medical record.

199 (e)~~(d)~~ The patient shall be seen by the physician at  
200 regular intervals, not to exceed 3 months, to assess the  
201 efficacy of treatment, ensure that controlled substance therapy  
202 remains indicated, evaluate the patient's progress toward  
203 treatment objectives, consider adverse drug effects, and review

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204 the etiology of the pain. Continuation or modification of  
205 therapy shall depend on the physician's evaluation of the  
206 patient's progress. If treatment goals are not being achieved,  
207 despite medication adjustments, the physician shall reevaluate  
208 the appropriateness of continued treatment. The physician shall  
209 monitor patient compliance in medication usage, related  
210 treatment plans, controlled substance agreements, and  
211 indications of substance abuse or diversion at a minimum of 3-  
212 month intervals.

213 (f)~~(e)~~ The physician shall refer the patient as necessary  
214 for additional evaluation and treatment in order to achieve  
215 treatment objectives. Special attention shall be given to those  
216 patients who are at risk for misusing their medications and  
217 those whose living arrangements pose a risk for medication  
218 misuse or diversion. The management of pain in patients with a  
219 history of substance abuse or with a comorbid psychiatric  
220 disorder requires extra care, monitoring, and documentation and  
221 requires consultation with or referral to an addiction medicine  
222 specialist or psychiatrist.

223 (g)~~(f)~~ A physician registered under this section must  
224 maintain accurate, current, and complete records that are  
225 accessible and readily available for review and comply with the  
226 requirements of this section, the applicable practice act, and  
227 applicable board rules. The medical records must include, but  
228 are not limited to:

- 229 1. The complete medical history and a physical examination,  
230 including history of drug abuse or dependence.
- 231 2. Diagnostic, therapeutic, and laboratory results.
- 232 3. Evaluations and consultations.



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- 233 4. Treatment objectives.
- 234 5. Discussion of risks and benefits.
- 235 6. Treatments.
- 236 7. Medications, including date, type, dosage, and quantity  
237 prescribed.
- 238 8. Instructions and agreements.
- 239 9. Periodic reviews.
- 240 10. Results of any drug testing.
- 241 11. A photocopy of the patient's government-issued photo  
242 identification.
- 243 12. If a written prescription for a controlled substance is  
244 given to the patient, a duplicate of the prescription.
- 245 13. The physician's full name presented in a legible  
246 manner.
- 247 (h) ~~(g)~~ Patients with signs or symptoms of substance abuse  
248 shall be immediately referred to a board-certified pain  
249 management physician, an addiction medicine specialist, or a  
250 mental health addiction facility as it pertains to drug abuse or  
251 addiction unless the physician is board-certified or board-  
252 eligible in pain management. Throughout the period of time  
253 before receiving the consultant's report, a prescribing  
254 physician shall clearly and completely document medical  
255 justification for continued treatment with controlled substances  
256 and those steps taken to ensure medically appropriate use of  
257 controlled substances by the patient. Upon receipt of the  
258 consultant's written report, the prescribing physician shall  
259 incorporate the consultant's recommendations for continuing,  
260 modifying, or discontinuing controlled substance therapy. The  
261 resulting changes in treatment shall be specifically documented

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262 in the patient's medical record. Evidence or behavioral  
263 indications of diversion shall be followed by discontinuation of  
264 controlled substance therapy, and the patient shall be  
265 discharged, and all results of testing and actions taken by the  
266 physician shall be documented in the patient's medical record.

267  
268 This subsection does not apply to a board-eligible or board-  
269 certified anesthesiologist, physiatrist, rheumatologist, or  
270 neurologist, or to a board-certified physician who has surgical  
271 privileges at a hospital or ambulatory surgery center and  
272 primarily provides surgical services. This subsection does not  
273 apply to a board-eligible or board-certified medical specialist  
274 who has also completed a fellowship in pain medicine approved by  
275 the Accreditation Council for Graduate Medical Education or the  
276 American Osteopathic Association, or who is board eligible or  
277 board certified in pain medicine by the American Board of Pain  
278 Medicine or a board approved by the American Board of Medical  
279 Specialties or the American Osteopathic Association and performs  
280 interventional pain procedures of the type routinely billed  
281 using surgical codes. This subsection does not apply to a  
282 physician who prescribes medically necessary controlled  
283 substances for a patient during an inpatient stay in a hospital  
284 licensed under chapter 395 or to a resident in a facility  
285 licensed under part II of chapter 400. This subsection does not  
286 apply to any physician licensed under chapter 458 or chapter 459  
287 who writes fewer than 50 prescriptions for a controlled  
288 substance for all of his or her patients during a 1-year period.

289 Section 4. Subsection (3) of section 458.326, Florida  
290 Statutes, is amended to read:

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291 458.326 Intractable pain; authorized treatment.-

292 (3) (a) Notwithstanding any other provision of law, a  
293 physician may prescribe or administer any controlled substance  
294 under Schedules II-V, as provided for in s. 893.03, to a person  
295 for the treatment of intractable pain, provided the physician  
296 does so in accordance with that level of care, skill, and  
297 treatment recognized by a reasonably prudent physician under  
298 similar conditions and circumstances.

299 (b) Before or during a new patient's visit for pain-  
300 treatment services, a physician shall consult the prescription  
301 drug monitoring program database provided under s. 893.055(2) (a)  
302 before prescribing a controlled substance listed in Schedule II  
303 or Schedule III in s. 893.03. The physician may designate an  
304 agent under his or her supervision to consult the database. The  
305 board shall adopt rules to establish a penalty for a physician  
306 who does not comply with this paragraph.

307 Section 5. Paragraphs (a) and (d) of subsection (1) of  
308 section 458.3265, Florida Statutes, are amended, present  
309 subsections (5) and (6) of that section are renumbered as  
310 subsections (6) and (7), respectively, and a new subsection (5)  
311 is added to that section, to read:

312 458.3265 Pain-management clinics.-

313 (1) REGISTRATION.-

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

315 a. "Board eligible" means successful completion of an  
316 anesthesia, physical medicine and rehabilitation, rheumatology,  
317 or neurology residency program approved by the Accreditation  
318 Council for Graduate Medical Education or the American  
319 Osteopathic Association for a period of 6 years from successful

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320 completion of such residency program.

321 b. "Chronic nonmalignant pain" means pain unrelated to  
322 cancer which persists beyond the usual course of disease or the  
323 injury that is the cause of the pain or more than 90 days after  
324 surgery.

325 c. "Pain-management clinic" or "clinic" means any publicly  
326 or privately owned facility:

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

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

332 2. Each pain-management clinic must register with the  
333 department unless:

334 a. That clinic is licensed as a facility pursuant to  
335 chapter 395;

336 b. The majority of the physicians who provide services in  
337 the clinic primarily provide surgical services;

338 ~~e. The clinic is owned by a publicly held corporation whose~~  
339 ~~shares are traded on a national exchange or on the over-the-~~  
340 ~~counter market and whose total assets at the end of the~~  
341 ~~corporation's most recent fiscal quarter exceeded \$50 million;~~

342 c.d. The clinic is affiliated with an accredited medical  
343 school at which training is provided for medical students,  
344 residents, or fellows;

345 d.e. The clinic does not prescribe controlled substances  
346 for the treatment of pain;

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

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349 ~~e.g.~~ The clinic is wholly owned and operated by one or more  
350 board-eligible or board-certified anesthesiologists,  
351 physiatrists, rheumatologists, or neurologists; or

352 ~~f.h.~~ The clinic is wholly owned and operated by a physician  
353 multispecialty practice where one or more board-eligible or  
354 board-certified medical specialists who have also completed  
355 fellowships in pain medicine approved by the Accreditation  
356 Council for Graduate Medical Education, or who are also board-  
357 certified in pain medicine by the American Board of Pain  
358 Medicine or a board approved by the American Board of Medical  
359 Specialties, the American Association of Physician Specialists,  
360 or the American Osteopathic Association and perform  
361 interventional pain procedures of the type routinely billed  
362 using surgical codes.

363 (d) The department shall deny registration to any clinic  
364 that is not fully owned by a physician licensed under this  
365 chapter or chapter 459 or a group of physicians, each of whom is  
366 licensed under this chapter or chapter 459; or that is not a  
367 health care clinic licensed under part X of chapter 400 which is  
368 fully owned by such physician or group of physicians.

369 (5) PREEMPTION.—This chapter preempts to the state all  
370 regulation of the licensure and activity of a physician licensed  
371 under this chapter who owns, operates, or works in a pain-  
372 management clinic or provides pain-management services. A local  
373 government or political subdivision of the state may not enact  
374 or enforce an ordinance that imposes a levy, charge, or fee  
375 upon, or that otherwise regulates, a physician licensed under  
376 this chapter who owns, operates, or works in a pain-management  
377 clinic or provides pain-management services, except that this

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378 preemption does not prohibit a local government or political  
379 subdivision from enacting an ordinance regarding the following:

380 (a) A registered pain-management clinic as defined in  
381 subsection (1).

382 (b) Local business taxes adopted pursuant to chapter 205.

383 (c) Land use development regulations adopted pursuant to  
384 chapter 163, which include regulation of any aspect of  
385 development, including a subdivision, building construction,  
386 sign regulation, and any other regulation concerning the  
387 development of land, landscaping, or tree protection, and which  
388 do not include restrictions on pain-management services, health  
389 care services, or the prescribing of controlled substances.  
390 However, a health care facility or clinic that treats pain or  
391 provides pain-management services is a permissible use in a land  
392 use or zoning category that permits hospitals, other health care  
393 facilities, or clinics as defined in chapter 395, s. 408.07, or  
394 part X of chapter 400.

395 Section 6. Paragraphs (a) and (d) of subsection (1) of  
396 section 459.0137, Florida Statutes, are amended, present  
397 subsections (5) and (6) of that section are renumbered as  
398 subsections (6) and (7), respectively, and a new subsection (5)  
399 is added to that section, to read:

400 459.0137 Pain-management clinics.—

401 (1) REGISTRATION.—

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

403 a. "Board eligible" means successful completion of an  
404 anesthesia, physical medicine and rehabilitation, rheumatology,  
405 or neurology residency program approved by the Accreditation  
406 Council for Graduate Medical Education or the American

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407 Osteopathic Association for a period of 6 years from successful  
408 completion of such residency program.

409 b. "Chronic nonmalignant pain" means pain unrelated to  
410 cancer which persists beyond the usual course of disease or the  
411 injury that is the cause of the pain or more than 90 days after  
412 surgery.

413 c. "Pain-management clinic" or "clinic" means any publicly  
414 or privately owned facility:

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

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

420 2. Each pain-management clinic must register with the  
421 department unless:

422 a. That clinic is licensed as a facility pursuant to  
423 chapter 395;

424 b. The majority of the physicians who provide services in  
425 the clinic primarily provide surgical services;

426 ~~e. The clinic is owned by a publicly held corporation whose  
427 shares are traded on a national exchange or on the over-the-  
428 counter market and whose total assets at the end of the  
429 corporation's most recent fiscal quarter exceeded \$50 million;~~

430 c.d. The clinic is affiliated with an accredited medical  
431 school at which training is provided for medical students,  
432 residents, or fellows;

433 ~~d.e.~~ The clinic does not prescribe controlled substances  
434 for the treatment of pain;

435 ~~f. The clinic is owned by a corporate entity exempt from~~

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436 ~~federal taxation under 26 U.S.C. s. 501(e)(3);~~

437 ~~e.g.~~ The clinic is wholly owned and operated by one or more  
438 board-eligible or board-certified anesthesiologists,  
439 physiatrists, rheumatologists, or neurologists; or

440 ~~f.h.~~ The clinic is wholly owned and operated by a physician  
441 multispecialty practice where one or more board-eligible or  
442 board-certified medical specialists who have also completed  
443 fellowships in pain medicine approved by the Accreditation  
444 Council for Graduate Medical Education or the American  
445 Osteopathic Association, or who are also board-certified in pain  
446 medicine by the American Board of Pain Medicine or a board  
447 approved by the American Board of Medical Specialties, the  
448 American Association of Physician Specialists, or the American  
449 Osteopathic Association and perform interventional pain  
450 procedures of the type routinely billed using surgical codes.

451 (d) The department shall deny registration to any clinic  
452 that is not fully owned by a physician licensed under chapter  
453 458 or this chapter or a group of physicians, each of whom is  
454 licensed under chapter 458 or this chapter; or that is not a  
455 health care clinic licensed under part X of chapter 400 which is  
456 fully owned by such physician or group of physicians.

457 (5) PREEMPTION.—This chapter preempts to the state all  
458 regulation of the licensure and activity of an osteopathic  
459 physician licensed under this chapter who owns, operates, or  
460 works in a pain-management clinic or provides pain-management  
461 services. A local government or political subdivision of the  
462 state may not enact or enforce an ordinance that imposes a levy,  
463 charge, or fee upon, or that otherwise regulates, an osteopathic  
464 physician licensed under this chapter who owns, operates, or



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465 works in a pain-management clinic, except that this preemption  
466 does not prohibit a local government or political subdivision  
467 from enacting an ordinance regarding the following:

468 (a) A registered pain-management clinic as defined in  
469 subsection (1).

470 (b) Local business taxes adopted pursuant to chapter 205.

471 (c) Land use development regulations adopted pursuant to  
472 chapter 163, which include regulation of any aspect of  
473 development, including a subdivision, building construction,  
474 sign regulation, and any other regulation concerning the  
475 development of land, landscaping, or tree protection, and which  
476 do not include restrictions on pain-management services, health  
477 care services, and the prescribing of controlled substances.  
478 However, a health care facility or clinic that treats pain or  
479 provides pain-management services is a permissible use in a land  
480 use or zoning category that permits hospitals, other health care  
481 facilities, or clinics as defined in chapter 395, s. 408.07, or  
482 part X of chapter 400.

483 Section 7. Present subsections (1) through (17) of section  
484 465.003, Florida Statutes, are renumbered as subsections (2)  
485 through (18), respectively, paragraph (a) of present subsection  
486 (11) of that section is amended, and a new subsection (1) is  
487 added to that section, to read:

488 465.003 Definitions.—As used in this chapter, the term:

489 (1) "Abandoned" means the status of a pharmacy permit of a  
490 person or entity that was issued the permit but fails to  
491 commence pharmacy operations within 180 days after issuance of  
492 the permit without good cause or fails to follow pharmacy  
493 closure requirements as set by the board.

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494        (12)~~(11)~~(a) "Pharmacy" includes a community pharmacy, an  
495 institutional pharmacy, a nuclear pharmacy, a special pharmacy,  
496 and an Internet pharmacy.

497            1. The term "community pharmacy" includes every location  
498 where medicinal drugs are compounded, dispensed, stored, or sold  
499 or where prescriptions are filled or dispensed on an outpatient  
500 basis.

501            2. The term "institutional pharmacy" includes every  
502 location in a hospital, clinic, nursing home, dispensary,  
503 sanitarium, extended care facility, or other facility,  
504 hereinafter referred to as "health care institutions," where  
505 medicinal drugs are compounded, dispensed, stored, or sold.

506            3. The term "nuclear pharmacy" includes every location  
507 where radioactive drugs and chemicals within the classification  
508 of medicinal drugs are compounded, dispensed, stored, or sold.  
509 The term "nuclear pharmacy" does not include hospitals licensed  
510 under chapter 395 or the nuclear medicine facilities of such  
511 hospitals.

512            4. The term "special pharmacy" includes every location  
513 where medicinal drugs are compounded, dispensed, stored, or sold  
514 if such locations are not otherwise defined in this subsection.

515            5. The term "Internet pharmacy" includes locations not  
516 otherwise licensed or issued a permit under this chapter, within  
517 or outside this state, which use the Internet to communicate  
518 with or obtain information from consumers in this state and use  
519 such communication or information to fill or refill  
520 prescriptions or to dispense, distribute, or otherwise engage in  
521 the practice of pharmacy in this state. Any act described in  
522 this definition constitutes the practice of pharmacy as defined

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523 in subsection (14)~~(13)~~.

524 Section 8. Section 465.0065, Florida Statutes, is created  
525 to read:

526 465.0065 Notices; form and service.—Each notice served by  
527 the department pursuant to this chapter must be in writing and  
528 must be delivered personally by an agent of the department or by  
529 certified mail to the pharmacy permittee or licensee. If the  
530 pharmacy permittee or licensee refuses to accept service or  
531 evades service or if the agent is otherwise unable to carry out  
532 service after due diligence, the department may post the notice  
533 in a conspicuous place at the pharmacy or at the home or  
534 business address for the licensee.

535 Section 9. Paragraphs (e) and (s) of subsection (1) of  
536 section 465.016, Florida Statutes, are amended, and paragraph  
537 (u) is added to that subsection to read:

538 465.016 Disciplinary actions.—

539 (1) The following acts constitute grounds for denial of a  
540 license or disciplinary action, as specified in s. 456.072(2):

541 (e) Violating chapter 499; 21 U.S.C. ss. 301-392, known as  
542 the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et  
543 seq., known as the Comprehensive Drug Abuse Prevention and  
544 Control Act; or chapter 893 or rules adopted thereunder.

545 (s) Dispensing any medicinal drug based upon a  
546 communication that purports to be a prescription as defined by  
547 s. 465.003 ~~s. 465.003(14)~~ or s. 893.02 when the pharmacist knows  
548 or has reason to believe that the purported prescription is not  
549 based upon a valid practitioner-patient relationship.

550 (u) Misappropriating drugs, supplies, or equipment from a  
551 pharmacy permittee.

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552 Section 10. Paragraph (j) of subsection (5) of section  
553 465.022, Florida Statutes, is amended, present subsections (10)  
554 through (14) are renumbered as subsections (11) through (15),  
555 respectively, present subsection (10) of that section is  
556 amended, and a new subsection (10) is added to that section, to  
557 read:

558 465.022 Pharmacies; general requirements; fees.—

559 (5) The department or board shall deny an application for a  
560 pharmacy permit if the applicant or an affiliated person,  
561 partner, officer, director, or prescription department manager  
562 or consultant pharmacist of record of the applicant:

563 (j) Has dispensed any medicinal drug based upon a  
564 communication that purports to be a prescription as defined by  
565 s. 465.003 ~~s. 465.003(14)~~ or s. 893.02 when the pharmacist knows  
566 or has reason to believe that the purported prescription is not  
567 based upon a valid practitioner-patient relationship that  
568 includes a documented patient evaluation, including history and  
569 a physical examination adequate to establish the diagnosis for  
570 which any drug is prescribed and any other requirement  
571 established by board rule under chapter 458, chapter 459,  
572 chapter 461, chapter 463, chapter 464, or chapter 466.

573  
574 For felonies in which the defendant entered a plea of guilty or  
575 nolo contendere in an agreement with the court to enter a  
576 pretrial intervention or drug diversion program, the department  
577 shall deny the application if upon final resolution of the case  
578 the licensee has failed to successfully complete the program.

579 (10) The permittee shall commence pharmacy operations  
580 within 180 days after issuance of the permit, or show good cause

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581 to the department why pharmacy operations were not commenced.  
582 Commencement of pharmacy operations includes, but is not limited  
583 to, acts within the scope of the practice of pharmacy, ordering  
584 or receiving drugs, and other similar activities. The board  
585 shall establish rules regarding commencement of pharmacy  
586 operations.

587 (11)-(10) A pharmacy permittee shall be supervised by a  
588 prescription department manager or consultant pharmacist of  
589 record at all times. A permittee must notify the department, on  
590 a form approved by the board, within 10 days after any change in  
591 prescription department manager or consultant pharmacist of  
592 record.

593 Section 11. Subsection (1) of section 465.023, Florida  
594 Statutes, is amended to read:

595 465.023 Pharmacy permittee; disciplinary action.—

596 (1) The department or the board may revoke or suspend the  
597 permit of any pharmacy permittee, and may fine, place on  
598 probation, or otherwise discipline any pharmacy permittee if the  
599 permittee, or any affiliated person, partner, officer, director,  
600 or agent of the permittee, including a person fingerprinted  
601 under s. 465.022(3), has:

602 (a) Obtained a permit by misrepresentation or fraud or  
603 through an error of the department or the board;

604 (b) Attempted to procure, or has procured, a permit for any  
605 other person by making, or causing to be made, any false  
606 representation;

607 (c) Violated any of the requirements of this chapter or any  
608 of the rules of the Board of Pharmacy; of chapter 499, known as  
609 the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss. 301-392,

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610 known as the "Federal Food, Drug, and Cosmetic Act"; of 21  
611 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse  
612 Prevention and Control Act; or of chapter 893 or rules adopted  
613 thereunder;

614 (d) Been convicted or found guilty, regardless of  
615 adjudication, of a felony or any other crime involving moral  
616 turpitude in any of the courts of this state, of any other  
617 state, or of the United States;

618 (e) Been convicted or disciplined by a regulatory agency of  
619 the Federal Government or a regulatory agency of another state  
620 for any offense that would constitute a violation of this  
621 chapter;

622 (f) Been convicted of, or entered a plea of guilty or nolo  
623 contendere to, regardless of adjudication, a crime in any  
624 jurisdiction which relates to the practice of, or the ability to  
625 practice, the profession of pharmacy;

626 (g) Been convicted of, or entered a plea of guilty or nolo  
627 contendere to, regardless of adjudication, a crime in any  
628 jurisdiction which relates to health care fraud; or

629 (h) Dispensed any medicinal drug based upon a communication  
630 that purports to be a prescription as defined by s. 465.003 ~~s.~~  
631 ~~465.003(14)~~ or s. 893.02 when the pharmacist knows or has reason  
632 to believe that the purported prescription is not based upon a  
633 valid practitioner-patient relationship that includes a  
634 documented patient evaluation, including history and a physical  
635 examination adequate to establish the diagnosis for which any  
636 drug is prescribed and any other requirement established by  
637 board rule under chapter 458, chapter 459, chapter 461, chapter  
638 463, chapter 464, or chapter 466.

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639 Section 12. Section 465.1902, Florida Statutes, is created  
640 to read:

641 465.1902 Preemption.—This chapter preempts to the state all  
642 regulation of the licensure, activity, and operation of  
643 pharmacies and pharmacists as defined in this chapter. A local  
644 government or political subdivision of the state may not enact  
645 or enforce an ordinance that imposes a levy, charge, or fee  
646 upon, or that otherwise regulates, pharmacies and pharmacists as  
647 defined in this chapter, except that this preemption does not  
648 prohibit a local government or political subdivision from  
649 enacting an ordinance regarding the following:

650 (1) Local business taxes adopted pursuant to chapter 205.

651 (2) Land use development regulations adopted pursuant to  
652 chapter 163, which include regulation of any aspect of  
653 development, including a subdivision, building construction,  
654 sign regulation, and any other regulation concerning the  
655 development of land, landscaping, or tree protection, and which  
656 do not include restrictions on pain-management services, health  
657 care services, or the prescribing of controlled substances.

658 Section 13. Paragraph (b) of subsection (2), subsection  
659 (10), and paragraph (c) of subsection (11) of section 893.055,  
660 Florida Statutes, are amended to read:

661 893.055 Prescription drug monitoring program.—

662 (2)

663 (b) ~~The department, when the direct support organization~~  
664 ~~receives at least \$20,000 in nonstate moneys or the state~~  
665 ~~receives at least \$20,000 in federal grants for the prescription~~  
666 ~~drug monitoring program,~~ shall adopt rules as necessary  
667 concerning the reporting, accessing the database, evaluation,

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668 management, development, implementation, operation, security,  
669 and storage of information within the system, including rules  
670 for when patient advisory reports are provided to pharmacies and  
671 prescribers. The patient advisory report shall be provided in  
672 accordance with s. 893.13(7)(a)8. The department shall work with  
673 the professional health care licensure boards, such as the Board  
674 of Medicine, the Board of Osteopathic Medicine, and the Board of  
675 Pharmacy; other appropriate organizations, such as the Florida  
676 Pharmacy Association, the Florida Medical Association, the  
677 Florida Retail Federation, and the Florida Osteopathic Medical  
678 Association, including those relating to pain management; and  
679 the Attorney General, the Department of Law Enforcement, and the  
680 Agency for Health Care Administration to develop rules  
681 appropriate for the prescription drug monitoring program.

682 (10) All costs incurred by the department in administering  
683 the prescription drug monitoring program shall be funded through  
684 state funds, federal grants, or private funding applied for or  
685 received by the state. The department may not commit funds for  
686 the monitoring program without ensuring funding is available.  
687 ~~The prescription drug monitoring program and the implementation~~  
688 ~~thereof are contingent upon receipt of the nonstate funding.~~ The  
689 department and state government shall cooperate with the direct-  
690 support organization established pursuant to subsection (11) in  
691 seeking state funds, federal grant funds, other nonstate grant  
692 funds, gifts, donations, or other private moneys for the  
693 department ~~if so long as~~ the costs of doing so are not  
694 considered material. Nonmaterial costs for this purpose include,  
695 but are not limited to, the costs of mailing and personnel  
696 assigned to research or apply for a grant. Notwithstanding the



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697 exemptions to competitive-solicitation requirements under s.  
698 287.057(3)(f), the department shall comply with the competitive-  
699 solicitation requirements under s. 287.057 for the procurement  
700 of any goods or services required by this section. Funds  
701 provided, directly or indirectly, by prescription drug  
702 manufacturers may not be used to implement the program.

703 (11) The department may establish a direct-support  
704 organization that has a board consisting of at least five  
705 members to provide assistance, funding, and promotional support  
706 for the activities authorized for the prescription drug  
707 monitoring program.

708 (c) The State Surgeon General shall appoint a board of  
709 directors for the direct-support organization. Members of the  
710 board shall serve at the pleasure of the State Surgeon General.  
711 The State Surgeon General shall provide guidance to members of  
712 the board to ensure that moneys received by the direct-support  
713 organization are not received from inappropriate sources.  
714 Inappropriate sources include, but are not limited to, donors,  
715 grantors, persons, and ~~or~~ organizations, excluding  
716 pharmaceutical companies, that may monetarily or substantively  
717 benefit from the purchase of goods or services by the department  
718 in furtherance of the prescription drug monitoring program.

719 Section 14. Subsection (1) of section 409.9201, Florida  
720 Statutes, is amended to read:

721 409.9201 Medicaid fraud.—

722 (1) As used in this section, the term:

723 (a) "Prescription drug" means any drug, including, but not  
724 limited to, finished dosage forms or active ingredients that are  
725 subject to, defined by, or described by s. 503(b) of the Federal

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726 Food, Drug, and Cosmetic Act or by s. 465.003 ~~s. 465.003(8)~~, s.  
727 499.003(46) or (53) or s. 499.007(13).

728 (b) "Value" means the amount billed to the Medicaid program  
729 for the property dispensed or the market value of a legend drug  
730 or goods or services at the time and place of the offense. If  
731 the market value cannot be determined, the term means the  
732 replacement cost of the legend drug or goods or services within  
733 a reasonable time after the offense.

734  
735 The value of individual items of the legend drugs or goods or  
736 services involved in distinct transactions committed during a  
737 single scheme or course of conduct, whether involving a single  
738 person or several persons, may be aggregated when determining  
739 the punishment for the offense.

740 Section 15. Paragraph (pp) of subsection (1) of section  
741 458.331, Florida Statutes, is amended to read:

742 458.331 Grounds for disciplinary action; action by the  
743 board and department.—

744 (1) The following acts constitute grounds for denial of a  
745 license or disciplinary action, as specified in s. 456.072(2):

746 (pp) Applicable to a licensee who serves as the designated  
747 physician of a pain-management clinic as defined in s. 458.3265  
748 or s. 459.0137:

749 1. Registering a pain-management clinic through  
750 misrepresentation or fraud;

751 2. Procuring, or attempting to procure, the registration of  
752 a pain-management clinic for any other person by making or  
753 causing to be made, any false representation;

754 3. Failing to comply with any requirement of chapter 499,

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755 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the  
756 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,  
757 the Drug Abuse Prevention and Control Act; or chapter 893, the  
758 Florida Comprehensive Drug Abuse Prevention and Control Act;

759 4. Being convicted or found guilty of, regardless of  
760 adjudication to, a felony or any other crime involving moral  
761 turpitude, fraud, dishonesty, or deceit in any jurisdiction of  
762 the courts of this state, of any other state, or of the United  
763 States;

764 5. Being convicted of, or disciplined by a regulatory  
765 agency of the Federal Government or a regulatory agency of  
766 another state for, any offense that would constitute a violation  
767 of this chapter;

768 6. Being convicted of, or entering a plea of guilty or nolo  
769 contendere to, regardless of adjudication, a crime in any  
770 jurisdiction of the courts of this state, of any other state, or  
771 of the United States which relates to the practice of, or the  
772 ability to practice, a licensed health care profession;

773 7. Being convicted of, or entering a plea of guilty or nolo  
774 contendere to, regardless of adjudication, a crime in any  
775 jurisdiction of the courts of this state, of any other state, or  
776 of the United States which relates to health care fraud;

777 8. Dispensing any medicinal drug based upon a communication  
778 that purports to be a prescription as defined in s. 465.003 ~~s.~~  
779 ~~465.003(14)~~ or s. 893.02 if the dispensing practitioner knows or  
780 has reason to believe that the purported prescription is not  
781 based upon a valid practitioner-patient relationship; or

782 9. Failing to timely notify the board of the date of his or  
783 her termination from a pain-management clinic as required by s.

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784 458.3265(2).

785 Section 16. Paragraph (rr) of subsection (1) of section  
786 459.015, Florida Statutes, is amended to read:

787 459.015 Grounds for disciplinary action; action by the  
788 board and department.—

789 (1) The following acts constitute grounds for denial of a  
790 license or disciplinary action, as specified in s. 456.072(2):

791 (rr) Applicable to a licensee who serves as the designated  
792 physician of a pain-management clinic as defined in s. 458.3265  
793 or s. 459.0137:

794 1. Registering a pain-management clinic through  
795 misrepresentation or fraud;

796 2. Procuring, or attempting to procure, the registration of  
797 a pain-management clinic for any other person by making or  
798 causing to be made, any false representation;

799 3. Failing to comply with any requirement of chapter 499,  
800 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the  
801 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,  
802 the Drug Abuse Prevention and Control Act; or chapter 893, the  
803 Florida Comprehensive Drug Abuse Prevention and Control Act;

804 4. Being convicted or found guilty of, regardless of  
805 adjudication to, a felony or any other crime involving moral  
806 turpitude, fraud, dishonesty, or deceit in any jurisdiction of  
807 the courts of this state, of any other state, or of the United  
808 States;

809 5. Being convicted of, or disciplined by a regulatory  
810 agency of the Federal Government or a regulatory agency of  
811 another state for, any offense that would constitute a violation  
812 of this chapter;

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813           6. Being convicted of, or entering a plea of guilty or nolo  
814           contendere to, regardless of adjudication, a crime in any  
815           jurisdiction of the courts of this state, of any other state, or  
816           of the United States which relates to the practice of, or the  
817           ability to practice, a licensed health care profession;

818           7. Being convicted of, or entering a plea of guilty or nolo  
819           contendere to, regardless of adjudication, a crime in any  
820           jurisdiction of the courts of this state, of any other state, or  
821           of the United States which relates to health care fraud;

822           8. Dispensing any medicinal drug based upon a communication  
823           that purports to be a prescription as defined in s. 465.003 ~~s.~~  
824           ~~465.003(14)~~ or s. 893.02 if the dispensing practitioner knows or  
825           has reason to believe that the purported prescription is not  
826           based upon a valid practitioner-patient relationship; or

827           9. Failing to timely notify the board of the date of his or  
828           her termination from a pain-management clinic as required by s.  
829           459.0137(2).

830           Section 17. Subsection (1) of section 465.014, Florida  
831           Statutes, is amended to read:

832           465.014 Pharmacy technician.—

833           (1) A person other than a licensed pharmacist or pharmacy  
834           intern may not engage in the practice of the profession of  
835           pharmacy, except that a licensed pharmacist may delegate to  
836           pharmacy technicians who are registered pursuant to this section  
837           those duties, tasks, and functions that do not fall within the  
838           purview of s. 465.003 ~~s. 465.003(13)~~. All such delegated acts  
839           shall be performed under the direct supervision of a licensed  
840           pharmacist who shall be responsible for all such acts performed  
841           by persons under his or her supervision. A pharmacy registered

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842 technician, under the supervision of a pharmacist, may initiate  
843 or receive communications with a practitioner or his or her  
844 agent, on behalf of a patient, regarding refill authorization  
845 requests. A licensed pharmacist may not supervise more than one  
846 registered pharmacy technician unless otherwise permitted by the  
847 guidelines adopted by the board. The board shall establish  
848 guidelines to be followed by licensees or permittees in  
849 determining the circumstances under which a licensed pharmacist  
850 may supervise more than one but not more than three pharmacy  
851 technicians.

852 Section 18. Paragraph (c) of subsection (2) of section  
853 465.015, Florida Statutes, is amended to read:

854 465.015 Violations and penalties.—

855 (2) It is unlawful for any person:

856 (c) To sell or dispense drugs as defined in s. 465.003 ~~s.~~  
857 ~~465.003(8)~~ without first being furnished with a prescription.

858 Section 19. Subsection (8) of section 465.0156, Florida  
859 Statutes, is amended to read:

860 465.0156 Registration of nonresident pharmacies.—

861 (8) Notwithstanding s. 465.003 ~~s. 465.003(10)~~, for purposes  
862 of this section, the registered pharmacy and the pharmacist  
863 designated by the registered pharmacy as the prescription  
864 department manager or the equivalent must be licensed in the  
865 state of location in order to dispense into this state.

866 Section 20. Subsection (4) of section 465.0197, Florida  
867 Statutes, is amended to read:

868 465.0197 Internet pharmacy permits.—

869 (4) Notwithstanding s. 465.003 ~~s. 465.003(10)~~, for purposes  
870 of this section, the Internet pharmacy and the pharmacist

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871 designated by the Internet pharmacy as the prescription  
872 department manager or the equivalent must be licensed in the  
873 state of location in order to dispense into this state.

874 Section 21. Section 465.1901, Florida Statutes, is amended  
875 to read:

876 465.1901 Practice of orthotics and pedorthics.—The  
877 provisions of chapter 468 relating to orthotics or pedorthics do  
878 not apply to any licensed pharmacist or to any person acting  
879 under the supervision of a licensed pharmacist. The practice of  
880 orthotics or pedorthics by a pharmacist or any of the  
881 pharmacist's employees acting under the supervision of a  
882 pharmacist shall be construed to be within the meaning of the  
883 term "practice of the profession of pharmacy" as set forth in s.  
884 465.003 ~~s. 465.003(13)~~, and shall be subject to regulation in  
885 the same manner as any other pharmacy practice. The Board of  
886 Pharmacy shall develop rules regarding the practice of orthotics  
887 and pedorthics by a pharmacist. Any pharmacist or person under  
888 the supervision of a pharmacist engaged in the practice of  
889 orthotics or pedorthics is not precluded from continuing that  
890 practice pending adoption of these rules.

891 Section 22. Subsection (43) of section 499.003, Florida  
892 Statutes, is amended to read:

893 499.003 Definitions of terms used in this part.—As used in  
894 this part, the term:

895 (43) "Prescription drug" means a prescription, medicinal,  
896 or legend drug, including, but not limited to, finished dosage  
897 forms or active pharmaceutical ingredients subject to, defined  
898 by, or described by s. 503(b) of the Federal Food, Drug, and  
899 Cosmetic Act or s. 465.003 ~~s. 465.003(8)~~, s. 499.007(13), or

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900 subsection (11), subsection (46), or subsection (53), except  
901 that an active pharmaceutical ingredient is a prescription drug  
902 only if substantially all finished dosage forms in which it may  
903 be lawfully dispensed or administered in this state are also  
904 prescription drugs.

905 Section 23. Subsection (22) of section 893.02, Florida  
906 Statutes, is amended to read:

907 893.02 Definitions.—The following words and phrases as used  
908 in this chapter shall have the following meanings, unless the  
909 context otherwise requires:

910 (22) "Prescription" means and includes an order for drugs  
911 or medicinal supplies written, signed, or transmitted by word of  
912 mouth, telephone, telegram, or other means of communication by a  
913 duly licensed practitioner licensed by the laws of the state to  
914 prescribe such drugs or medicinal supplies, issued in good faith  
915 and in the course of professional practice, intended to be  
916 filled, compounded, or dispensed by another person licensed by  
917 the laws of the state to do so, and meeting the requirements of  
918 s. 893.04. The term also includes an order for drugs or  
919 medicinal supplies so transmitted or written by a physician,  
920 dentist, veterinarian, or other practitioner licensed to  
921 practice in a state other than Florida, but only if the  
922 pharmacist called upon to fill such an order determines, in the  
923 exercise of his or her professional judgment, that the order was  
924 issued pursuant to a valid patient-physician relationship, that  
925 it is authentic, and that the drugs or medicinal supplies so  
926 ordered are considered necessary for the continuation of  
927 treatment of a chronic or recurrent illness. However, if the  
928 physician writing the prescription is not known to the



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929 pharmacist, the pharmacist shall obtain proof to a reasonable  
930 certainty of the validity of said prescription. A prescription  
931 order for a controlled substance shall not be issued on the same  
932 prescription blank with another prescription order for a  
933 controlled substance which is named or described in a different  
934 schedule, nor shall any prescription order for a controlled  
935 substance be issued on the same prescription blank as a  
936 prescription order for a medicinal drug, as defined in s.  
937 465.003 ~~s. 465.003(8)~~, which does not fall within the definition  
938 of a controlled substance as defined in this act.

939 Section 24. This act shall take effect July 1, 2013.