

By the Committees on Community Affairs; and 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; amending s. 456.44, F.S.;
4 limiting the application of requirements for
5 prescribing controlled substances; requiring a
6 physician to consult the prescription drug monitoring
7 program database before prescribing certain controlled
8 substances; authorizing the appropriate board to adopt
9 a penalty for failure to consult the database;
10 exempting nursing home residents and certain
11 physicians from requirements regarding prescriptions
12 of controlled substances; amending s. 465.003, F.S.;
13 defining a term; conforming a cross-reference;
14 creating s. 465.0065, F.S.; providing notice
15 requirements for inspection of a pharmacy; amending s.
16 465.016, F.S.; providing additional grounds for
17 disciplinary action; conforming a cross-reference;
18 amending s. 465.022, F.S.; conforming a cross-
19 reference; requiring a pharmacy permittee to commence
20 operations within 180 days after permit issuance or
21 show good cause why operations were not commenced;
22 requiring the Board of Pharmacy to establish rules;
23 requiring a pharmacy permittee to be supervised by a
24 prescription department manager or consultant
25 pharmacist of record; amending s. 465.023, F.S.;
26 providing additional grounds for disciplinary action;
27 conforming a cross-reference; creating s. 465.1902,
28 F.S.; providing that regulation of the licensure,
29 activity, and operation of pharmacies and pharmacists

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30 is preempted to the state; prohibiting a local
31 government or political subdivision of the state from
32 enacting or enforcing an ordinance that imposes a
33 levy, charge, or fee upon, or that otherwise
34 regulates, pharmacies and pharmacists, except for
35 ordinances regarding local business taxes and land
36 development; amending s. 893.055, F.S.; deleting an
37 obsolete provision; deleting a provision that
38 prohibits funds from prescription drug manufacturers
39 to be used to implement the prescription drug
40 monitoring program; authorizing the prescription drug
41 monitoring program to be funded by state funds;
42 revising the sources of money which are inappropriate
43 for the direct-support organization of the
44 prescription drug monitoring program to receive;
45 creating s. 893.0552, F.S.; providing that regulation
46 of the licensure, activity, and operation of pain-
47 management clinics is preempted to the state under
48 certain circumstances; authorizing a local government
49 or political subdivision of the state to enact certain
50 ordinances regarding local business taxes and land
51 development; amending ss. 409.9201, 458.331, 459.015,
52 465.014, 465.015, 465.0156, 465.0197, 465.1901,
53 499.003, and 893.02, F.S.; conforming cross-
54 references; providing an effective date.

55
56 Be It Enacted by the Legislature of the State of Florida:

57
58 Section 1. Subsections (2) and (3) of section 456.44,

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59 Florida Statutes, are amended to read:

60 456.44 Controlled substance prescribing.—

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

67 (a) Designate himself or herself as a controlled substance
68 prescribing practitioner on the physician's practitioner
69 profile.

70 (b) Comply with the requirements of this section and
71 applicable board rules.

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

76 (a) A complete medical history and a physical examination
77 must be conducted before beginning any treatment and must be
78 documented in the medical record. The exact components of the
79 physical examination shall be left to the judgment of the
80 clinician who is expected to perform a physical examination
81 proportionate to the diagnosis that justifies a treatment. The
82 medical record must, at a minimum, document the nature and
83 intensity of the pain, current and past treatments for pain,
84 underlying or coexisting diseases or conditions, the effect of
85 the pain on physical and psychological function, a review of
86 previous medical records, previous diagnostic studies, and
87 history of alcohol and substance abuse. The medical record shall

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88 also document the presence of one or more recognized medical
89 indications for the use of a controlled substance. Each
90 registrant must develop a written plan for assessing each
91 patient's risk of aberrant drug-related behavior, which may
92 include patient drug testing. Registrants must assess each
93 patient's risk for aberrant drug-related behavior and monitor
94 that risk on an ongoing basis in accordance with the plan.

95 (b) Before or during a new patient's visit for pain-
96 treatment services at a pain-management clinic registered under
97 s. 458.3265 or s. 459.0137, a physician shall consult the
98 prescription drug monitoring program database provided under s.
99 893.055(2) (a) before prescribing a controlled substance listed
100 in Schedule II or Schedule III in s. 893.03. The physician may
101 designate an agent under his or her supervision to consult the
102 database. The board shall adopt rules to establish a penalty for
103 a physician who does not comply with this subsection.

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

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

126 1. Number and frequency of controlled substance
127 prescriptions and refills.

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

130 3. An agreement that controlled substances for the
131 treatment of chronic nonmalignant pain shall be prescribed by a
132 single treating physician unless otherwise authorized by the
133 treating physician and documented in the medical record.

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

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146 indications of substance abuse or diversion at a minimum of 3-
147 month intervals.

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

158 (g)~~(f)~~ A physician registered under this section must
159 maintain accurate, current, and complete records that are
160 accessible and readily available for review and comply with the
161 requirements of this section, the applicable practice act, and
162 applicable board rules. The medical records must include, but
163 are not limited to:

- 164 1. The complete medical history and a physical examination,
165 including history of drug abuse or dependence.
- 166 2. Diagnostic, therapeutic, and laboratory results.
- 167 3. Evaluations and consultations.
- 168 4. Treatment objectives.
- 169 5. Discussion of risks and benefits.
- 170 6. Treatments.
- 171 7. Medications, including date, type, dosage, and quantity
172 prescribed.
- 173 8. Instructions and agreements.
- 174 9. Periodic reviews.

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175 10. Results of any drug testing.

176 11. A photocopy of the patient's government-issued photo
177 identification.

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

180 13. The physician's full name presented in a legible
181 manner.

182 (h) ~~(g)~~ Patients with signs or symptoms of substance abuse
183 shall be immediately referred to a board-certified pain
184 management physician, an addiction medicine specialist, or a
185 mental health addiction facility as it pertains to drug abuse or
186 addiction unless the physician is board-certified or board-
187 eligible in pain management. Throughout the period of time
188 before receiving the consultant's report, a prescribing
189 physician shall clearly and completely document medical
190 justification for continued treatment with controlled substances
191 and those steps taken to ensure medically appropriate use of
192 controlled substances by the patient. Upon receipt of the
193 consultant's written report, the prescribing physician shall
194 incorporate the consultant's recommendations for continuing,
195 modifying, or discontinuing controlled substance therapy. The
196 resulting changes in treatment shall be specifically documented
197 in the patient's medical record. Evidence or behavioral
198 indications of diversion shall be followed by discontinuation of
199 controlled substance therapy, and the patient shall be
200 discharged, and all results of testing and actions taken by the
201 physician shall be documented in the patient's medical record.

202

203 This subsection does not apply to a board-eligible or board-

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204 certified anesthesiologist, physiatrist, rheumatologist, or
205 neurologist, or to a board-certified physician who has surgical
206 privileges at a hospital or ambulatory surgery center and
207 primarily provides surgical services. This subsection does not
208 apply to a board-eligible or board-certified medical specialist
209 who has also completed a fellowship in pain medicine approved by
210 the Accreditation Council for Graduate Medical Education or the
211 American Osteopathic Association, or who is board eligible or
212 board certified in pain medicine by the American Board of Pain
213 Medicine or a board approved by the American Board of Medical
214 Specialties or the American Osteopathic Association and performs
215 interventional pain procedures of the type routinely billed
216 using surgical codes. This subsection does not apply to a
217 physician who prescribes medically necessary controlled
218 substances for a patient during an inpatient stay in a hospital
219 licensed under chapter 395 or to a resident in a facility
220 licensed under part II of chapter 400. This subsection does not
221 apply to any physician licensed under chapter 458 or chapter 459
222 who writes fewer than 50 prescriptions for a controlled
223 substance for all of his or her patients during a 1-year period.

224 Section 2. Present subsections (1) through (17) of section
225 465.003, Florida Statutes, are renumbered as subsections (2)
226 through (18), respectively, paragraph (a) of present subsection
227 (11) of that section is amended, and a new subsection (1) is
228 added to that section, to read:

229 465.003 Definitions.—As used in this chapter, the term:

230 (1) "Abandoned" means the status of a pharmacy permit of a
231 person or entity that was issued the permit but fails to
232 commence pharmacy operations within 180 days after issuance of

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233 the permit without good cause or fails to follow pharmacy
234 closure requirements as set by the board.

235 (12)~~(11)~~(a) "Pharmacy" includes a community pharmacy, an
236 institutional pharmacy, a nuclear pharmacy, a special pharmacy,
237 and an Internet pharmacy.

238 1. The term "community pharmacy" includes every location
239 where medicinal drugs are compounded, dispensed, stored, or sold
240 or where prescriptions are filled or dispensed on an outpatient
241 basis.

242 2. The term "institutional pharmacy" includes every
243 location in a hospital, clinic, nursing home, dispensary,
244 sanitarium, extended care facility, or other facility,
245 hereinafter referred to as "health care institutions," where
246 medicinal drugs are compounded, dispensed, stored, or sold.

247 3. The term "nuclear pharmacy" includes every location
248 where radioactive drugs and chemicals within the classification
249 of medicinal drugs are compounded, dispensed, stored, or sold.
250 The term "nuclear pharmacy" does not include hospitals licensed
251 under chapter 395 or the nuclear medicine facilities of such
252 hospitals.

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

256 5. The term "Internet pharmacy" includes locations not
257 otherwise licensed or issued a permit under this chapter, within
258 or outside this state, which use the Internet to communicate
259 with or obtain information from consumers in this state and use
260 such communication or information to fill or refill
261 prescriptions or to dispense, distribute, or otherwise engage in

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262 the practice of pharmacy in this state. Any act described in
263 this definition constitutes the practice of pharmacy as defined
264 in subsection (14) ~~(13)~~.

265 Section 3. Section 465.0065, Florida Statutes, is created
266 to read:

267 465.0065 Notices; form and service.—Each notice served by
268 the department pursuant to this chapter must be in writing and
269 must be delivered personally by an agent of the department or by
270 certified mail to the pharmacy permittee or licensee. If the
271 pharmacy permittee or licensee refuses to accept service or
272 evades service or if the agent is otherwise unable to carry out
273 service after due diligence, the department may post the notice
274 in a conspicuous place at the pharmacy or at the home or
275 business address for the licensee.

276 Section 4. Paragraphs (e) and (s) of subsection (1) of
277 section 465.016, Florida Statutes, are amended, and paragraph
278 (u) is added to that subsection, to read:

279 465.016 Disciplinary actions.—

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

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

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

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291 (u) Misappropriating drugs, supplies, or equipment from a
292 pharmacy permittee.

293 Section 5. Paragraph (j) of subsection (5) of section
294 465.022, Florida Statutes, is amended, present subsections (10)
295 through (14) are renumbered as subsections (11) through (15),
296 respectively, present subsection (10) of that section is
297 amended, and a new subsection (10) is added to that section, to
298 read:

299 465.022 Pharmacies; general requirements; fees.—

300 (5) The department or board shall deny an application for a
301 pharmacy permit if the applicant or an affiliated person,
302 partner, officer, director, or prescription department manager
303 or consultant pharmacist of record of the applicant:

304 (j) Has dispensed any medicinal drug based upon a
305 communication that purports to be a prescription as defined by
306 s. 465.003 ~~s. 465.003(14)~~ or s. 893.02 when the pharmacist knows
307 or has reason to believe that the purported prescription is not
308 based upon a valid practitioner-patient relationship that
309 includes a documented patient evaluation, including history and
310 a physical examination adequate to establish the diagnosis for
311 which any drug is prescribed and any other requirement
312 established by board rule under chapter 458, chapter 459,
313 chapter 461, chapter 463, chapter 464, or chapter 466.

314
315 For felonies in which the defendant entered a plea of guilty or
316 nolo contendere in an agreement with the court to enter a
317 pretrial intervention or drug diversion program, the department
318 shall deny the application if upon final resolution of the case
319 the licensee has failed to successfully complete the program.

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320 (10) The permittee shall commence pharmacy operations
321 within 180 days after issuance of the permit, or show good cause
322 to the department why pharmacy operations were not commenced.
323 Commencement of pharmacy operations includes, but is not limited
324 to, acts within the scope of the practice of pharmacy, ordering
325 or receiving drugs, and other similar activities. The board
326 shall establish rules regarding commencement of pharmacy
327 operations.

328 (11)~~(10)~~ A pharmacy permittee shall be supervised by a
329 prescription department manager or consultant pharmacist of
330 record at all times. A permittee must notify the department, on
331 a form approved by the board, within 10 days after any change in
332 prescription department manager or consultant pharmacist of
333 record.

334 Section 6. Subsection (1) of section 465.023, Florida
335 Statutes, is amended to read:

336 465.023 Pharmacy permittee; disciplinary action.—

337 (1) The department or the board may revoke or suspend the
338 permit of any pharmacy permittee, and may fine, place on
339 probation, or otherwise discipline any pharmacy permittee if the
340 permittee, or any affiliated person, partner, officer, director,
341 or agent of the permittee, including a person fingerprinted
342 under s. 465.022(3), has:

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

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

348 (c) Violated any of the requirements of this chapter or any

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349 of the rules of the Board of Pharmacy; of chapter 499, known as
350 the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss. 301-392,
351 known as the "Federal Food, Drug, and Cosmetic Act"; of 21
352 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse
353 Prevention and Control Act; or of chapter 893 or rules adopted
354 thereunder;

355 (d) Been convicted or found guilty, regardless of
356 adjudication, of a felony or any other crime involving moral
357 turpitude in any of the courts of this state, of any other
358 state, or of the United States;

359 (e) Been convicted or disciplined by a regulatory agency of
360 the Federal Government or a regulatory agency of another state
361 for any offense that would constitute a violation of this
362 chapter;

363 (f) Been convicted of, or entered a plea of guilty or nolo
364 contendere to, regardless of adjudication, a crime in any
365 jurisdiction which relates to the practice of, or the ability to
366 practice, the profession of pharmacy;

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

370 (h) Dispensed any medicinal drug based upon a communication
371 that purports to be a prescription as defined by s. 465.003 ~~s.~~
372 ~~465.003(14)~~ or s. 893.02 when the pharmacist knows or has reason
373 to believe that the purported prescription is not based upon a
374 valid practitioner-patient relationship that includes a
375 documented patient evaluation, including history and a physical
376 examination adequate to establish the diagnosis for which any
377 drug is prescribed and any other requirement established by

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378 board rule under chapter 458, chapter 459, chapter 461, chapter
379 463, chapter 464, or chapter 466.

380 Section 7. Section 465.1902, Florida Statutes, is created
381 to read:

382 465.1902 Preemption.—This chapter preempts to the state all
383 regulation of the licensure, activity, and operation of
384 pharmacies and pharmacists as defined in this chapter. A local
385 government or political subdivision of the state may not enact
386 or enforce an ordinance that imposes a levy, charge, or fee
387 upon, or that otherwise regulates, pharmacies and pharmacists as
388 defined in this chapter, except that this preemption does not
389 prohibit a local government or political subdivision from
390 enacting an ordinance regarding the following:

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

392 (2) Land use development regulations adopted pursuant to
393 chapter 163, which include regulation of any aspect of
394 development, including a subdivision, building construction,
395 sign regulation, and any other regulation concerning the
396 development of land, landscaping, or tree protection, and which
397 do not include restrictions on pain-management services, health
398 care services, or the prescribing of controlled substances.

399 Section 8. Paragraph (b) of subsection (2), subsection
400 (10), and paragraph (c) of subsection (11) of section 893.055,
401 Florida Statutes, are amended to read:

402 893.055 Prescription drug monitoring program.—

403 (2)

404 (b) The department, ~~when the direct support organization~~
405 ~~receives at least \$20,000 in nonstate moneys or the state~~
406 ~~receives at least \$20,000 in federal grants for the prescription~~

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407 ~~drug monitoring program,~~ shall adopt rules as necessary
408 concerning the reporting, accessing the database, evaluation,
409 management, development, implementation, operation, security,
410 and storage of information within the system, including rules
411 for when patient advisory reports are provided to pharmacies and
412 prescribers. The patient advisory report shall be provided in
413 accordance with s. 893.13(7)(a)8. The department shall work with
414 the professional health care licensure boards, such as the Board
415 of Medicine, the Board of Osteopathic Medicine, and the Board of
416 Pharmacy; other appropriate organizations, such as the Florida
417 Pharmacy Association, the Florida Medical Association, the
418 Florida Retail Federation, and the Florida Osteopathic Medical
419 Association, including those relating to pain management; and
420 the Attorney General, the Department of Law Enforcement, and the
421 Agency for Health Care Administration to develop rules
422 appropriate for the prescription drug monitoring program.

423 (10) All costs incurred by the department in administering
424 the prescription drug monitoring program shall be funded through
425 state funds, federal grants, or private funding applied for or
426 received by the state. The department may not commit funds for
427 the monitoring program without ensuring funding is available.
428 ~~The prescription drug monitoring program and the implementation~~
429 ~~thereof are contingent upon receipt of the nonstate funding.~~ The
430 department and state government shall cooperate with the direct-
431 support organization established pursuant to subsection (11) in
432 seeking state funds, federal grant funds, other nonstate grant
433 funds, gifts, donations, or other private moneys for the
434 department if so long as the costs of doing so are not
435 considered material. Nonmaterial costs for this purpose include,

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436 but are not limited to, the costs of mailing and personnel
437 assigned to research or apply for a grant. Notwithstanding the
438 exemptions to competitive-solicitation requirements under s.
439 287.057(3)(f), the department shall comply with the competitive-
440 solicitation requirements under s. 287.057 for the procurement
441 of any goods or services required by this section. ~~Funds~~
442 ~~provided, directly or indirectly, by prescription drug~~
443 ~~manufacturers may not be used to implement the program.~~

444 (11) The department may establish a direct-support
445 organization that has a board consisting of at least five
446 members to provide assistance, funding, and promotional support
447 for the activities authorized for the prescription drug
448 monitoring program.

449 (c) The State Surgeon General shall appoint a board of
450 directors for the direct-support organization. Members of the
451 board shall serve at the pleasure of the State Surgeon General.
452 The State Surgeon General shall provide guidance to members of
453 the board to ensure that moneys received by the direct-support
454 organization are not received from inappropriate sources.
455 Inappropriate sources include, but are not limited to, donors,
456 grantors, persons, ~~or~~ organizations, or pharmaceutical
457 companies, that may monetarily or substantively benefit from the
458 purchase of goods or services by the department in furtherance
459 of the prescription drug monitoring program.

460 Section 9. Section 893.0552, Florida Statutes, is created
461 to read:

462 893.0552 Preemption of regulation.—

463 (1) This section preempts to the state all regulation of
464 the licensure, activity, and operation of pain-management

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465 clinics as defined in ss. 458.3265 and 459.0137 in the following
466 circumstances:

467 (a) The clinic is wholly owned and operated by a physician
468 who performs interventional pain procedures of the type
469 routinely billed using surgical codes, who has never been
470 suspended or revoked for prescribing a controlled substance in
471 Schedule II or Schedule III of s. 893.03 and drugs containing
472 Alprazolam in excessive or inappropriate quantities that are not
473 in the best interest of a patient, and who:

474 1. Has completed a fellowship in pain medicine which is
475 approved by the Accreditation Council for Graduate Medical
476 Education or the American Osteopathic Association;

477 2. Is board-certified in pain medicine by the American
478 Board of Pain Medicine, board-certified by the American Board of
479 Interventional Pain Physicians; or

480 3. Has a board certification or subcertification in pain
481 management or pain medicine by a specialty board approved by the
482 American Board of Medical Specialties or the American
483 Osteopathic Association.

484 (b) The clinic is wholly owned and operated by a physician-
485 multispecialty practice if one or more board-eligible or board-
486 certified medical specialists has one of the qualifications
487 specified in subparagraph (a)1., subparagraph (a)2., or
488 subparagraph (a)3., performs interventional pain procedures of
489 the type routinely billed using surgical codes, and has never
490 been suspended or revoked for prescribing a controlled substance
491 in Schedule II or Schedule III of s. 893.03 and drugs containing
492 Alprazolam in excessive or inappropriate quantities that are not
493 in the best interest of a patient.

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494 (2) Notwithstanding subsection (1), the preemption does not
495 prohibit a local government or political subdivision from
496 enacting an ordinance regarding local business taxes adopted
497 pursuant to chapter 205 and land use development regulations
498 adopted pursuant to chapter 163. A pain-management clinic in
499 which the regulation of its licensure, activity, and operation
500 is preempted to the state pursuant to subsection (1) is a
501 permissible use in a land use or zoning category that permits
502 hospitals and other health care facilities or clinics as defined
503 in chapter 395 or s. 408.07. Upon the request of a local
504 government, a pain-management clinic must annually demonstrate
505 that it qualifies for preemption pursuant to subsection (1).

506 Section 10. Subsection (1) of section 409.9201, Florida
507 Statutes, is amended to read:

508 409.9201 Medicaid fraud.—

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

510 (a) "Prescription drug" means any drug, including, but not
511 limited to, finished dosage forms or active ingredients that are
512 subject to, defined by, or described by s. 503(b) of the Federal
513 Food, Drug, and Cosmetic Act or by s. 465.003 ~~s. 465.003(8)~~, s.
514 499.003(46) or (53) or s. 499.007(13).

515 (b) "Value" means the amount billed to the Medicaid program
516 for the property dispensed or the market value of a legend drug
517 or goods or services at the time and place of the offense. If
518 the market value cannot be determined, the term means the
519 replacement cost of the legend drug or goods or services within
520 a reasonable time after the offense.

521
522 The value of individual items of the legend drugs or goods or

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523 services involved in distinct transactions committed during a
524 single scheme or course of conduct, whether involving a single
525 person or several persons, may be aggregated when determining
526 the punishment for the offense.

527 Section 11. Paragraph (pp) of subsection (1) of section
528 458.331, Florida Statutes, is amended to read:

529 458.331 Grounds for disciplinary action; action by the
530 board and department.—

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

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

536 1. Registering a pain-management clinic through
537 misrepresentation or fraud;

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

541 3. Failing to comply with any requirement of chapter 499,
542 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
543 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
544 the Drug Abuse Prevention and Control Act; or chapter 893, the
545 Florida Comprehensive Drug Abuse Prevention and Control Act;

546 4. Being convicted or found guilty of, regardless of
547 adjudication to, a felony or any other crime involving moral
548 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
549 the courts of this state, of any other state, or of the United
550 States;

551 5. Being convicted of, or disciplined by a regulatory

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552 agency of the Federal Government or a regulatory agency of
553 another state for, any offense that would constitute a violation
554 of this chapter;

555 6. Being convicted of, or entering a plea of guilty or nolo
556 contendere to, regardless of adjudication, a crime in any
557 jurisdiction of the courts of this state, of any other state, or
558 of the United States which relates to the practice of, or the
559 ability to practice, a licensed health care profession;

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

564 8. Dispensing any medicinal drug based upon a communication
565 that purports to be a prescription as defined in s. 465.003 ~~s.~~
566 ~~465.003(14)~~ or s. 893.02 if the dispensing practitioner knows or
567 has reason to believe that the purported prescription is not
568 based upon a valid practitioner-patient relationship; or

569 9. Failing to timely notify the board of the date of his or
570 her termination from a pain-management clinic as required by s.
571 458.3265(2).

572 Section 12. Paragraph (rr) of subsection (1) of section
573 459.015, Florida Statutes, is amended to read:

574 459.015 Grounds for disciplinary action; action by the
575 board and department.—

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

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

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- 581 1. Registering a pain-management clinic through
582 misrepresentation or fraud;
- 583 2. Procuring, or attempting to procure, the registration of
584 a pain-management clinic for any other person by making or
585 causing to be made, any false representation;
- 586 3. Failing to comply with any requirement of chapter 499,
587 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
588 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
589 the Drug Abuse Prevention and Control Act; or chapter 893, the
590 Florida Comprehensive Drug Abuse Prevention and Control Act;
- 591 4. Being convicted or found guilty of, regardless of
592 adjudication to, a felony or any other crime involving moral
593 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
594 the courts of this state, of any other state, or of the United
595 States;
- 596 5. Being convicted of, or disciplined by a regulatory
597 agency of the Federal Government or a regulatory agency of
598 another state for, any offense that would constitute a violation
599 of this chapter;
- 600 6. Being convicted of, or entering a plea of guilty or nolo
601 contendere to, regardless of adjudication, a crime in any
602 jurisdiction of the courts of this state, of any other state, or
603 of the United States which relates to the practice of, or the
604 ability to practice, a licensed health care profession;
- 605 7. Being convicted of, or entering a plea of guilty or nolo
606 contendere to, regardless of adjudication, a crime in any
607 jurisdiction of the courts of this state, of any other state, or
608 of the United States which relates to health care fraud;
- 609 8. Dispensing any medicinal drug based upon a communication

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610 that purports to be a prescription as defined in s. 465.003 ~~s.~~
611 ~~465.003(14)~~ or s. 893.02 if the dispensing practitioner knows or
612 has reason to believe that the purported prescription is not
613 based upon a valid practitioner-patient relationship; or

614 9. Failing to timely notify the board of the date of his or
615 her termination from a pain-management clinic as required by s.
616 459.0137(2).

617 Section 13. Subsection (1) of section 465.014, Florida
618 Statutes, is amended to read:

619 465.014 Pharmacy technician.—

620 (1) A person other than a licensed pharmacist or pharmacy
621 intern may not engage in the practice of the profession of
622 pharmacy, except that a licensed pharmacist may delegate to
623 pharmacy technicians who are registered pursuant to this section
624 those duties, tasks, and functions that do not fall within the
625 purview of s. 465.003 ~~s. 465.003(13)~~. All such delegated acts
626 shall be performed under the direct supervision of a licensed
627 pharmacist who shall be responsible for all such acts performed
628 by persons under his or her supervision. A pharmacy registered
629 technician, under the supervision of a pharmacist, may initiate
630 or receive communications with a practitioner or his or her
631 agent, on behalf of a patient, regarding refill authorization
632 requests. A licensed pharmacist may not supervise more than one
633 registered pharmacy technician unless otherwise permitted by the
634 guidelines adopted by the board. The board shall establish
635 guidelines to be followed by licensees or permittees in
636 determining the circumstances under which a licensed pharmacist
637 may supervise more than one but not more than three pharmacy
638 technicians.

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639 Section 14. Paragraph (c) of subsection (2) of section
640 465.015, Florida Statutes, is amended to read:

641 465.015 Violations and penalties.—

642 (2) It is unlawful for any person:

643 (c) To sell or dispense drugs as defined in s. 465.003 ~~s.~~
644 ~~465.003(8)~~ without first being furnished with a prescription.

645 Section 15. Subsection (8) of section 465.0156, Florida
646 Statutes, is amended to read:

647 465.0156 Registration of nonresident pharmacies.—

648 (8) Notwithstanding s. 465.003 ~~s. 465.003(10)~~, for purposes
649 of this section, the registered pharmacy and the pharmacist
650 designated by the registered pharmacy as the prescription
651 department manager or the equivalent must be licensed in the
652 state of location in order to dispense into this state.

653 Section 16. Subsection (4) of section 465.0197, Florida
654 Statutes, is amended to read:

655 465.0197 Internet pharmacy permits.—

656 (4) Notwithstanding s. 465.003 ~~s. 465.003(10)~~, for purposes
657 of this section, the Internet pharmacy and the pharmacist
658 designated by the Internet pharmacy as the prescription
659 department manager or the equivalent must be licensed in the
660 state of location in order to dispense into this state.

661 Section 17. Section 465.1901, Florida Statutes, is amended
662 to read:

663 465.1901 Practice of orthotics and pedorthics.—The
664 provisions of chapter 468 relating to orthotics or pedorthics do
665 not apply to any licensed pharmacist or to any person acting
666 under the supervision of a licensed pharmacist. The practice of
667 orthotics or pedorthics by a pharmacist or any of the

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668 pharmacist's employees acting under the supervision of a
669 pharmacist shall be construed to be within the meaning of the
670 term "practice of the profession of pharmacy" as set forth in s.
671 465.003 ~~s. 465.003(13)~~, and shall be subject to regulation in
672 the same manner as any other pharmacy practice. The Board of
673 Pharmacy shall develop rules regarding the practice of orthotics
674 and pedorthics by a pharmacist. Any pharmacist or person under
675 the supervision of a pharmacist engaged in the practice of
676 orthotics or pedorthics is not precluded from continuing that
677 practice pending adoption of these rules.

678 Section 18. Subsection (43) of section 499.003, Florida
679 Statutes, is amended to read:

680 499.003 Definitions of terms used in this part.—As used in
681 this part, the term:

682 (43) "Prescription drug" means a prescription, medicinal,
683 or legend drug, including, but not limited to, finished dosage
684 forms or active pharmaceutical ingredients subject to, defined
685 by, or described by s. 503(b) of the Federal Food, Drug, and
686 Cosmetic Act or s. 465.003 ~~s. 465.003(8)~~, s. 499.007(13), or
687 subsection (11), subsection (46), or subsection (53), except
688 that an active pharmaceutical ingredient is a prescription drug
689 only if substantially all finished dosage forms in which it may
690 be lawfully dispensed or administered in this state are also
691 prescription drugs.

692 Section 19. Subsection (22) of section 893.02, Florida
693 Statutes, is amended to read:

694 893.02 Definitions.—The following words and phrases as used
695 in this chapter shall have the following meanings, unless the
696 context otherwise requires:

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697 (22) "Prescription" means and includes an order for drugs
698 or medicinal supplies written, signed, or transmitted by word of
699 mouth, telephone, telegram, or other means of communication by a
700 duly licensed practitioner licensed by the laws of the state to
701 prescribe such drugs or medicinal supplies, issued in good faith
702 and in the course of professional practice, intended to be
703 filled, compounded, or dispensed by another person licensed by
704 the laws of the state to do so, and meeting the requirements of
705 s. 893.04. The term also includes an order for drugs or
706 medicinal supplies so transmitted or written by a physician,
707 dentist, veterinarian, or other practitioner licensed to
708 practice in a state other than Florida, but only if the
709 pharmacist called upon to fill such an order determines, in the
710 exercise of his or her professional judgment, that the order was
711 issued pursuant to a valid patient-physician relationship, that
712 it is authentic, and that the drugs or medicinal supplies so
713 ordered are considered necessary for the continuation of
714 treatment of a chronic or recurrent illness. However, if the
715 physician writing the prescription is not known to the
716 pharmacist, the pharmacist shall obtain proof to a reasonable
717 certainty of the validity of said prescription. A prescription
718 order for a controlled substance shall not be issued on the same
719 prescription blank with another prescription order for a
720 controlled substance which is named or described in a different
721 schedule, nor shall any prescription order for a controlled
722 substance be issued on the same prescription blank as a
723 prescription order for a medicinal drug, as defined in s.
724 465.003 ~~s. 465.003(8)~~, which does not fall within the definition
725 of a controlled substance as defined in this act.

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Section 20. This act shall take effect July 1, 2013.