

By Senator Grimsley

21-00222-13

20131192

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

21-00222-13

20131192

30 development; amending s. 465.003, F.S.; defining a
31 term; conforming a cross-reference; creating s.
32 465.0065, F.S.; providing notice requirements for
33 inspection of a pharmacy; amending s. 465.016, F.S.;
34 providing additional grounds for disciplinary action;
35 conforming a cross-reference; amending s. 465.022,
36 F.S.; conforming a cross-reference; requiring a
37 pharmacy permittee to commence operations within 180
38 days after permit issuance or show good cause why
39 operations were not commenced; requiring the board to
40 establish rules; requiring a pharmacy permittee to be
41 supervised by a prescription department manager or
42 consultant pharmacist of record; amending s. 465.023,
43 F.S.; providing additional grounds for disciplinary
44 action; conforming a cross-reference; amending s.
45 893.055, F.S.; deleting an obsolete provision;
46 authorizing the prescription drug monitoring program
47 to be funded by state funds and pharmaceutical company
48 donations; amending ss. 409.9201, 458.331, 459.015,
49 465.014, 465.015, 465.0156, 465.0197, 465.1901,
50 499.003, and 893.02, F.S.; conforming cross-
51 references; providing an effective date.

52
53 Be It Enacted by the Legislature of the State of Florida:

54
55 Section 1. 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

21-00222-13

20131192__

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
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

21-00222-13

20131192

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) Pursuant to s. 458.326, before or during a new
93 patient's visit for pain-treatment services, a physician shall
94 consult the prescription drug monitoring program database
95 provided under s. 893.055(2) (a) before prescribing a controlled
96 substance listed in Schedule II or Schedule III in s. 893.03.
97 The physician may designate an agent under his or her
98 supervision to consult the database. The board shall adopt rules
99 to establish a penalty for a physician who does not comply with
100 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)-~~(c)~~ 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

21-00222-13

20131192

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
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

21-00222-13

20131192

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
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.

21-00222-13

20131192

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
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

21-00222-13

20131192

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
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 2. 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

21-00222-13

20131192

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 3. 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.—

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

21-00222-13

20131192__

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 ~~e. 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;~~

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(c)(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

21-00222-13

20131192

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, activity, and operation of
303 pharmacies and pharmacists as defined in chapter 465, health
304 care facilities as defined in s. 408.07, and clinics under part
305 X of chapter 400, including registration and licensing for pain-
306 management clinics and practitioners. A local government or
307 political subdivision of the state may not enact or enforce an
308 ordinance that imposes a levy, charge, or fee upon, or that
309 otherwise regulates, pharmacies and pharmacists as defined in
310 chapter 465, health care facilities as defined in s. 408.07, and
311 clinics under part X of chapter 400, including services provided
312 within such facilities, except that this preemption does not
313 prohibit a local government or political subdivision from
314 enacting an ordinance regarding the following:

315 (a) Local business taxes adopted pursuant to chapter 205.

316 (b) Land use development regulations adopted pursuant to
317 chapter 163, which include regulation of any aspect of
318 development, including a subdivision, building construction,
319 sign regulation, and any other regulation concerning the

21-00222-13

20131192

320 development of land, landscaping, or tree protection, and which
 321 do not include restrictions on pain-management services, health
 322 care services, or the prescribing of controlled substances.
 323 However, a health care facility or clinic that treats pain or
 324 provides pain-management services is a permissible use in a land
 325 use or zoning category that permits hospitals, other health care
 326 facilities, or clinics as defined in chapter 395, s. 408.907, or
 327 under part X of chapter 400.

328 Section 4. Paragraphs (a) and (d) of subsection (1) of
 329 section 459.0137, Florida Statutes, are amended, present
 330 subsections (5) and (6) of that section are renumbered as
 331 subsections (6) and (7), respectively, and a new subsection (5)
 332 is added to that section, to read:

333 459.0137 Pain-management clinics.—

334 (1) REGISTRATION.—

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

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

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

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

348 (I) That advertises in any medium for any type of pain-

21-00222-13

20131192__

349 management services; or

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

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

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

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

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

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

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

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

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

373 f.h. The clinic is wholly owned and operated by a physician
374 multispecialty practice where one or more board-eligible or
375 board-certified medical specialists who have also completed
376 fellowships in pain medicine approved by the Accreditation
377 Council for Graduate Medical Education or the American

21-00222-13

20131192

378 Osteopathic Association, or who are also board-certified in pain
379 medicine by the American Board of Pain Medicine or a board
380 approved by the American Board of Medical Specialties, the
381 American Association of Physician Specialists, or the American
382 Osteopathic Association and perform interventional pain
383 procedures of the type routinely billed using surgical codes.

384 (d) The department shall deny registration to any clinic
385 that is not fully owned by a physician licensed under chapter
386 458 or this chapter or a group of physicians, each of whom is
387 licensed under chapter 458 or this chapter; or that is not a
388 health care clinic licensed under part X of chapter 400 which is
389 fully owned by such physician or group of physicians.

390 (5) PREEMPTION.—This chapter preempts to the state all
391 regulation of the licensure, activity, and operation of
392 pharmacies and pharmacists as defined in chapter 465, health
393 care facilities as defined in s. 408.07, and clinics under part
394 X of chapter 400, including registration and licensing for pain-
395 management clinics and practitioners. A local government or
396 political subdivision of the state may not enact or enforce an
397 ordinance that imposes a levy, charge, or fee upon, or that
398 otherwise regulates, pharmacies and pharmacists as defined in
399 chapter 465, health care facilities as defined in s. 408.07, and
400 clinics under part X of chapter 400, including services provided
401 within such facilities, except that this preemption does not
402 prohibit a local government or political subdivision from
403 enacting an ordinance regarding the following:

404 (a) Local business taxes adopted pursuant to chapter 205.

405 (b) Land use development regulations adopted pursuant to
406 chapter 163, which include regulation of any aspect of

21-00222-13

20131192

407 development, including a subdivision, building construction,
408 sign regulation, and any other regulation concerning the
409 development of land, landscaping, or tree protection, and which
410 do not include restrictions on pain-management services, health
411 care services, and the prescribing of controlled substances.
412 However, a health care facility or clinic that treats pain or
413 provides pain-management services is a permissible use in a land
414 use or zoning category that permits hospitals, other health care
415 facilities, or clinics as defined in chapter 395, s. 408.907, or
416 under part X of chapter 400.

417 Section 5. Present subsections (1) through (17) of section
418 465.003, Florida Statutes, are renumbered as subsections (2)
419 through (18), respectively, paragraph (a) of present subsection
420 (11) of that section is amended, and a new subsection (1) is
421 added to that section, to read:

422 465.003 Definitions.—As used in this chapter, the term:

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

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

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

435 2. The term "institutional pharmacy" includes every

21-00222-13

20131192

436 location in a hospital, clinic, nursing home, dispensary,
437 sanitarium, extended care facility, or other facility,
438 hereinafter referred to as "health care institutions," where
439 medicinal drugs are compounded, dispensed, stored, or sold.

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

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

449 5. The term "Internet pharmacy" includes locations not
450 otherwise licensed or issued a permit under this chapter, within
451 or outside this state, which use the Internet to communicate
452 with or obtain information from consumers in this state and use
453 such communication or information to fill or refill
454 prescriptions or to dispense, distribute, or otherwise engage in
455 the practice of pharmacy in this state. Any act described in
456 this definition constitutes the practice of pharmacy as defined
457 in subsection (14) ~~(13)~~.

458 Section 6. Section 465.0065, Florida Statutes, is created
459 to read:

460 465.0065 Notices; form and service.—Each notice served by
461 the department pursuant to this chapter must be in writing and
462 must be delivered personally by an agent of the department or by
463 certified mail to the pharmacy permittee. If the pharmacy
464 permittee refuses to accept service or evades service or if the

21-00222-13

20131192

465 agent is otherwise unable to carry out service after due
466 diligence, the department may post the notice in a conspicuous
467 place at the pharmacy.

468 Section 7. Paragraphs (e) and (s) of subsection (1) of
469 section 465.016, Florida Statutes, are amended, and paragraph
470 (u) is added to that subsection to read:

471 465.016 Disciplinary actions.—

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

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

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

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

485 Section 8. Paragraph (j) of subsection (5) of section
486 465.022, Florida Statutes, is amended, present subsections (10)
487 through (14) are renumbered as subsections (11) through (15),
488 respectively, present subsection (10) of that section is
489 amended, and a new subsection (10) is added to that section, to
490 read:

491 465.022 Pharmacies; general requirements; fees.—

492 (5) The department or board shall deny an application for a
493 pharmacy permit if the applicant or an affiliated person,

21-00222-13

20131192

494 partner, officer, director, or prescription department manager
495 or consultant pharmacist of record of the applicant:

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

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

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

520 (11) ~~(10)~~ A pharmacy permittee shall be supervised by a
521 prescription department manager or consultant pharmacist of
522 record at all times. A permittee must notify the department, on

21-00222-13

20131192__

523 a form approved by the board, within 10 days after any change in
524 prescription department manager or consultant pharmacist of
525 record.

526 Section 9. Subsection (1) of section 465.023, Florida
527 Statutes, is amended to read:

528 465.023 Pharmacy permittee; disciplinary action.—

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

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

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

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

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

551 (e) Been convicted or disciplined by a regulatory agency of

21-00222-13

20131192

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

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

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

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

572 Section 10. Paragraph (b) of subsection (2), subsection
573 (10), and paragraph (c) of subsection (11) of section 893.055,
574 Florida Statutes, are amended to read:

575 893.055 Prescription drug monitoring program.—

576 (2)

577 (b) The department, ~~when the direct support organization~~
578 ~~receives at least \$20,000 in nonstate moneys or the state~~
579 ~~receives at least \$20,000 in federal grants for the prescription~~
580 ~~drug monitoring program,~~ shall adopt rules as necessary

21-00222-13

20131192

581 concerning the reporting, accessing the database, evaluation,
582 management, development, implementation, operation, security,
583 and storage of information within the system, including rules
584 for when patient advisory reports are provided to pharmacies and
585 prescribers. The patient advisory report shall be provided in
586 accordance with s. 893.13(7)(a)8. The department shall work with
587 the professional health care licensure boards, such as the Board
588 of Medicine, the Board of Osteopathic Medicine, and the Board of
589 Pharmacy; other appropriate organizations, such as the Florida
590 Pharmacy Association, the Florida Medical Association, the
591 Florida Retail Federation, and the Florida Osteopathic Medical
592 Association, including those relating to pain management; and
593 the Attorney General, the Department of Law Enforcement, and the
594 Agency for Health Care Administration to develop rules
595 appropriate for the prescription drug monitoring program.

596 (10) All costs incurred by the department in administering
597 the prescription drug monitoring program shall be funded through
598 state funds, federal grants, or private funding applied for or
599 received by the state. The department may not commit funds for
600 the monitoring program without ensuring funding is available.
601 ~~The prescription drug monitoring program and the implementation~~
602 ~~thereof are contingent upon receipt of the nonstate funding.~~ The
603 department and state government shall cooperate with the direct-
604 support organization established pursuant to subsection (11) in
605 seeking state funds, federal grant funds, other nonstate grant
606 funds, gifts, donations, or other private moneys for the
607 department if so long as the costs of doing so are not
608 considered material. Nonmaterial costs for this purpose include,
609 but are not limited to, the costs of mailing and personnel

21-00222-13

20131192

610 assigned to research or apply for a grant. Notwithstanding the
611 exemptions to competitive-solicitation requirements under s.
612 287.057(3)(f), the department shall comply with the competitive-
613 solicitation requirements under s. 287.057 for the procurement
614 of any goods or services required by this section. Funds
615 provided, directly or indirectly, by prescription drug
616 manufacturers may not be used to implement the program.

617 (11) The department may establish a direct-support
618 organization that has a board consisting of at least five
619 members to provide assistance, funding, and promotional support
620 for the activities authorized for the prescription drug
621 monitoring program.

622 (c) The State Surgeon General shall appoint a board of
623 directors for the direct-support organization. Members of the
624 board shall serve at the pleasure of the State Surgeon General.
625 The State Surgeon General shall provide guidance to members of
626 the board to ensure that moneys received by the direct-support
627 organization are not received from inappropriate sources.
628 Inappropriate sources include, but are not limited to, donors,
629 grantors, persons, and ~~or~~ organizations, excluding
630 pharmaceutical companies, that may monetarily or substantively
631 benefit from the purchase of goods or services by the department
632 in furtherance of the prescription drug monitoring program.

633 Section 11. Subsection (1) of section 409.9201, Florida
634 Statutes, is amended to read:

635 409.9201 Medicaid fraud.—

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

637 (a) "Prescription drug" means any drug, including, but not
638 limited to, finished dosage forms or active ingredients that are

21-00222-13

20131192

639 subject to, defined by, or described by s. 503(b) of the Federal
640 Food, Drug, and Cosmetic Act or by s. 465.003 ~~s. 465.003(8)~~, s.
641 499.003(46) or (53) or s. 499.007(13).

642 (b) "Value" means the amount billed to the Medicaid program
643 for the property dispensed or the market value of a legend drug
644 or goods or services at the time and place of the offense. If
645 the market value cannot be determined, the term means the
646 replacement cost of the legend drug or goods or services within
647 a reasonable time after the offense.

648

649 The value of individual items of the legend drugs or goods or
650 services involved in distinct transactions committed during a
651 single scheme or course of conduct, whether involving a single
652 person or several persons, may be aggregated when determining
653 the punishment for the offense.

654 Section 12. Paragraph (pp) of subsection (1) of section
655 458.331, Florida Statutes, is amended to read:

656 458.331 Grounds for disciplinary action; action by the
657 board and department.—

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

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

663 1. Registering a pain-management clinic through
664 misrepresentation or fraud;

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

21-00222-13

20131192

668 3. Failing to comply with any requirement of chapter 499,
669 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
670 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
671 the Drug Abuse Prevention and Control Act; or chapter 893, the
672 Florida Comprehensive Drug Abuse Prevention and Control Act;

673 4. Being convicted or found guilty of, regardless of
674 adjudication to, a felony or any other crime involving moral
675 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
676 the courts of this state, of any other state, or of the United
677 States;

678 5. Being convicted of, or disciplined by a regulatory
679 agency of the Federal Government or a regulatory agency of
680 another state for, any offense that would constitute a violation
681 of this chapter;

682 6. Being convicted of, or entering a plea of guilty or nolo
683 contendere to, regardless of adjudication, a crime in any
684 jurisdiction of the courts of this state, of any other state, or
685 of the United States which relates to the practice of, or the
686 ability to practice, a licensed health care profession;

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

691 8. Dispensing any medicinal drug based upon a communication
692 that purports to be a prescription as defined in s. 465.003 ~~s.~~
693 ~~465.003(14)~~ or s. 893.02 if the dispensing practitioner knows or
694 has reason to believe that the purported prescription is not
695 based upon a valid practitioner-patient relationship; or

696 9. Failing to timely notify the board of the date of his or

21-00222-13

20131192

697 her termination from a pain-management clinic as required by s.
698 458.3265(2).

699 Section 13. Paragraph (rr) of subsection (1) of section
700 459.015, Florida Statutes, is amended to read:

701 459.015 Grounds for disciplinary action; action by the
702 board and department.—

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

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

708 1. Registering a pain-management clinic through
709 misrepresentation or fraud;

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

713 3. Failing to comply with any requirement of chapter 499,
714 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
715 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
716 the Drug Abuse Prevention and Control Act; or chapter 893, the
717 Florida Comprehensive Drug Abuse Prevention and Control Act;

718 4. Being convicted or found guilty of, regardless of
719 adjudication to, a felony or any other crime involving moral
720 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
721 the courts of this state, of any other state, or of the United
722 States;

723 5. Being convicted of, or disciplined by a regulatory
724 agency of the Federal Government or a regulatory agency of
725 another state for, any offense that would constitute a violation

21-00222-13

20131192__

726 of this chapter;

727 6. Being convicted of, or entering a plea of guilty or nolo
728 contendere to, regardless of adjudication, a crime in any
729 jurisdiction of the courts of this state, of any other state, or
730 of the United States which relates to the practice of, or the
731 ability to practice, a licensed health care profession;

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

736 8. Dispensing any medicinal drug based upon a communication
737 that purports to be a prescription as defined in s. 465.003 ~~s.~~
738 ~~465.003(14)~~ or s. 893.02 if the dispensing practitioner knows or
739 has reason to believe that the purported prescription is not
740 based upon a valid practitioner-patient relationship; or

741 9. Failing to timely notify the board of the date of his or
742 her termination from a pain-management clinic as required by s.
743 459.0137(2).

744 Section 14. Subsection (1) of section 465.014, Florida
745 Statutes, is amended to read:

746 465.014 Pharmacy technician.—

747 (1) A person other than a licensed pharmacist or pharmacy
748 intern may not engage in the practice of the profession of
749 pharmacy, except that a licensed pharmacist may delegate to
750 pharmacy technicians who are registered pursuant to this section
751 those duties, tasks, and functions that do not fall within the
752 purview of s. 465.003 ~~s. 465.003(13)~~. All such delegated acts
753 shall be performed under the direct supervision of a licensed
754 pharmacist who shall be responsible for all such acts performed

21-00222-13

20131192

755 by persons under his or her supervision. A pharmacy registered
756 technician, under the supervision of a pharmacist, may initiate
757 or receive communications with a practitioner or his or her
758 agent, on behalf of a patient, regarding refill authorization
759 requests. A licensed pharmacist may not supervise more than one
760 registered pharmacy technician unless otherwise permitted by the
761 guidelines adopted by the board. The board shall establish
762 guidelines to be followed by licensees or permittees in
763 determining the circumstances under which a licensed pharmacist
764 may supervise more than one but not more than three pharmacy
765 technicians.

766 Section 15. Paragraph (c) of subsection (2) of section
767 465.015, Florida Statutes, is amended to read:

768 465.015 Violations and penalties.—

769 (2) It is unlawful for any person:

770 (c) To sell or dispense drugs as defined in s. 465.003 ~~s.~~
771 ~~465.003(8)~~ without first being furnished with a prescription.

772 Section 16. Subsection (8) of section 465.0156, Florida
773 Statutes, is amended to read:

774 465.0156 Registration of nonresident pharmacies.—

775 (8) Notwithstanding s. 465.003 ~~s. 465.003(10)~~, for purposes
776 of this section, the registered pharmacy and the pharmacist
777 designated by the registered pharmacy as the prescription
778 department manager or the equivalent must be licensed in the
779 state of location in order to dispense into this state.

780 Section 17. Subsection (4) of section 465.0197, Florida
781 Statutes, is amended to read:

782 465.0197 Internet pharmacy permits.—

783 (4) Notwithstanding s. 465.003 ~~s. 465.003(10)~~, for purposes

21-00222-13

20131192

784 of this section, the Internet pharmacy and the pharmacist
785 designated by the Internet pharmacy as the prescription
786 department manager or the equivalent must be licensed in the
787 state of location in order to dispense into this state.

788 Section 18. Section 465.1901, Florida Statutes, is amended
789 to read:

790 465.1901 Practice of orthotics and pedorthics.—The
791 provisions of chapter 468 relating to orthotics or pedorthics do
792 not apply to any licensed pharmacist or to any person acting
793 under the supervision of a licensed pharmacist. The practice of
794 orthotics or pedorthics by a pharmacist or any of the
795 pharmacist's employees acting under the supervision of a
796 pharmacist shall be construed to be within the meaning of the
797 term "practice of the profession of pharmacy" as set forth in s.
798 465.003 ~~s. 465.003(13)~~, and shall be subject to regulation in
799 the same manner as any other pharmacy practice. The Board of
800 Pharmacy shall develop rules regarding the practice of orthotics
801 and pedorthics by a pharmacist. Any pharmacist or person under
802 the supervision of a pharmacist engaged in the practice of
803 orthotics or pedorthics is not precluded from continuing that
804 practice pending adoption of these rules.

805 Section 19. Subsection (43) of section 499.003, Florida
806 Statutes, is amended to read:

807 499.003 Definitions of terms used in this part.—As used in
808 this part, the term:

809 (43) "Prescription drug" means a prescription, medicinal,
810 or legend drug, including, but not limited to, finished dosage
811 forms or active pharmaceutical ingredients subject to, defined
812 by, or described by s. 503(b) of the Federal Food, Drug, and

21-00222-13

20131192

813 Cosmetic Act or s. 465.003 ~~s. 465.003(8)~~, s. 499.007(13), or
814 subsection (11), subsection (46), or subsection (53), except
815 that an active pharmaceutical ingredient is a prescription drug
816 only if substantially all finished dosage forms in which it may
817 be lawfully dispensed or administered in this state are also
818 prescription drugs.

819 Section 20. Subsection (22) of section 893.02, Florida
820 Statutes, is amended to read:

821 893.02 Definitions.—The following words and phrases as used
822 in this chapter shall have the following meanings, unless the
823 context otherwise requires:

824 (22) "Prescription" means and includes an order for drugs
825 or medicinal supplies written, signed, or transmitted by word of
826 mouth, telephone, telegram, or other means of communication by a
827 duly licensed practitioner licensed by the laws of the state to
828 prescribe such drugs or medicinal supplies, issued in good faith
829 and in the course of professional practice, intended to be
830 filled, compounded, or dispensed by another person licensed by
831 the laws of the state to do so, and meeting the requirements of
832 s. 893.04. The term also includes an order for drugs or
833 medicinal supplies so transmitted or written by a physician,
834 dentist, veterinarian, or other practitioner licensed to
835 practice in a state other than Florida, but only if the
836 pharmacist called upon to fill such an order determines, in the
837 exercise of his or her professional judgment, that the order was
838 issued pursuant to a valid patient-physician relationship, that
839 it is authentic, and that the drugs or medicinal supplies so
840 ordered are considered necessary for the continuation of
841 treatment of a chronic or recurrent illness. However, if the

21-00222-13

20131192__

842 physician writing the prescription is not known to the
843 pharmacist, the pharmacist shall obtain proof to a reasonable
844 certainty of the validity of said prescription. A prescription
845 order for a controlled substance shall not be issued on the same
846 prescription blank with another prescription order for a
847 controlled substance which is named or described in a different
848 schedule, nor shall any prescription order for a controlled
849 substance be issued on the same prescription blank as a
850 prescription order for a medicinal drug, as defined in s.
851 465.003 ~~s. 465.003(8)~~, which does not fall within the definition
852 of a controlled substance as defined in this act.

853 Section 21. This act shall take effect July 1, 2013.