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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/20/2013	.	
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The Committee on Health Policy (Grimsley) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

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

400.996 Preemption.—This chapter preempts to the state all regulation of the licensure, activity, and operation of clinics under part X of chapter 400, excluding registration and licensing for pain-management clinics. A local government or political subdivision of the state may not enact or enforce an ordinance that imposes a levy, charge, or fee upon, or that



769960

13 otherwise regulates, clinics under part X of chapter 400,
14 including services provided within such facilities, except that
15 this preemption does not prohibit a local government or
16 political subdivision from enacting an ordinance regarding the
17 following:

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

19 (2) Land use development regulations adopted pursuant to
20 chapter 163, which include regulation of any aspect of
21 development, including a subdivision, building construction,
22 sign regulation, and any other regulation concerning the
23 development of land, landscaping, or tree protection, and which
24 do not include restrictions on pain-management services, health
25 care services, or the prescribing of controlled substances.
26 However, a clinic that treats pain or provides pain-management
27 services is a permissible use in a land use or zoning category
28 that permits hospitals, other health care facilities, or clinics
29 as defined in chapter 395, s. 408.07, or part X of chapter 400.

30 Section 2. Section 408.833, Florida Statutes, is created to
31 read:

32 408.833 Preemption.—This chapter preempts to the state all
33 regulation of the licensure, activity, and operation of health
34 care facilities as defined in s. 408.07. A local government or
35 political subdivision of the state may not enact or enforce an
36 ordinance that imposes a levy, charge, or fee upon, or that
37 otherwise regulates health care facilities as defined in s.
38 408.07, including services provided within such facilities,
39 except that this preemption does not prohibit a local government
40 or political subdivision from enacting an ordinance regarding
41 the following:



769960

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

43 (2) Land use development regulations adopted pursuant to
44 chapter 163, which include regulation of any aspect of
45 development, including a subdivision, building construction,
46 sign regulation, and any other regulation concerning the
47 development of land, landscaping, or tree protection, and which
48 do not include restrictions on pain-management services, health
49 care services, or the prescribing of controlled substances.
50 However, a health care facility or clinic that treats pain or
51 provides pain-management services is a permissible use in a land
52 use or zoning category that permits hospitals, other health care
53 facilities, or clinics as defined in chapter 395, s. 408.07, or
54 part X of chapter 400.

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

57 456.44 Controlled substance prescribing.—

58 (2) REGISTRATION.—~~Effective January 1, 2012,~~ A physician
59 licensed under chapter 458, chapter 459, chapter 461, or chapter
60 466 who prescribes more than a 30-day supply of any controlled
61 substance, listed in Schedule II, Schedule III, or Schedule IV
62 as defined in s. 893.03, over a 6-month period to any one
63 patient for the treatment of chronic nonmalignant pain, must:

64 (a) Designate himself or herself as a controlled substance
65 prescribing practitioner on the physician's practitioner
66 profile.

67 (b) Comply with the requirements of this section and
68 applicable board rules.

69 (3) STANDARDS OF PRACTICE.—The standards of practice in
70 this section do not supersede the level of care, skill, and



769960

71 treatment recognized in general law related to health care
72 licensure.

73 (a) A complete medical history and a physical examination
74 must be conducted before beginning any treatment and must be
75 documented in the medical record. The exact components of the
76 physical examination shall be left to the judgment of the
77 clinician who is expected to perform a physical examination
78 proportionate to the diagnosis that justifies a treatment. The
79 medical record must, at a minimum, document the nature and
80 intensity of the pain, current and past treatments for pain,
81 underlying or coexisting diseases or conditions, the effect of
82 the pain on physical and psychological function, a review of
83 previous medical records, previous diagnostic studies, and
84 history of alcohol and substance abuse. The medical record shall
85 also document the presence of one or more recognized medical
86 indications for the use of a controlled substance. Each
87 registrant must develop a written plan for assessing each
88 patient's risk of aberrant drug-related behavior, which may
89 include patient drug testing. Registrants must assess each
90 patient's risk for aberrant drug-related behavior and monitor
91 that risk on an ongoing basis in accordance with the plan.

92 (b) Before or during a new patient's visit for pain-
93 treatment services at a pain-management clinic registered under
94 s. 458.3265 or s. 459.0137, a physician shall consult the
95 prescription drug monitoring program database provided under s.
96 893.055(2) (a) before prescribing a controlled substance listed
97 in Schedule II or Schedule III in s. 893.03. The physician may
98 designate an agent under his or her supervision to consult the
99 database. The board shall adopt rules to establish a penalty for



769960

100 a physician who does not comply with this subsection.

101 (c)~~(b)~~ Each registrant must develop a written
102 individualized treatment plan for each patient. The treatment
103 plan shall state objectives that will be used to determine
104 treatment success, such as pain relief and improved physical and
105 psychosocial function, and shall indicate if any further
106 diagnostic evaluations or other treatments are planned. After
107 treatment begins, the physician shall adjust drug therapy to the
108 individual medical needs of each patient. Other treatment
109 modalities, including a rehabilitation program, shall be
110 considered depending on the etiology of the pain and the extent
111 to which the pain is associated with physical and psychosocial
112 impairment. The interdisciplinary nature of the treatment plan
113 shall be documented.

114 (d)~~(e)~~ The physician shall discuss the risks and benefits
115 of the use of controlled substances, including the risks of
116 abuse and addiction, as well as physical dependence and its
117 consequences, with the patient, persons designated by the
118 patient, or the patient's surrogate or guardian if the patient
119 is incompetent. The physician shall use a written controlled
120 substance agreement between the physician and the patient
121 outlining the patient's responsibilities, including, but not
122 limited to:

123 1. Number and frequency of controlled substance
124 prescriptions and refills.

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

127 3. An agreement that controlled substances for the
128 treatment of chronic nonmalignant pain shall be prescribed by a



769960

129 single treating physician unless otherwise authorized by the
130 treating physician and documented in the medical record.

131 (e)~~(d)~~ The patient shall be seen by the physician at
132 regular intervals, not to exceed 3 months, to assess the
133 efficacy of treatment, ensure that controlled substance therapy
134 remains indicated, evaluate the patient's progress toward
135 treatment objectives, consider adverse drug effects, and review
136 the etiology of the pain. Continuation or modification of
137 therapy shall depend on the physician's evaluation of the
138 patient's progress. If treatment goals are not being achieved,
139 despite medication adjustments, the physician shall reevaluate
140 the appropriateness of continued treatment. The physician shall
141 monitor patient compliance in medication usage, related
142 treatment plans, controlled substance agreements, and
143 indications of substance abuse or diversion at a minimum of 3-
144 month intervals.

145 (f)~~(e)~~ The physician shall refer the patient as necessary
146 for additional evaluation and treatment in order to achieve
147 treatment objectives. Special attention shall be given to those
148 patients who are at risk for misusing their medications and
149 those whose living arrangements pose a risk for medication
150 misuse or diversion. The management of pain in patients with a
151 history of substance abuse or with a comorbid psychiatric
152 disorder requires extra care, monitoring, and documentation and
153 requires consultation with or referral to an addiction medicine
154 specialist or psychiatrist.

155 (g)~~(f)~~ A physician registered under this section must
156 maintain accurate, current, and complete records that are
157 accessible and readily available for review and comply with the



769960

158 requirements of this section, the applicable practice act, and
159 applicable board rules. The medical records must include, but
160 are not limited to:

161 1. The complete medical history and a physical examination,
162 including history of drug abuse or dependence.

163 2. Diagnostic, therapeutic, and laboratory results.

164 3. Evaluations and consultations.

165 4. Treatment objectives.

166 5. Discussion of risks and benefits.

167 6. Treatments.

168 7. Medications, including date, type, dosage, and quantity
169 prescribed.

170 8. Instructions and agreements.

171 9. Periodic reviews.

172 10. Results of any drug testing.

173 11. A photocopy of the patient's government-issued photo
174 identification.

175 12. If a written prescription for a controlled substance is
176 given to the patient, a duplicate of the prescription.

177 13. The physician's full name presented in a legible
178 manner.

179 (h) ~~(g)~~ Patients with signs or symptoms of substance abuse
180 shall be immediately referred to a board-certified pain
181 management physician, an addiction medicine specialist, or a
182 mental health addiction facility as it pertains to drug abuse or
183 addiction unless the physician is board-certified or board-
184 eligible in pain management. Throughout the period of time
185 before receiving the consultant's report, a prescribing
186 physician shall clearly and completely document medical



769960

187 justification for continued treatment with controlled substances
188 and those steps taken to ensure medically appropriate use of
189 controlled substances by the patient. Upon receipt of the
190 consultant's written report, the prescribing physician shall
191 incorporate the consultant's recommendations for continuing,
192 modifying, or discontinuing controlled substance therapy. The
193 resulting changes in treatment shall be specifically documented
194 in the patient's medical record. Evidence or behavioral
195 indications of diversion shall be followed by discontinuation of
196 controlled substance therapy, and the patient shall be
197 discharged, and all results of testing and actions taken by the
198 physician shall be documented in the patient's medical record.
199

200 This subsection does not apply to a board-eligible or board-
201 certified anesthesiologist, physiatrist, rheumatologist, or
202 neurologist, or to a board-certified physician who has surgical
203 privileges at a hospital or ambulatory surgery center and
204 primarily provides surgical services. This subsection does not
205 apply to a board-eligible or board-certified medical specialist
206 who has also completed a fellowship in pain medicine approved by
207 the Accreditation Council for Graduate Medical Education or the
208 American Osteopathic Association, or who is board eligible or
209 board certified in pain medicine by the American Board of Pain
210 Medicine or a board approved by the American Board of Medical
211 Specialties or the American Osteopathic Association and performs
212 interventional pain procedures of the type routinely billed
213 using surgical codes. This subsection does not apply to a
214 physician who prescribes medically necessary controlled
215 substances for a patient during an inpatient stay in a hospital



769960

216 licensed under chapter 395 or to a resident in a facility
217 licensed under part II of chapter 400. This subsection does not
218 apply to any physician licensed under chapter 458 or chapter 459
219 who writes fewer than 50 prescriptions for a controlled
220 substance for all of his or her patients during a 1-year period.

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

223 458.326 Intractable pain; authorized treatment.—

224 (3) (a) Notwithstanding any other provision of law, a
225 physician may prescribe or administer any controlled substance
226 under Schedules II-V, as provided for in s. 893.03, to a person
227 for the treatment of intractable pain, provided the physician
228 does so in accordance with that level of care, skill, and
229 treatment recognized by a reasonably prudent physician under
230 similar conditions and circumstances.

231 (b) Before or during a new patient's visit for pain-
232 treatment services, a physician shall consult the prescription
233 drug monitoring program database provided under s. 893.055(2) (a)
234 before prescribing a controlled substance listed in Schedule II
235 or Schedule III in s. 893.03. The physician may designate an
236 agent under his or her supervision to consult the database. The
237 board shall adopt rules to establish a penalty for a physician
238 who does not comply with this paragraph.

239 Section 5. Paragraphs (a) and (d) of subsection (1) of
240 section 458.3265, Florida Statutes, are amended, present
241 subsections (5) and (6) of that section are renumbered as
242 subsections (6) and (7), respectively, and a new subsection (5)
243 is added to that section, to read:

244 458.3265 Pain-management clinics.—



769960

245 (1) REGISTRATION.—
246 (a)1. As used in this section, the term:
247 a. "Board eligible" means successful completion of an
248 anesthesia, physical medicine and rehabilitation, rheumatology,
249 or neurology residency program approved by the Accreditation
250 Council for Graduate Medical Education or the American
251 Osteopathic Association for a period of 6 years from successful
252 completion of such residency program.
253 b. "Chronic nonmalignant pain" means pain unrelated to
254 cancer which persists beyond the usual course of disease or the
255 injury that is the cause of the pain or more than 90 days after
256 surgery.
257 c. "Pain-management clinic" or "clinic" means any publicly
258 or privately owned facility:
259 (I) That advertises in any medium for any type of pain-
260 management services; or
261 (II) Where in any month a majority of patients are
262 prescribed opioids, benzodiazepines, barbiturates, or
263 carisoprodol for the treatment of chronic nonmalignant pain.
264 2. Each pain-management clinic must register with the
265 department unless:
266 a. That clinic is licensed as a facility pursuant to
267 chapter 395;
268 b. The majority of the physicians who provide services in
269 the clinic primarily provide surgical services;
270 ~~c. The clinic is owned by a publicly held corporation whose~~
271 ~~shares are traded on a national exchange or on the over-the-~~
272 ~~counter market and whose total assets at the end of the~~
273 ~~corporation's most recent fiscal quarter exceeded \$50 million;~~



769960

274 ~~c.d.~~ The clinic is affiliated with an accredited medical
275 school at which training is provided for medical students,
276 residents, or fellows;

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

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

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

284 ~~f.h.~~ The clinic is wholly owned and operated by a physician
285 multispecialty practice where one or more board-eligible or
286 board-certified medical specialists who have also completed
287 fellowships in pain medicine approved by the Accreditation
288 Council for Graduate Medical Education, or who are also board-
289 certified in pain medicine by the American Board of Pain
290 Medicine or a board approved by the American Board of Medical
291 Specialties, the American Association of Physician Specialists,
292 or the American Osteopathic Association and perform
293 interventional pain procedures of the type routinely billed
294 using surgical codes.

295 (d) The department shall deny registration to any clinic
296 that is not fully owned by a physician licensed under this
297 chapter or chapter 459 or a group of physicians, each of whom is
298 licensed under this chapter or chapter 459; or that is not a
299 health care clinic licensed under part X of chapter 400 which is
300 fully owned by such physician or group of physicians.

301 (5) PREEMPTION.—This chapter preempts to the state all
302 regulation of the licensure and activity of a physician licensed



769960

303 under this chapter who owns, operates, or works in a pain-
304 management clinic or provides pain-management services. A local
305 government or political subdivision of the state may not enact
306 or enforce an ordinance that imposes a levy, charge, or fee
307 upon, or that otherwise regulates, a physician licensed under
308 this chapter who owns, operates, or works in a pain-management
309 clinic or provides pain-management services, except that this
310 preemption does not prohibit a local government or political
311 subdivision from enacting an ordinance regarding the following:

312 (a) A registered pain-management clinic as defined in
313 subsection (1).

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

315 (c) Land use development regulations adopted pursuant to
316 chapter 163, which include regulation of any aspect of
317 development, including a subdivision, building construction,
318 sign regulation, and any other regulation concerning the
319 development of land, landscaping, or tree protection, and which
320 do not include restrictions on pain-management services, health
321 care services, or the prescribing of controlled substances.
322 However, a health care facility or clinic that treats pain or
323 provides pain-management services is a permissible use in a land
324 use or zoning category that permits hospitals, other health care
325 facilities, or clinics as defined in chapter 395, s. 408.07, or
326 part X of chapter 400.

327 Section 6. Paragraphs (a) and (d) of subsection (1) of
328 section 459.0137, Florida Statutes, are amended, present
329 subsections (5) and (6) of that section are renumbered as
330 subsections (6) and (7), respectively, and a new subsection (5)
331 is added to that section, to read:



769960

332 459.0137 Pain-management clinics.-

333 (1) REGISTRATION.-

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

335 a. "Board eligible" means successful completion of an
336 anesthesia, physical medicine and rehabilitation, rheumatology,
337 or neurology residency program approved by the Accreditation
338 Council for Graduate Medical Education or the American
339 Osteopathic Association for a period of 6 years from successful
340 completion of such residency program.

341 b. "Chronic nonmalignant pain" means pain unrelated to
342 cancer which persists beyond the usual course of disease or the
343 injury that is the cause of the pain or more than 90 days after
344 surgery.

345 c. "Pain-management clinic" or "clinic" means any publicly
346 or privately owned facility:

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

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

352 2. Each pain-management clinic must register with the
353 department unless:

354 a. That clinic is licensed as a facility pursuant to
355 chapter 395;

356 b. The majority of the physicians who provide services in
357 the clinic primarily provide surgical services;

358 ~~e. The clinic is owned by a publicly held corporation whose~~
359 ~~shares are traded on a national exchange or on the over the~~
360 ~~counter market and whose total assets at the end of the~~



769960

~~corporation's most recent fiscal quarter exceeded \$50 million;~~

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

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

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

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

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

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

(5) PREEMPTION.—This chapter preempts to the state all



769960

390 regulation of the licensure and activity of an osteopathic
391 physician licensed under this chapter who owns, operates, or
392 works in a pain-management clinic or provides pain-management
393 services. A local government or political subdivision of the
394 state may not enact or enforce an ordinance that imposes a levy,
395 charge, or fee upon, or that otherwise regulates, an osteopathic
396 physician licensed under this chapter who owns, operates, or
397 works in a pain-management clinic, except that this preemption
398 does not prohibit a local government or political subdivision
399 from enacting an ordinance regarding the following:

400 (a) A registered pain-management clinic as defined in
401 subsection (1).

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

403 (c) Land use development regulations adopted pursuant to
404 chapter 163, which include regulation of any aspect of
405 development, including a subdivision, building construction,
406 sign regulation, and any other regulation concerning the
407 development of land, landscaping, or tree protection, and which
408 do not include restrictions on pain-management services, health
409 care services, and the prescribing of controlled substances.
410 However, a health care facility or clinic that treats pain or
411 provides pain-management services is a permissible use in a land
412 use or zoning category that permits hospitals, other health care
413 facilities, or clinics as defined in chapter 395, s. 408.07, or
414 part X of chapter 400.

415 Section 7. Present subsections (1) through (17) of section
416 465.003, Florida Statutes, are renumbered as subsections (2)
417 through (18), respectively, paragraph (a) of present subsection
418 (11) of that section is amended, and a new subsection (1) is



769960

419 added to that section, to read:

420 465.003 Definitions.—As used in this chapter, the term:

421 (1) "Abandoned" means the status of a pharmacy permit of a
422 person or entity that was issued the permit but fails to
423 commence pharmacy operations within 180 days after issuance of
424 the permit without good cause or fails to follow pharmacy
425 closure requirements as set by the board.

426 (12)-(11)(a) "Pharmacy" includes a community pharmacy, an
427 institutional pharmacy, a nuclear pharmacy, a special pharmacy,
428 and an Internet pharmacy.

429 1. The term "community pharmacy" includes every location
430 where medicinal drugs are compounded, dispensed, stored, or sold
431 or where prescriptions are filled or dispensed on an outpatient
432 basis.

433 2. The term "institutional pharmacy" includes every
434 location in a hospital, clinic, nursing home, dispensary,
435 sanitarium, extended care facility, or other facility,
436 hereinafter referred to as "health care institutions," where
437 medicinal drugs are compounded, dispensed, stored, or sold.

438 3. The term "nuclear pharmacy" includes every location
439 where radioactive drugs and chemicals within the classification
440 of medicinal drugs are compounded, dispensed, stored, or sold.
441 The term "nuclear pharmacy" does not include hospitals licensed
442 under chapter 395 or the nuclear medicine facilities of such
443 hospitals.

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

447 5. The term "Internet pharmacy" includes locations not



769960

448 otherwise licensed or issued a permit under this chapter, within
449 or outside this state, which use the Internet to communicate
450 with or obtain information from consumers in this state and use
451 such communication or information to fill or refill
452 prescriptions or to dispense, distribute, or otherwise engage in
453 the practice of pharmacy in this state. Any act described in
454 this definition constitutes the practice of pharmacy as defined
455 in subsection (14) ~~(13)~~.

456 Section 8. Section 465.0065, Florida Statutes, is created
457 to read:

458 465.0065 Notices; form and service.—Each notice served by
459 the department pursuant to this chapter must be in writing and
460 must be delivered personally by an agent of the department or by
461 certified mail to the pharmacy permittee or licensee. If the
462 pharmacy permittee or licensee refuses to accept service or
463 evades service or if the agent is otherwise unable to carry out
464 service after due diligence, the department may post the notice
465 in a conspicuous place at the pharmacy or at the home or
466 business address for the licensee.

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

470 465.016 Disciplinary actions.—

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

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



769960

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

482 (u) Misappropriating drugs, supplies, or equipment from a
483 pharmacy permittee.

484 Section 10. Paragraph (j) of subsection (5) of section
485 465.022, Florida Statutes, is amended, present subsections (10)
486 through (14) are renumbered as subsections (11) through (15),
487 respectively, present subsection (10) of that section is
488 amended, and a new subsection (10) is added to that section, to
489 read:

490 465.022 Pharmacies; general requirements; fees.—

491 (5) The department or board shall deny an application for a
492 pharmacy permit if the applicant or an affiliated person,
493 partner, officer, director, or prescription department manager
494 or consultant pharmacist of record of the applicant:

495 (j) Has dispensed any medicinal drug based upon a
496 communication that purports to be a prescription as defined by
497 s. 465.003 ~~s. 465.003(14)~~ or s. 893.02 when the pharmacist knows
498 or has reason to believe that the purported prescription is not
499 based upon a valid practitioner-patient relationship that
500 includes a documented patient evaluation, including history and
501 a physical examination adequate to establish the diagnosis for
502 which any drug is prescribed and any other requirement
503 established by board rule under chapter 458, chapter 459,
504 chapter 461, chapter 463, chapter 464, or chapter 466.

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769960

506 For felonies in which the defendant entered a plea of guilty or
507 nolo contendere in an agreement with the court to enter a
508 pretrial intervention or drug diversion program, the department
509 shall deny the application if upon final resolution of the case
510 the licensee has failed to successfully complete the program.

511 (10) The permittee shall commence pharmacy operations
512 within 180 days after issuance of the permit, or show good cause
513 to the department why pharmacy operations were not commenced.
514 Commencement of pharmacy operations includes, but is not limited
515 to, acts within the scope of the practice of pharmacy, ordering
516 or receiving drugs, and other similar activities. The board
517 shall establish rules regarding commencement of pharmacy
518 operations.

519 (11)-(10) A pharmacy permittee shall be supervised by a
520 prescription department manager or consultant pharmacist of
521 record at all times. A permittee must notify the department, on
522 a form approved by the board, within 10 days after any change in
523 prescription department manager or consultant pharmacist of
524 record.

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

527 465.023 Pharmacy permittee; disciplinary action.—

528 (1) The department or the board may revoke or suspend the
529 permit of any pharmacy permittee, and may fine, place on
530 probation, or otherwise discipline any pharmacy permittee if the
531 permittee, or any affiliated person, partner, officer, director,
532 or agent of the permittee, including a person fingerprinted
533 under s. 465.022(3), has:

534 (a) Obtained a permit by misrepresentation or fraud or



769960

535 through an error of the department or the board;

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

539 (c) Violated any of the requirements of this chapter or any
540 of the rules of the Board of Pharmacy; of chapter 499, known as
541 the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss. 301-392,
542 known as the "Federal Food, Drug, and Cosmetic Act"; of 21
543 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse
544 Prevention and Control Act; or of chapter 893 or rules adopted
545 thereunder;

546 (d) Been convicted or found guilty, regardless of
547 adjudication, of a felony or any other crime involving moral
548 turpitude in any of the courts of this state, of any other
549 state, or of the United States;

550 (e) Been convicted or disciplined by a regulatory agency of
551 the Federal Government or a regulatory agency of another state
552 for any offense that would constitute a violation of this
553 chapter;

554 (f) Been convicted of, or entered a plea of guilty or nolo
555 contendere to, regardless of adjudication, a crime in any
556 jurisdiction which relates to the practice of, or the ability to
557 practice, the profession of pharmacy;

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

561 (h) Dispensed any medicinal drug based upon a communication
562 that purports to be a prescription as defined by s. 465.003 ~~or~~
563 ~~465.003(14)~~ or s. 893.02 when the pharmacist knows or has reason



769960

564 to believe that the purported prescription is not based upon a
565 valid practitioner-patient relationship that includes a
566 documented patient evaluation, including history and a physical
567 examination adequate to establish the diagnosis for which any
568 drug is prescribed and any other requirement established by
569 board rule under chapter 458, chapter 459, chapter 461, chapter
570 463, chapter 464, or chapter 466.

571 Section 12. Section 465.1902, Florida Statutes, is created
572 to read:

573 465.1902 Preemption.—This chapter preempts to the state all
574 regulation of the licensure, activity, and operation of
575 pharmacies and pharmacists as defined in this chapter. A local
576 government or political subdivision of the state may not enact
577 or enforce an ordinance that imposes a levy, charge, or fee
578 upon, or that otherwise regulates, pharmacies and pharmacists as
579 defined in this chapter, except that this preemption does not
580 prohibit a local government or political subdivision from
581 enacting an ordinance regarding the following:

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

583 (2) Land use development regulations adopted pursuant to
584 chapter 163, which include regulation of any aspect of
585 development, including a subdivision, building construction,
586 sign regulation, and any other regulation concerning the
587 development of land, landscaping, or tree protection, and which
588 do not include restrictions on pain-management services, health
589 care services, or the prescribing of controlled substances.

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



769960

593 893.055 Prescription drug monitoring program.—

594 (2)

595 (b) The department, ~~when the direct support organization~~
596 ~~receives at least \$20,000 in nonstate moneys or the state~~
597 ~~receives at least \$20,000 in federal grants for the prescription~~
598 ~~drug monitoring program,~~ shall adopt rules as necessary
599 concerning the reporting, accessing the database, evaluation,
600 management, development, implementation, operation, security,
601 and storage of information within the system, including rules
602 for when patient advisory reports are provided to pharmacies and
603 prescribers. The patient advisory report shall be provided in
604 accordance with s. 893.13(7)(a)8. The department shall work with
605 the professional health care licensure boards, such as the Board
606 of Medicine, the Board of Osteopathic Medicine, and the Board of
607 Pharmacy; other appropriate organizations, such as the Florida
608 Pharmacy Association, the Florida Medical Association, the
609 Florida Retail Federation, and the Florida Osteopathic Medical
610 Association, including those relating to pain management; and
611 the Attorney General, the Department of Law Enforcement, and the
612 Agency for Health Care Administration to develop rules
613 appropriate for the prescription drug monitoring program.

614 (10) All costs incurred by the department in administering
615 the prescription drug monitoring program shall be funded through
616 state funds, federal grants, or private funding applied for or
617 received by the state. The department may not commit funds for
618 the monitoring program without ensuring funding is available.
619 ~~The prescription drug monitoring program and the implementation~~
620 ~~thereof are contingent upon receipt of the nonstate funding.~~ The
621 department and state government shall cooperate with the direct-



769960

622 support organization established pursuant to subsection (11) in
623 seeking state funds, federal grant funds, other nonstate grant
624 funds, gifts, donations, or other private moneys for the
625 department if so long as the costs of doing so are not
626 considered material. Nonmaterial costs for this purpose include,
627 but are not limited to, the costs of mailing and personnel
628 assigned to research or apply for a grant. Notwithstanding the
629 exemptions to competitive-solicitation requirements under s.
630 287.057(3)(f), the department shall comply with the competitive-
631 solicitation requirements under s. 287.057 for the procurement
632 of any goods or services required by this section. Funds
633 provided, directly or indirectly, by prescription drug
634 manufacturers may not be used to implement the program.

635 (11) The department may establish a direct-support
636 organization that has a board consisting of at least five
637 members to provide assistance, funding, and promotional support
638 for the activities authorized for the prescription drug
639 monitoring program.

640 (c) The State Surgeon General shall appoint a board of
641 directors for the direct-support organization. Members of the
642 board shall serve at the pleasure of the State Surgeon General.
643 The State Surgeon General shall provide guidance to members of
644 the board to ensure that moneys received by the direct-support
645 organization are not received from inappropriate sources.
646 Inappropriate sources include, but are not limited to, donors,
647 grantors, persons, and ~~or~~ organizations, excluding
648 pharmaceutical companies, that may monetarily or substantively
649 benefit from the purchase of goods or services by the department
650 in furtherance of the prescription drug monitoring program.



769960

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

653 409.9201 Medicaid fraud.—

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

655 (a) "Prescription drug" means any drug, including, but not
656 limited to, finished dosage forms or active ingredients that are
657 subject to, defined by, or described by s. 503(b) of the Federal
658 Food, Drug, and Cosmetic Act or by s. 465.003 ~~s. 465.003(8)~~, s.
659 499.003(46) or (53) or s. 499.007(13).

660 (b) "Value" means the amount billed to the Medicaid program
661 for the property dispensed or the market value of a legend drug
662 or goods or services at the time and place of the offense. If
663 the market value cannot be determined, the term means the
664 replacement cost of the legend drug or goods or services within
665 a reasonable time after the offense.

666
667 The value of individual items of the legend drugs or goods or
668 services involved in distinct transactions committed during a
669 single scheme or course of conduct, whether involving a single
670 person or several persons, may be aggregated when determining
671 the punishment for the offense.

672 Section 15. Paragraph (pp) of subsection (1) of section
673 458.331, Florida Statutes, is amended to read:

674 458.331 Grounds for disciplinary action; action by the
675 board and department.—

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

678 (pp) Applicable to a licensee who serves as the designated
679 physician of a pain-management clinic as defined in s. 458.3265



769960

680 or s. 459.0137:

681 1. Registering a pain-management clinic through
682 misrepresentation or fraud;

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

686 3. Failing to comply with any requirement of chapter 499,
687 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
688 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
689 the Drug Abuse Prevention and Control Act; or chapter 893, the
690 Florida Comprehensive Drug Abuse Prevention and Control Act;

691 4. Being convicted or found guilty of, regardless of
692 adjudication to, a felony or any other crime involving moral
693 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
694 the courts of this state, of any other state, or of the United
695 States;

696 5. Being convicted of, or disciplined by a regulatory
697 agency of the Federal Government or a regulatory agency of
698 another state for, any offense that would constitute a violation
699 of this chapter;

700 6. Being convicted of, or entering a plea of guilty or nolo
701 contendere to, regardless of adjudication, a crime in any
702 jurisdiction of the courts of this state, of any other state, or
703 of the United States which relates to the practice of, or the
704 ability to practice, a licensed health care profession;

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



769960

709 8. Dispensing any medicinal drug based upon a communication
710 that purports to be a prescription as defined in s. 465.003 ~~s.~~
711 ~~465.003(14)~~ or s. 893.02 if the dispensing practitioner knows or
712 has reason to believe that the purported prescription is not
713 based upon a valid practitioner-patient relationship; or

714 9. Failing to timely notify the board of the date of his or
715 her termination from a pain-management clinic as required by s.
716 458.3265(2).

717 Section 16. Paragraph (rr) of subsection (1) of section
718 459.015, Florida Statutes, is amended to read:

719 459.015 Grounds for disciplinary action; action by the
720 board and department.—

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

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

726 1. Registering a pain-management clinic through
727 misrepresentation or fraud;

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

731 3. Failing to comply with any requirement of chapter 499,
732 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
733 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
734 the Drug Abuse Prevention and Control Act; or chapter 893, the
735 Florida Comprehensive Drug Abuse Prevention and Control Act;

736 4. Being convicted or found guilty of, regardless of
737 adjudication to, a felony or any other crime involving moral



769960

738 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
739 the courts of this state, of any other state, or of the United
740 States;

741 5. Being convicted of, or disciplined by a regulatory
742 agency of the Federal Government or a regulatory agency of
743 another state for, any offense that would constitute a violation
744 of this chapter;

745 6. Being convicted of, or entering a plea of guilty or nolo
746 contendere to, regardless of adjudication, a crime in any
747 jurisdiction of the courts of this state, of any other state, or
748 of the United States which relates to the practice of, or the
749 ability to practice, a licensed health care profession;

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

754 8. Dispensing any medicinal drug based upon a communication
755 that purports to be a prescription as defined in s. 465.003 ~~s.~~
756 ~~465.003(14)~~ or s. 893.02 if the dispensing practitioner knows or
757 has reason to believe that the purported prescription is not
758 based upon a valid practitioner-patient relationship; or

759 9. Failing to timely notify the board of the date of his or
760 her termination from a pain-management clinic as required by s.
761 459.0137(2).

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

764 465.014 Pharmacy technician.—

765 (1) A person other than a licensed pharmacist or pharmacy
766 intern may not engage in the practice of the profession of



769960

767 pharmacy, except that a licensed pharmacist may delegate to
768 pharmacy technicians who are registered pursuant to this section
769 those duties, tasks, and functions that do not fall within the
770 purview of s. 465.003 ~~s. 465.003(13)~~. All such delegated acts
771 shall be performed under the direct supervision of a licensed
772 pharmacist who shall be responsible for all such acts performed
773 by persons under his or her supervision. A pharmacy registered
774 technician, under the supervision of a pharmacist, may initiate
775 or receive communications with a practitioner or his or her
776 agent, on behalf of a patient, regarding refill authorization
777 requests. A licensed pharmacist may not supervise more than one
778 registered pharmacy technician unless otherwise permitted by the
779 guidelines adopted by the board. The board shall establish
780 guidelines to be followed by licensees or permittees in
781 determining the circumstances under which a licensed pharmacist
782 may supervise more than one but not more than three pharmacy
783 technicians.

784 Section 18. Paragraph (c) of subsection (2) of section
785 465.015, Florida Statutes, is amended to read:

786 465.015 Violations and penalties.—

787 (2) It is unlawful for any person:

788 (c) To sell or dispense drugs as defined in s. 465.003 ~~s.~~
789 ~~465.003(8)~~ without first being furnished with a prescription.

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

792 465.0156 Registration of nonresident pharmacies.—

793 (8) Notwithstanding s. 465.003 ~~s. 465.003(10)~~, for purposes
794 of this section, the registered pharmacy and the pharmacist
795 designated by the registered pharmacy as the prescription



769960

796 department manager or the equivalent must be licensed in the
797 state of location in order to dispense into this state.

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

800 465.0197 Internet pharmacy permits.—

801 (4) Notwithstanding s. 465.003 ~~s. 465.003(10)~~, for purposes
802 of this section, the Internet pharmacy and the pharmacist
803 designated by the Internet pharmacy as the prescription
804 department manager or the equivalent must be licensed in the
805 state of location in order to dispense into this state.

806 Section 21. Section 465.1901, Florida Statutes, is amended
807 to read:

808 465.1901 Practice of orthotics and pedorthics.—The
809 provisions of chapter 468 relating to orthotics or pedorthics do
810 not apply to any licensed pharmacist or to any person acting
811 under the supervision of a licensed pharmacist. The practice of
812 orthotics or pedorthics by a pharmacist or any of the
813 pharmacist's employees acting under the supervision of a
814 pharmacist shall be construed to be within the meaning of the
815 term "practice of the profession of pharmacy" as set forth in s.
816 465.003 ~~s. 465.003(13)~~, and shall be subject to regulation in
817 the same manner as any other pharmacy practice. The Board of
818 Pharmacy shall develop rules regarding the practice of orthotics
819 and pedorthics by a pharmacist. Any pharmacist or person under
820 the supervision of a pharmacist engaged in the practice of
821 orthotics or pedorthics is not precluded from continuing that
822 practice pending adoption of these rules.

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



769960

825 499.003 Definitions of terms used in this part.—As used in
826 this part, the term:

827 (43) "Prescription drug" means a prescription, medicinal,
828 or legend drug, including, but not limited to, finished dosage
829 forms or active pharmaceutical ingredients subject to, defined
830 by, or described by s. 503(b) of the Federal Food, Drug, and
831 Cosmetic Act or s. 465.003 ~~s. 465.003(8)~~, s. 499.007(13), or
832 subsection (11), subsection (46), or subsection (53), except
833 that an active pharmaceutical ingredient is a prescription drug
834 only if substantially all finished dosage forms in which it may
835 be lawfully dispensed or administered in this state are also
836 prescription drugs.

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

839 893.02 Definitions.—The following words and phrases as used
840 in this chapter shall have the following meanings, unless the
841 context otherwise requires:

842 (22) "Prescription" means and includes an order for drugs
843 or medicinal supplies written, signed, or transmitted by word of
844 mouth, telephone, telegram, or other means of communication by a
845 duly licensed practitioner licensed by the laws of the state to
846 prescribe such drugs or medicinal supplies, issued in good faith
847 and in the course of professional practice, intended to be
848 filled, compounded, or dispensed by another person licensed by
849 the laws of the state to do so, and meeting the requirements of
850 s. 893.04. The term also includes an order for drugs or
851 medicinal supplies so transmitted or written by a physician,
852 dentist, veterinarian, or other practitioner licensed to
853 practice in a state other than Florida, but only if the



854 pharmacist called upon to fill such an order determines, in the
855 exercise of his or her professional judgment, that the order was
856 issued pursuant to a valid patient-physician relationship, that
857 it is authentic, and that the drugs or medicinal supplies so
858 ordered are considered necessary for the continuation of
859 treatment of a chronic or recurrent illness. However, if the
860 physician writing the prescription is not known to the
861 pharmacist, the pharmacist shall obtain proof to a reasonable
862 certainty of the validity of said prescription. A prescription
863 order for a controlled substance shall not be issued on the same
864 prescription blank with another prescription order for a
865 controlled substance which is named or described in a different
866 schedule, nor shall any prescription order for a controlled
867 substance be issued on the same prescription blank as a
868 prescription order for a medicinal drug, as defined in s.
869 465.003 ~~s. 465.003(8)~~, which does not fall within the definition
870 of a controlled substance as defined in this act.

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

872
873 ===== T I T L E A M E N D M E N T =====

874 And the title is amended as follows:

875 Delete everything before the enacting clause
876 and insert:

877 A bill to be entitled
878 An act relating to the provision of health care with
879 controlled substances; creating ss. 400.996 and
880 408.833, F.S.; providing that regulation of the
881 licensure, activity, and operation of clinics and
882 health care facilities is preempted to the state;



769960

883 prohibiting a local government or political
884 subdivision of the state from enacting or enforcing an
885 ordinance that imposes a levy, charge, or fee upon, or
886 that otherwise regulates, clinics and health care
887 facilities, except for ordinances regarding local
888 business taxes and land development; amending s.
889 456.44, F.S.; limiting the application of requirements
890 for prescribing controlled substances; requiring a
891 physician to consult the prescription drug monitoring
892 program database before prescribing certain controlled
893 substances; authorizing the board to adopt a penalty
894 for failure to consult the database; exempting nursing
895 home residents and certain physicians from
896 requirements regarding prescriptions of controlled
897 substances; amending s. 458.326, F.S.; requiring a
898 physician to consult the prescription drug monitoring
899 program database or designate an agent to consult the
900 database before prescribing certain controlled
901 substances; authorizing the board to adopt a penalty
902 for failure to consult the database; amending ss.
903 458.3265 and 459.0137, F.S.; requiring that owners of
904 pain-management clinics be licensed physicians;
905 removing language regarding nonphysician-owned pain-
906 management clinics; providing that regulation of the
907 licensure and activity of certain physicians and
908 osteopathic physicians is preempted to the state;
909 prohibiting a local government or political
910 subdivision of the state from enacting or enforcing an
911 ordinance that imposes a levy, charge, or fee upon, or



769960

912 that otherwise regulates, physicians and osteopathic
913 physicians, except for ordinances regarding local
914 business taxes and land development; amending s.
915 465.003, F.S.; defining a term; conforming a cross-
916 reference; creating s. 465.0065, F.S.; providing
917 notice requirements for inspection of a pharmacy;
918 amending s. 465.016, F.S.; providing additional
919 grounds for disciplinary action; conforming a cross-
920 reference; amending s. 465.022, F.S.; conforming a
921 cross-reference; requiring a pharmacy permittee to
922 commence operations within 180 days after permit
923 issuance or show good cause why operations were not
924 commenced; requiring the board to establish rules;
925 requiring a pharmacy permittee to be supervised by a
926 prescription department manager or consultant
927 pharmacist of record; amending s. 465.023, F.S.;
928 providing additional grounds for disciplinary action;
929 conforming a cross-reference; creating s. 465.1902,
930 F.S.; providing that regulation of the licensure,
931 activity, and operation of pharmacies and pharmacists
932 is preempted to the state; prohibiting a local
933 government or political subdivision of the state from
934 enacting or enforcing an ordinance that imposes a
935 levy, charge, or fee upon, or that otherwise
936 regulates, pharmacies and pharmacists, except for
937 ordinances regarding local business taxes and land
938 development; amending s. 893.055, F.S.; deleting an
939 obsolete provision; authorizing the prescription drug
940 monitoring program to be funded by state funds and



769960

941 pharmaceutical company donations; amending ss.
942 409.9201, 458.331, 459.015, 465.014, 465.015,
943 465.0156, 465.0197, 465.1901, 499.003, and 893.02,
944 F.S.; conforming cross-references; providing an
945 effective date.