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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 physicians 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 prescription of controlled substance; amending s.
12 458.326, F.S.; requiring physicians 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;
21 prohibiting municipalities and counties from enacting
22 ordinances related to pain-management clinics until a
23 specified date; providing for development of a model
24 local ordinance; prohibiting adoption of a local
25 ordinance after a specified date with restrictions on
26 pain-management clinics stricter than those in the
27 model local ordinance; amending s. 465.003, F.S.;
28 defining a term; conforming a cross-reference;

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

50 |
 51 | Be It Enacted by the Legislature of the State of Florida:

52 |
 53 | Section 1. Subsections (2) and (3) of section 456.44,
 54 | Florida Statutes, are amended to read:

55 | 456.44 Controlled substance prescribing.—

56 | (2) REGISTRATION.—~~Effective January 1, 2012,~~ A physician

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57 licensed under chapter 458, chapter 459, chapter 461, or chapter
58 466 who prescribes more than a 30-day supply of any controlled
59 substance, listed in Schedule II, Schedule III, or Schedule IV
60 as defined in s. 893.03, over a 6-month period to any one
61 patient for the treatment of chronic nonmalignant pain, must:

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

65 (b) Comply with the requirements of this section and
66 applicable board rules.

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

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

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85 | registrant must develop a written plan for assessing each
86 | patient's risk of aberrant drug-related behavior, which may
87 | include patient drug testing. Registrants must assess each
88 | patient's risk for aberrant drug-related behavior and monitor
89 | that risk on an ongoing basis in accordance with the plan.

90 | (b) Pursuant to s. 458.326, before prescribing a
91 | controlled substance listed in Schedule II or Schedule III, as
92 | provided in s. 893.03, a physician shall consult the
93 | prescription drug monitoring program database, as provided in s.
94 | 893.055(2) (a), before seeing a new patient or during a new
95 | patient visit. A physician may designate an agent under his or
96 | her supervision to consult the database. The board shall adopt
97 | rules to establish a penalty for a physician that does not
98 | comply with this subsection.

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

112 | (d)~~(e)~~ The physician shall discuss the risks and benefits

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

121 1. Number and frequency of controlled substance
122 prescriptions and refills.

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

125 3. An agreement that controlled substances for the
126 treatment of chronic nonmalignant pain shall be prescribed by a
127 single treating physician unless otherwise authorized by the
128 treating physician and documented in the medical record.

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

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141 | indications of substance abuse or diversion at a minimum of 3-
142 | month intervals.

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

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

- 159 | 1. The complete medical history and a physical
160 | examination, including history of drug abuse or dependence.
161 | 2. Diagnostic, therapeutic, and laboratory results.
162 | 3. Evaluations and consultations.
163 | 4. Treatment objectives.
164 | 5. Discussion of risks and benefits.
165 | 6. Treatments.
166 | 7. Medications, including date, type, dosage, and quantity
167 | prescribed.
168 | 8. Instructions and agreements.

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169 9. Periodic reviews.

170 10. Results of any drug testing.

171 11. A photocopy of the patient's government-issued photo
172 identification.

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

175 13. The physician's full name presented in a legible
176 manner.

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

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

219 Section 2. Subsection (3) of section 458.326, Florida
220 Statutes, is amended to read:

221 458.326 Intractable pain; authorized treatment.—

222 (3) (a) Notwithstanding any other provision of law, a
223 physician may prescribe or administer any controlled substance
224 under Schedules II-V, as provided for in s. 893.03, to a person

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225 for the treatment of intractable pain, provided the physician
226 does so in accordance with that level of care, skill, and
227 treatment recognized by a reasonably prudent physician under
228 similar conditions and circumstances.

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

237 Section 3. Paragraphs (a) and (d) of subsection (1) of
238 section 458.3265, Florida Statutes, are amended, subsections (5)
239 and (6) of that section are renumbered as subsections (6) and
240 (7), respectively, and a new subsection (5) is added to that
241 section, to read:

242 458.3265 Pain-management clinics.—

243 (1) REGISTRATION.—

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

245 a. "Board eligible" means successful completion of an
246 anesthesia, physical medicine and rehabilitation, rheumatology,
247 or neurology residency program approved by the Accreditation
248 Council for Graduate Medical Education or the American
249 Osteopathic Association for a period of 6 years from successful
250 completion of such residency program.

251 b. "Chronic nonmalignant pain" means pain unrelated to
252 cancer which persists beyond the usual course of disease or the

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253 injury that is the cause of the pain or more than 90 days after
254 surgery.

255 c. "Pain-management clinic" or "clinic" means any publicly
256 or privately owned facility:

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

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

262 2. Each pain-management clinic must register with the
263 department unless:

264 a. That clinic is licensed as a facility pursuant to
265 chapter 395;

266 b. The majority of the physicians who provide services in
267 the clinic primarily provide surgical services;

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

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

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

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

279 e.g. The clinic is wholly owned and operated by one or
280 more board-eligible or board-certified anesthesiologists,

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

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

299 | (5) LOCAL ORDINANCES.—

300 | (a) The Legislature finds that it is necessary to promote
301 | uniformity throughout the state in the fight against
302 | prescription drug abuse. Municipalities and counties are
303 | prohibited from enacting further ordinances related to pain-
304 | management clinics until June 30, 2014.

305 | (b) After June 30, 2014, a municipality or county that
306 | chooses to regulate pain-management clinics may not adopt
307 | regulations stricter than those identified in the model local
308 | ordinance developed under section 5 of this act. If an existing

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309 local ordinance exceeds the scope of the model local ordinance,
310 the local government shall amend its ordinance to bring it into
311 conformity with the model local ordinance.

312 Section 4. Paragraphs (a) and (d) of subsection (1) of
313 section 459.0137, Florida Statutes, are amended, subsections (5)
314 and (6) of that section are renumbered as subsections (6) and
315 (7), respectively, and a new subsection (5) is added to that
316 section, to read:

317 459.0137 Pain-management clinics.—

318 (1) REGISTRATION.—

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

320 a. "Board eligible" means successful completion of an
321 anesthesia, physical medicine and rehabilitation, rheumatology,
322 or neurology residency program approved by the Accreditation
323 Council for Graduate Medical Education or the American
324 Osteopathic Association for a period of 6 years from successful
325 completion of such residency program.

326 b. "Chronic nonmalignant pain" means pain unrelated to
327 cancer which persists beyond the usual course of disease or the
328 injury that is the cause of the pain or more than 90 days after
329 surgery.

330 c. "Pain-management clinic" or "clinic" means any publicly
331 or privately owned facility:

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

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

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337 2. Each pain-management clinic must register with the
338 department unless:

339 a. That clinic is licensed as a facility pursuant to
340 chapter 395;

341 b. The majority of the physicians who provide services in
342 the clinic primarily provide surgical services;

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

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

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

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

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

357 f.h. The clinic is wholly owned and operated by a
358 physician multispecialty practice where one or more board-
359 eligible or board-certified medical specialists who have also
360 completed fellowships in pain medicine approved by the
361 Accreditation Council for Graduate Medical Education or the
362 American Osteopathic Association, or who are also board-
363 certified in pain medicine by the American Board of Pain
364 Medicine or a board approved by the American Board of Medical

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365 Specialties, the American Association of Physician Specialists,
366 or the American Osteopathic Association and perform
367 interventional pain procedures of the type routinely billed
368 using surgical codes.

369 (d) The department shall deny registration to any clinic
370 that is not fully owned by a physician licensed under chapter
371 458 or this chapter or a group of physicians, each of whom is
372 licensed under chapter 458 or this chapter; or that is not a
373 health care clinic licensed under part X of chapter 400 that is
374 fully owned by such physician or group of physicians.

375 (5) LOCAL ORDINANCES.—

376 (a) The Legislature finds that it is necessary to promote
377 uniformity throughout the state in the fight against
378 prescription drug abuse. Municipalities and counties are
379 prohibited from enacting further ordinances related to pain-
380 management clinics until June 30, 2014.

381 (b) After June 30, 2014, a municipality or county that
382 chooses to regulate pain-management clinics may not adopt
383 regulations stricter than those identified in the model local
384 ordinance developed under section 5 of this act. If an existing
385 local ordinance exceeds the scope of the model local ordinance,
386 the local government shall amend its ordinance to bring it into
387 conformity with the model local ordinance.

388 Section 5. In an effort to stop the proliferation of
389 prescription drug abuse, promote uniformity in the law, and
390 protect the bona fide practice of medicine, the Florida
391 Department of Health in conjunction with the Florida Association
392 of Counties, the Florida League of Cities, the Florida Medical

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393 Association, the Florida Osteopathic Medical Association, and
394 the appropriate specialty societies of those associations shall
395 develop a model local ordinance for pain-management clinics that
396 register with the state under s. 458.3265 or s. 459.0137,
397 Florida Statutes. The agencies and entities specified in this
398 section shall complete the model local ordinance by October 1,
399 2013, and shall issue a report containing the model local
400 ordinance to the Governor, the President of the Senate, and the
401 Speaker of the House of Representatives on or before that date.
402 In drafting the model local ordinance, the agencies and entities
403 specified in this section shall ensure that the local regulation
404 of pain-management clinics does not intrude on the state's power
405 to regulate the practice of medicine. The model local ordinance
406 shall only address the following areas of local concern:

407 (1) Zoning.

408 (2) Certificates of use.

409 (3) Permitting.

410 (4) Building codes.

411 (5) General business facility regulations, including
412 design, operation, and maintenance.

413 (6) Appropriate penalties for ordinance violations.

414 Section 6. Subsections (1) through (17) of section
415 465.003, Florida Statutes, are renumbered as subsections (2)
416 through (18), respectively, paragraph (a) of present subsection
417 (11) of that section is amended, and a new subsection (1) is
418 added to that section, to read:

419 465.003 Definitions.—As used in this chapter, the term:

420 (1) "Abandoned" means when a person who is issued a

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421 pharmacy permit fails to commence pharmacy operations within 180
422 days after issuance of the pharmacy permit without good cause or
423 fails to follow pharmacy closure requirements as set by the
424 board.

425 (12)-(11)-(a) "Pharmacy" includes a community pharmacy, an
426 institutional pharmacy, a nuclear pharmacy, a special pharmacy,
427 and an Internet pharmacy.

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

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

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

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

446 5. The term "Internet pharmacy" includes locations not
447 otherwise licensed or issued a permit under this chapter, within
448 or outside this state, which use the Internet to communicate

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449 with or obtain information from consumers in this state and use
450 such communication or information to fill or refill
451 prescriptions or to dispense, distribute, or otherwise engage in
452 the practice of pharmacy in this state. Any act described in
453 this definition constitutes the practice of pharmacy as defined
454 in this section ~~subsection (13)~~.

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

458 465.016 Disciplinary actions.—

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

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

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

470 (u) Misappropriating drugs, supplies, or equipment from a
471 pharmacy permittee.

472 Section 8. Section 465.0065, Florida Statutes, is created
473 to read:

474 465.0065 Notices; form and service.—Each notice served by
475 the department pursuant to this chapter must be in writing and
476 must be delivered personally by an agent of the department or by

477 certified mail to the pharmacy permittee. If the pharmacy
 478 permittee refuses to accept service, evades service, or the
 479 agent is otherwise unable to effect service after due diligence,
 480 the department may post such notice in a conspicuous place at
 481 the pharmacy.

482 Section 9. Subsections (10) through (14) of section
 483 465.022, Florida Statutes, are renumbered as subsections (11)
 484 through (15), respectively, present subsection (10) of that
 485 section is amended, and a new subsection (10) is added to that
 486 section, to read:

487 465.022 Pharmacies; general requirements; fees.—

488 (10) The permittee shall commence pharmacy operations
 489 within 180 days after issuance of the permit, or show good cause
 490 to the department why pharmacy operations were not commenced.
 491 Commencement of pharmacy operations includes, but is not limited
 492 to, acts within the scope of the practice of pharmacy, ordering
 493 or receiving drugs, and other similar activities. The board
 494 shall establish rules regarding commencement of pharmacy
 495 operations.

496 (11)-(10) A pharmacy permittee shall be supervised by a
 497 prescription department manager or consultant pharmacist of
 498 record at all times. A permittee must notify the department, on
 499 a form approved by the board, within 10 days after any change in
 500 prescription department manager or consultant pharmacist of
 501 record.

502 Section 10. Paragraph (c) of subsection (1) of section
 503 465.023, Florida Statutes, is amended to read:

504 465.023 Pharmacy permittee; disciplinary action.—

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505 (1) The department or the board may revoke or suspend the
506 permit of any pharmacy permittee, and may fine, place on
507 probation, or otherwise discipline any pharmacy permittee if the
508 permittee, or any affiliated person, partner, officer, director,
509 or agent of the permittee, including a person fingerprinted
510 under s. 465.022(3), has:

511 (c) Violated any of the requirements of this chapter or
512 any of the rules of the Board of Pharmacy; of chapter 499, known
513 as the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss. 301-
514 392, known as the "Federal Food, Drug, and Cosmetic Act"; of 21
515 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse
516 Prevention and Control Act; or of chapter 893 or rules adopted
517 thereunder;

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

521 893.055 Prescription drug monitoring program.—

522 (2)

523 (b) The department, ~~when the direct support organization~~
524 ~~receives at least \$20,000 in nonstate moneys or the state~~
525 ~~receives at least \$20,000 in federal grants for the prescription~~
526 ~~drug monitoring program,~~ shall adopt rules as necessary
527 concerning the reporting, accessing the database, evaluation,
528 management, development, implementation, operation, security,
529 and storage of information within the system, including rules
530 for when patient advisory reports are provided to pharmacies and
531 prescribers. The patient advisory report shall be provided in
532 accordance with s. 893.13(7)(a)8. The department shall work with

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533 the professional health care licensure boards, such as the Board
534 of Medicine, the Board of Osteopathic Medicine, and the Board of
535 Pharmacy; other appropriate organizations, such as the Florida
536 Pharmacy Association, the Florida Medical Association, the
537 Florida Retail Federation, and the Florida Osteopathic Medical
538 Association, including those relating to pain management; and
539 the Attorney General, the Department of Law Enforcement, and the
540 Agency for Health Care Administration to develop rules
541 appropriate for the prescription drug monitoring program.

542 (10) All costs incurred by the department in administering
543 the prescription drug monitoring program shall be funded through
544 state funds, federal grants, or private funding applied for or
545 received by the state. The department may not commit funds for
546 the monitoring program without ensuring funding is available.
547 ~~The prescription drug monitoring program and the implementation~~
548 ~~thereof are contingent upon receipt of the nonstate funding.~~ The
549 department and state government shall cooperate with the direct-
550 support organization established pursuant to subsection (11) in
551 seeking state funds, federal grant funds, other nonstate grant
552 funds, gifts, donations, or other private moneys for the
553 department so long as the costs of doing so are not considered
554 material. Nonmaterial costs for this purpose include, but are
555 not limited to, the costs of mailing and personnel assigned to
556 research or apply for a grant. Notwithstanding the exemptions to
557 competitive-solicitation requirements under s. 287.057(3)(f),
558 the department shall comply with the competitive-solicitation
559 requirements under s. 287.057 for the procurement of any goods
560 or services required by this section. Funds provided, directly

561 or indirectly, by prescription drug manufacturers may not be
 562 used to implement the program.

563 (11) The department may establish a direct-support
 564 organization that has a board consisting of at least five
 565 members to provide assistance, funding, and promotional support
 566 for the activities authorized for the prescription drug
 567 monitoring program.

568 (c) The State Surgeon General shall appoint a board of
 569 directors for the direct-support organization. Members of the
 570 board shall serve at the pleasure of the State Surgeon General.
 571 The State Surgeon General shall provide guidance to members of
 572 the board to ensure that moneys received by the direct-support
 573 organization are not received from inappropriate sources.
 574 Inappropriate sources include, but are not limited to, donors,
 575 grantors, persons, or organizations, excluding pharmaceutical
 576 companies, that may monetarily or substantively benefit from the
 577 purchase of goods or services by the department in furtherance
 578 of the prescription drug monitoring program.

579 Section 12. Paragraph (a) of subsection (1) of section
 580 409.9201, Florida Statutes, is amended to read:

581 409.9201 Medicaid fraud.—

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

583 (a) "Prescription drug" means any drug, including, but not
 584 limited to, finished dosage forms or active ingredients that are
 585 subject to, defined by, or described by s. 503(b) of the Federal
 586 Food, Drug, and Cosmetic Act or by s. 465.003~~(8)~~, s. 499.003(46)
 587 or (53) or s. 499.007(13).
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589 The value of individual items of the legend drugs or goods or
590 services involved in distinct transactions committed during a
591 single scheme or course of conduct, whether involving a single
592 person or several persons, may be aggregated when determining
593 the punishment for the offense.

594 Section 13. Paragraph (pp) of subsection (1) of section
595 458.331, Florida Statutes, is amended to read:

596 458.331 Grounds for disciplinary action; action by the
597 board and department.—

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

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

603 1. Registering a pain-management clinic through
604 misrepresentation or fraud;

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

608 3. Failing to comply with any requirement of chapter 499,
609 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
610 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
611 the Drug Abuse Prevention and Control Act; or chapter 893, the
612 Florida Comprehensive Drug Abuse Prevention and Control Act;

613 4. Being convicted or found guilty of, regardless of
614 adjudication to, a felony or any other crime involving moral
615 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
616 the courts of this state, of any other state, or of the United

617 States;

618 5. Being convicted of, or disciplined by a regulatory
 619 agency of the Federal Government or a regulatory agency of
 620 another state for, any offense that would constitute a violation
 621 of this chapter;

622 6. Being convicted of, or entering a plea of guilty or
 623 nolo contendere to, regardless of adjudication, a crime in any
 624 jurisdiction of the courts of this state, of any other state, or
 625 of the United States which relates to the practice of, or the
 626 ability to practice, a licensed health care profession;

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

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

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

639 Section 14. Paragraph (rr) of subsection (1) of section
 640 459.015, Florida Statutes, is amended to read:

641 459.015 Grounds for disciplinary action; action by the
 642 board and department.-

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

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

648 1. Registering a pain-management clinic through
649 misrepresentation or fraud;

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

653 3. Failing to comply with any requirement of chapter 499,
654 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
655 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
656 the Drug Abuse Prevention and Control Act; or chapter 893, the
657 Florida Comprehensive Drug Abuse Prevention and Control Act;

658 4. Being convicted or found guilty of, regardless of
659 adjudication to, a felony or any other crime involving moral
660 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
661 the courts of this state, of any other state, or of the United
662 States;

663 5. Being convicted of, or disciplined by a regulatory
664 agency of the Federal Government or a regulatory agency of
665 another state for, any offense that would constitute a violation
666 of this chapter;

667 6. Being convicted of, or entering a plea of guilty or
668 nolo contendere to, regardless of adjudication, a crime in any
669 jurisdiction of the courts of this state, of any other state, or
670 of the United States which relates to the practice of, or the
671 ability to practice, a licensed health care profession;

672 7. Being convicted of, or entering a plea of guilty or

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673 nolo contendere to, regardless of adjudication, a crime in any
674 jurisdiction of the courts of this state, of any other state, or
675 of the United States which relates to health care fraud;

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

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

684 Section 15. Subsection (1) of section 465.014, Florida
685 Statutes, is amended to read:

686 465.014 Pharmacy technician.—

687 (1) A person other than a licensed pharmacist or pharmacy
688 intern may not engage in the practice of the profession of
689 pharmacy, except that a licensed pharmacist may delegate to
690 pharmacy technicians who are registered pursuant to this section
691 those duties, tasks, and functions that do not fall within the
692 purview of s. 465.003~~(13)~~. All such delegated acts shall be
693 performed under the direct supervision of a licensed pharmacist
694 who shall be responsible for all such acts performed by persons
695 under his or her supervision. A pharmacy registered technician,
696 under the supervision of a pharmacist, may initiate or receive
697 communications with a practitioner or his or her agent, on
698 behalf of a patient, regarding refill authorization requests. A
699 licensed pharmacist may not supervise more than one registered
700 pharmacy technician unless otherwise permitted by the guidelines

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701 adopted by the board. The board shall establish guidelines to be
 702 followed by licensees or permittees in determining the
 703 circumstances under which a licensed pharmacist may supervise
 704 more than one but not more than three pharmacy technicians.

705 Section 16. Paragraph (c) of subsection (2) of section
 706 465.015, Florida Statutes, is amended to read:

707 465.015 Violations and penalties.—

708 (2) It is unlawful for any person:

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

711 Section 17. Subsection (8) of section 465.0156, Florida
 712 Statutes, is amended to read:

713 465.0156 Registration of nonresident pharmacies.—

714 (8) Notwithstanding s. 465.003~~(10)~~, for purposes of this
 715 section, the registered pharmacy and the pharmacist designated
 716 by the registered pharmacy as the prescription department
 717 manager or the equivalent must be licensed in the state of
 718 location in order to dispense into this state.

719 Section 18. Subsection (4) of section 465.0197, Florida
 720 Statutes, is amended to read:

721 465.0197 Internet pharmacy permits.—

722 (4) Notwithstanding s. 465.003~~(10)~~, for purposes of this
 723 section, the Internet pharmacy and the pharmacist designated by
 724 the Internet pharmacy as the prescription department manager or
 725 the equivalent must be licensed in the state of location in
 726 order to dispense into this state.

727 Section 19. Paragraph (j) of subsection (5) of section
 728 465.022, Florida Statutes, is amended to read:

729 465.022 Pharmacies; general requirements; fees.—

730 (5) The department or board shall deny an application for
 731 a pharmacy permit if the applicant or an affiliated person,
 732 partner, officer, director, or prescription department manager
 733 or consultant pharmacist of record of the applicant:

734 (j) Has dispensed any medicinal drug based upon a
 735 communication that purports to be a prescription as defined by
 736 s. 465.003~~(14)~~ or s. 893.02 when the pharmacist knows or has
 737 reason to believe that the purported prescription is not based
 738 upon a valid practitioner-patient relationship that includes a
 739 documented patient evaluation, including history and a physical
 740 examination adequate to establish the diagnosis for which any
 741 drug is prescribed and any other requirement established by
 742 board rule under chapter 458, chapter 459, chapter 461, chapter
 743 463, chapter 464, or chapter 466.

744
 745 For felonies in which the defendant entered a plea of guilty or
 746 nolo contendere in an agreement with the court to enter a
 747 pretrial intervention or drug diversion program, the department
 748 shall deny the application if upon final resolution of the case
 749 the licensee has failed to successfully complete the program.

750 Section 20. Paragraph (h) of subsection (1) of section
 751 465.023, Florida Statutes, is amended to read:

752 465.023 Pharmacy permittee; disciplinary action.—

753 (1) The department or the board may revoke or suspend the
 754 permit of any pharmacy permittee, and may fine, place on
 755 probation, or otherwise discipline any pharmacy permittee if the
 756 permittee, or any affiliated person, partner, officer, director,

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757 or agent of the permittee, including a person fingerprinted
758 under s. 465.022(3), has:

759 (h) Dispensed any medicinal drug based upon a
760 communication that purports to be a prescription as defined by
761 s. 465.003~~(14)~~ or s. 893.02 when the pharmacist knows or has
762 reason to believe that the purported prescription is not based
763 upon a valid practitioner-patient relationship that includes a
764 documented patient evaluation, including history and a physical
765 examination adequate to establish the diagnosis for which any
766 drug is prescribed and any other requirement established by
767 board rule under chapter 458, chapter 459, chapter 461, chapter
768 463, chapter 464, or chapter 466.

769 Section 21. Section 465.1901, Florida Statutes, is amended
770 to read:

771 465.1901 Practice of orthotics and pedorthics.—The
772 provisions of chapter 468 relating to orthotics or pedorthics do
773 not apply to any licensed pharmacist or to any person acting
774 under the supervision of a licensed pharmacist. The practice of
775 orthotics or pedorthics by a pharmacist or any of the
776 pharmacist's employees acting under the supervision of a
777 pharmacist shall be construed to be within the meaning of the
778 term "practice of the profession of pharmacy" as set forth in s.
779 465.003~~(13)~~, and shall be subject to regulation in the same
780 manner as any other pharmacy practice. The Board of Pharmacy
781 shall develop rules regarding the practice of orthotics and
782 pedorthics by a pharmacist. Any pharmacist or person under the
783 supervision of a pharmacist engaged in the practice of orthotics
784 or pedorthics is not precluded from continuing that practice

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785 pending adoption of these rules.

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

788 499.003 Definitions of terms used in this part.—As used in
789 this part, the term:

790 (43) "Prescription drug" means a prescription, medicinal,
791 or legend drug, including, but not limited to, finished dosage
792 forms or active pharmaceutical ingredients subject to, defined
793 by, or described by s. 503(b) of the Federal Food, Drug, and
794 Cosmetic Act or s. 465.003~~(8)~~, s. 499.007(13), or subsection
795 (11), subsection (46), or subsection (53), except that an active
796 pharmaceutical ingredient is a prescription drug only if
797 substantially all finished dosage forms in which it may be
798 lawfully dispensed or administered in this state are also
799 prescription drugs.

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

802 893.02 Definitions.—The following words and phrases as
803 used in this chapter shall have the following meanings, unless
804 the context otherwise requires:

805 (22) "Prescription" means and includes an order for drugs
806 or medicinal supplies written, signed, or transmitted by word of
807 mouth, telephone, telegram, or other means of communication by a
808 duly licensed practitioner licensed by the laws of the state to
809 prescribe such drugs or medicinal supplies, issued in good faith
810 and in the course of professional practice, intended to be
811 filled, compounded, or dispensed by another person licensed by
812 the laws of the state to do so, and meeting the requirements of

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813 s. 893.04. The term also includes an order for drugs or
814 medicinal supplies so transmitted or written by a physician,
815 dentist, veterinarian, or other practitioner licensed to
816 practice in a state other than Florida, but only if the
817 pharmacist called upon to fill such an order determines, in the
818 exercise of his or her professional judgment, that the order was
819 issued pursuant to a valid patient-physician relationship, that
820 it is authentic, and that the drugs or medicinal supplies so
821 ordered are considered necessary for the continuation of
822 treatment of a chronic or recurrent illness. However, if the
823 physician writing the prescription is not known to the
824 pharmacist, the pharmacist shall obtain proof to a reasonable
825 certainty of the validity of said prescription. A prescription
826 order for a controlled substance shall not be issued on the same
827 prescription blank with another prescription order for a
828 controlled substance which is named or described in a different
829 schedule, nor shall any prescription order for a controlled
830 substance be issued on the same prescription blank as a
831 prescription order for a medicinal drug, as defined in s.
832 465.003~~(8)~~, which does not fall within the definition of a
833 controlled substance as defined in this act.

834 Section 24. The Division of Law Revision and Information
835 is directed to replace the phrase "this act" wherever it occurs
836 in sections 458.3265 and 459.0137, Florida Statutes, as amended
837 by this act, with the assigned chapter number of this act.

838 Section 25. This act shall take effect July 1, 2013.