

20102272er

1  
2 An act relating to controlled substances; amending s.  
3 456.037, F.S.; providing that pain-management clinics  
4 that are required to be registered with the Department  
5 of Health are business establishments; amending s.  
6 456.057, F.S.; providing that the Department of Health  
7 is not required to attempt to obtain authorization  
8 from a patient for the release of the patient's  
9 medical records under certain circumstances;  
10 authorizing the department to obtain patient records  
11 without authorization or subpoena if the department  
12 has probable cause to believe that certain violations  
13 have occurred or are occurring; repealing s.  
14 458.309(4), (5), and (6), F.S., relating to pain-  
15 management clinics; creating s. 458.3265, F.S.;  
16 requiring all privately owned pain-management clinics,  
17 or offices that primarily engage in the treatment of  
18 pain by prescribing or dispensing controlled substance  
19 medications or by employing a physician who is  
20 primarily engaged in the treatment of pain by  
21 prescribing or dispensing controlled substance  
22 medications, to register with the Department of  
23 Health; providing exceptions; requiring each location  
24 of a pain-management clinic to register separately;  
25 requiring a clinic to designate a physician who is  
26 responsible for complying with requirements related to  
27 registration and operation of the clinic; requiring  
28 the department to deny registration or revoke the  
29 registration of a pain-management clinic for certain

20102272er

30 conditions; authorizing the department to revoke a  
31 clinic's certificate of registration and prohibit  
32 physicians associated with the clinic from practicing  
33 at the clinic's location; requiring a pain-management  
34 clinic to cease operating if its registration  
35 certificate is revoked or suspended; requiring certain  
36 named persons to remove all signs and symbols  
37 identifying the premises as a pain-management clinic;  
38 requiring a pain-management clinic that has had its  
39 registration revoked or suspended to advise the  
40 department of the disposition of the medicinal drugs  
41 located on the premises; providing that medicinal  
42 drugs that are purchased or held by a pain-management  
43 clinic that is not registered may be deemed  
44 adulterated; prohibiting any person acting as an  
45 individual or as part of a group from applying for a  
46 certificate to operate a pain-management clinic for a  
47 certain period after the date the person's  
48 registration certificate is revoked; providing that a  
49 change of ownership of a registered pain-management  
50 clinic requires submission of a new registration  
51 application; providing the responsibilities of a  
52 physician who provides professional services at a  
53 pain-management clinic; requiring the department to  
54 inspect pain-management clinics and its patient  
55 records; providing an exception to inspection by the  
56 department; requiring a pain-management clinic to  
57 document corrective action; requiring the department  
58 and the Board of Medicine to adopt rules; authorizing

20102272er

59 the department to impose fines, deny a clinic's  
60 registration, or revoke a clinic's registration;  
61 amending s. 458.327, F.S.; providing that the  
62 commission of certain specified acts involving a  
63 nonregistered pain-management clinic constitutes a  
64 felony of the third degree or a misdemeanor of the  
65 first degree; amending s. 458.331, F.S.; providing  
66 additional acts that constitute grounds for  
67 disciplinary actions against health professional  
68 licensees; repealing s. 459.005(3), (4), and (5),  
69 F.S., relating to pain-management clinics; creating s.  
70 459.0137, F.S.; requiring all privately owned pain-  
71 management clinics, or offices that primarily engage  
72 in the treatment of pain by prescribing or dispensing  
73 controlled substance medications or by employing an  
74 osteopathic physician who is primarily engaged in the  
75 treatment of pain by prescribing or dispensing  
76 controlled substance medications, to register with the  
77 department; providing exceptions; requiring each  
78 location of a pain-management clinic to register  
79 separately; requiring a clinic to designate an  
80 osteopathic physician who is responsible for complying  
81 with requirements related to registration and  
82 operation of the clinic; requiring the department to  
83 deny registration or revoke the registration of a  
84 pain-management clinic for certain conditions;  
85 authorizing the department to revoke a clinic's  
86 certificate of registration and prohibit osteopathic  
87 physicians associated with the clinic from practicing

20102272er

88 at the clinic's location; requiring a pain-management  
89 clinic to cease operating if its registration  
90 certificate is revoked or suspended; requiring certain  
91 named persons to remove all signs and symbols  
92 identifying the premises as a pain-management clinic;  
93 requiring a pain-management clinic that has had its  
94 registration revoked or suspended to advise the  
95 department of the disposition of the medicinal drugs  
96 located on the premises; providing that medicinal  
97 drugs that are purchased or held by a pain-management  
98 clinic that is not registered may be deemed  
99 adulterated; prohibiting any person acting as an  
100 individual or as part of a group from applying for a  
101 certificate to operate a pain-management clinic for a  
102 certain period after the date the person's  
103 registration certificate is revoked; providing that a  
104 change of ownership of a registered pain-management  
105 clinic requires submission of a new registration  
106 application; providing the responsibilities of an  
107 osteopathic physician who provides professional  
108 services at a pain-management clinic; requiring the  
109 department to inspect pain-management clinics and its  
110 patient records; providing an exception to inspection  
111 by the department; requiring a pain-management clinic  
112 to document corrective action; requiring the  
113 department and the Board of Osteopathic Medicine to  
114 adopt rules; authorizing the department to impose  
115 fines, deny a clinic's registration, or revoke a  
116 clinic's registration; amending s. 459.013, F.S.;

20102272er

117 providing that the commission of certain specified  
118 acts involving a nonregistered pain-management clinic  
119 constitutes a felony of the third degree or a  
120 misdemeanor of the first degree; amending s. 459.015,  
121 F.S.; providing additional acts that constitute  
122 grounds for disciplinary actions against health  
123 professional licensees; amending s. 465.0276, F.S.;

124 prohibiting registered dispensing practitioners from  
125 dispensing more than a specified amount of certain  
126 controlled substances; providing penalties; providing  
127 exceptions; amending s. 893.055, F.S.; defining the  
128 term "program manager"; requiring that the program  
129 manager work with certain licensure boards and  
130 stakeholders to develop rules; authorizing the program  
131 manager to provide relevant information to law  
132 enforcement agencies under certain circumstances;

133 amending s. 893.0551, F.S.; providing for disclosure  
134 of confidential and exempt information to applicable  
135 law enforcement; providing an effective date.

136  
137 Be It Enacted by the Legislature of the State of Florida:

138  
139 Section 1. Subsection (5) of section 456.037, Florida  
140 Statutes, is amended to read:

141 456.037 Business establishments; requirements for active  
142 status licenses; delinquency; discipline; applicability.—

143 (5) This section applies to any business establishment  
144 registered, permitted, or licensed by the department to do  
145 business. Business establishments include, but are not limited

20102272er

146 to, dental laboratories, electrology facilities, massage  
147 establishments, ~~and~~ pharmacies, and pain-management clinics  
148 required to be registered under s. 458.3265 or s. 459.0137.

149 Section 2. Paragraph (a) of subsection (9) of section  
150 456.057, Florida Statutes, is amended to read:

151 456.057 Ownership and control of patient records; report or  
152 copies of records to be furnished.—

153 (9) (a) 1. The department may obtain patient records pursuant  
154 to a subpoena without written authorization from the patient if  
155 the department and the probable cause panel of the appropriate  
156 board, if any, find reasonable cause to believe that a health  
157 care practitioner has excessively or inappropriately prescribed  
158 any controlled substance specified in chapter 893 in violation  
159 of this chapter or any professional practice act or that a  
160 health care practitioner has practiced his or her profession  
161 below that level of care, skill, and treatment required as  
162 defined by this chapter or any professional practice act and  
163 also find that appropriate, reasonable attempts were made to  
164 obtain a patient release. Notwithstanding the foregoing, the  
165 department need not attempt to obtain a patient release when  
166 investigating an offense involving the inappropriate  
167 prescribing, overprescribing, or diversion of controlled  
168 substances and the offense involves a pain-management clinic.  
169 The department may obtain patient records without patient  
170 authorization or subpoena from any pain-management clinic  
171 required to be licensed if the department has probable cause to  
172 believe that a violation of any provision of s. 458.3265 or s.  
173 459.0137 is occurring or has occurred and reasonably believes  
174 that obtaining such authorization is not feasible due to the

20102272er

175 volume of the dispensing and prescribing activity involving  
176 controlled substances and that obtaining patient authorization  
177 or the issuance of a subpoena would jeopardize the  
178 investigation.

179 2. The department may obtain patient records and insurance  
180 information pursuant to a subpoena without written authorization  
181 from the patient if the department and the probable cause panel  
182 of the appropriate board, if any, find reasonable cause to  
183 believe that a health care practitioner has provided inadequate  
184 medical care based on termination of insurance and also find  
185 that appropriate, reasonable attempts were made to obtain a  
186 patient release.

187 3. The department may obtain patient records, billing  
188 records, insurance information, provider contracts, and all  
189 attachments thereto pursuant to a subpoena without written  
190 authorization from the patient if the department and probable  
191 cause panel of the appropriate board, if any, find reasonable  
192 cause to believe that a health care practitioner has submitted a  
193 claim, statement, or bill using a billing code that would result  
194 in payment greater in amount than would be paid using a billing  
195 code that accurately describes the services performed, requested  
196 payment for services that were not performed by that health care  
197 practitioner, used information derived from a written report of  
198 an automobile accident generated pursuant to chapter 316 to  
199 solicit or obtain patients personally or through an agent  
200 regardless of whether the information is derived directly from  
201 the report or a summary of that report or from another person,  
202 solicited patients fraudulently, received a kickback as defined  
203 in s. 456.054, violated the patient brokering provisions of s.

20102272er

204 817.505, or presented or caused to be presented a false or  
205 fraudulent insurance claim within the meaning of s.  
206 817.234(1) (a), and also find that, within the meaning of s.  
207 817.234(1) (a), patient authorization cannot be obtained because  
208 the patient cannot be located or is deceased, incapacitated, or  
209 suspected of being a participant in the fraud or scheme, and if  
210 the subpoena is issued for specific and relevant records.

211 4. Notwithstanding subparagraphs 1.-3., when the department  
212 investigates a professional liability claim or undertakes action  
213 pursuant to s. 456.049 or s. 627.912, the department may obtain  
214 patient records pursuant to a subpoena without written  
215 authorization from the patient if the patient refuses to  
216 cooperate or if the department attempts to obtain a patient  
217 release and the failure to obtain the patient records would be  
218 detrimental to the investigation.

219 Section 3. Subsections (4), (5), and (6) of section  
220 458.309, Florida Statutes, are repealed.

221 Section 4. Section 458.3265, Florida Statutes, is created  
222 to read:

223 458.3265 Pain-management clinics.-

224 (1) REGISTRATION.-

225 (a) All privately owned pain-management clinics,  
226 facilities, or offices, hereinafter referred to as "clinics,"  
227 which advertise in any medium for any type of pain-management  
228 services, or employ a physician who is primarily engaged in the  
229 treatment of pain by prescribing or dispensing controlled  
230 substance medications, must register with the department unless:

231 1. That clinic is licensed as a facility pursuant to  
232 chapter 395;

20102272er

233       2. The majority of the physicians who provide services in  
234 the clinic primarily provide surgical services;

235       3. The clinic is owned by a publicly held corporation whose  
236 shares are traded on a national exchange or on the over-the-  
237 counter market and whose total assets at the end of the  
238 corporation's most recent fiscal quarter exceeded \$50 million;

239       4. The clinic is affiliated with an accredited medical  
240 school at which training is provided for medical students,  
241 residents, or fellows;

242       5. The clinic does not prescribe or dispense controlled  
243 substances for the treatment of pain; or

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

246       (b) Each clinic location shall be registered separately  
247 regardless of whether the clinic is operated under the same  
248 business name or management as another clinic.

249       (c) As a part of registration, a clinic must designate a  
250 physician who is responsible for complying with all requirements  
251 related to registration and operation of the clinic in  
252 compliance with this section. Within 10 days after termination  
253 of a designated physician, the clinic must notify the department  
254 of the identity of another designated physician for that clinic.  
255 The designated physician shall have a full, active, and  
256 unencumbered license under this chapter or chapter 459 and shall  
257 practice at the clinic location for which the physician has  
258 assumed responsibility. Failing to have a licensed designated  
259 physician practicing at the location of the registered clinic  
260 may be the basis for a summary suspension of the clinic  
261 registration certificate as described in s. 456.073(8) for a

20102272er

262 license or s. 120.60(6).

263 (d) The department shall deny registration to any clinic  
264 that is not fully owned by a physician licensed under this  
265 chapter or chapter 459 or a group of physicians, each of whom is  
266 licensed under this chapter or chapter 459; or that is not a  
267 health care clinic licensed under part X of chapter 400.

268 (e) The department shall deny registration to any pain-  
269 management clinic owned by or with any contractual or employment  
270 relationship with a physician:

271 1. Whose Drug Enforcement Administration number has ever  
272 been revoked.

273 2. Whose application for a license to prescribe, dispense,  
274 or administer a controlled substance has been denied by any  
275 jurisdiction.

276 3. Who has been convicted of or plead guilty or nolo  
277 contendere to, regardless of adjudication, an offense that  
278 constitutes a felony for receipt of illicit and diverted drugs,  
279 including a controlled substance listed in Schedule I, Schedule  
280 II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in  
281 this state, any other state, or the United States.

282 (f) If the department finds that a pain-management clinic  
283 does not meet the requirement of paragraph (d) or is owned,  
284 directly or indirectly, by a person meeting any criteria listed  
285 in paragraph (e), the department shall revoke the certificate of  
286 registration previously issued by the department. As determined  
287 by rule, the department may grant an exemption to denying a  
288 registration or revoking a previously issued registration if  
289 more than 10 years have elapsed since adjudication. As used in  
290 this subsection, the term "convicted" includes an adjudication

20102272er

291 of guilt following a plea of guilty or nolo contendere or the  
292 forfeiture of a bond when charged with a crime.

293 (g) The department may revoke the clinic's certificate of  
294 registration and prohibit all physicians associated with that  
295 pain-management clinic from practicing at that clinic location  
296 based upon an annual inspection and evaluation of the factors  
297 described in subsection (3).

298 (h) If the registration of a pain-management clinic is  
299 revoked or suspended, the designated physician of the pain-  
300 management clinic, the owner or lessor of the pain-management  
301 clinic property, the manager, and the proprietor shall cease to  
302 operate the facility as a pain-management clinic as of the  
303 effective date of the suspension or revocation.

304 (i) If a pain-management clinic registration is revoked or  
305 suspended, the designated physician of the pain-management  
306 clinic, the owner or lessor of the clinic property, the manager,  
307 or the proprietor is responsible for removing all signs and  
308 symbols identifying the premises as a pain-management clinic.

309 (j) Upon the effective date of the suspension or  
310 revocation, the designated physician of the pain-management  
311 clinic shall advise the department of the disposition of the  
312 medicinal drugs located on the premises. The disposition is  
313 subject to the supervision and approval of the department.  
314 Medicinal drugs that are purchased or held by a pain-management  
315 clinic that is not registered may be deemed adulterated pursuant  
316 to s. 499.006.

317 (k) If the clinic's registration is revoked, any person  
318 named in the registration documents of the pain-management  
319 clinic, including persons owning or operating the pain-

20102272er

320 management clinic, may not, as an individual or as a part of a  
321 group, apply to operate a pain-management clinic for 5 years  
322 after the date the registration is revoked.

323 (1) The period of suspension for the registration of a pain  
324 management clinic shall be prescribed by the department, but may  
325 not exceed 1 year.

326 (m) A change of ownership of a registered pain-management  
327 clinic requires submission of a new registration application.

328 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities  
329 apply to any physician who provides professional services in a  
330 pain-management clinic that is required to be registered in  
331 subsection (1).

332 (a) A physician may not practice medicine in a pain-  
333 management clinic, as described in subsection (4), if:

334 1. The pain-management clinic is not registered with the  
335 department as required by this section; or

336 2. Effective July 1, 2012, the physician has not  
337 successfully completed a pain medicine fellowship that is  
338 accredited by the Accreditation Council for Graduate Medical  
339 Education or a pain medicine residency that is accredited by the  
340 Accreditation Council for Graduate Medical Education or, prior  
341 to July 1, 2012, does not comply with rules adopted by the  
342 board.

343  
344 Any physician who qualifies to practice medicine in a pain-  
345 management clinic pursuant to rules adopted by the Board of  
346 Medicine as of July 1, 2012, may continue to practice medicine  
347 in a pain-management clinic as long as the physician continues  
348 to meet the qualifications set forth in the board rules. A

20102272er

349 physician who violates this paragraph is subject to disciplinary  
350 action by his or her appropriate medical regulatory board.

351 (b) A person may not dispense any medication, including a  
352 controlled substance, on the premises of a registered pain-  
353 management clinic unless he or she is a physician licensed under  
354 this chapter or chapter 459.

355 (c) A physician must perform a physical examination of a  
356 patient on the same day that he or she dispenses or prescribes a  
357 controlled substance to a patient at a pain-management clinic.  
358 If the physician prescribes or dispenses more than a 72-hour  
359 dose of controlled substances for the treatment of chronic  
360 nonmalignant pain, the physician must document in the patient's  
361 record the reason for prescribing or dispensing that quantity.

362 (d) A physician authorized to prescribe controlled  
363 substances who practices at a pain-management clinic is  
364 responsible for maintaining the control and security of his or  
365 her prescription blanks and any other method used for  
366 prescribing controlled substance pain medication. The physician  
367 shall comply with the requirements for counterfeit-resistant  
368 prescription blanks in s. 893.065 and the rules adopted pursuant  
369 to that section. The physician shall notify in writing the  
370 department within 24 hours following any theft or loss of a  
371 prescription blank or breach of any other method for prescribing  
372 pain medication.

373 (e) The designated physician of a pain-management clinic  
374 shall notify the applicable board in writing of the date of  
375 termination of employment within 10 days after terminating his  
376 or her employment with a pain-management clinic that is required  
377 to be registered under subsection (1).

20102272er

378 (3) INSPECTION.—

379 (a) The department shall inspect the pain-management clinic  
380 annually, including a review of the patient records, to ensure  
381 that it complies with this section and the rules of the Board of  
382 Medicine adopted pursuant to subsection (4) unless the clinic is  
383 accredited by a nationally recognized accrediting agency  
384 approved by the Board of Medicine.

385 (b) During an onsite inspection, the department shall make  
386 a reasonable attempt to discuss each violation with the owner or  
387 designated physician of the pain-management clinic before  
388 issuing a formal written notification.

389 (c) Any action taken to correct a violation shall be  
390 documented in writing by the owner or designated physician of  
391 the pain-management clinic and verified by followup visits by  
392 departmental personnel.

393 (4) RULEMAKING.—

394 (a) The department shall adopt rules necessary to  
395 administer the registration and inspection of pain-management  
396 clinics which establish the specific requirements, procedures,  
397 forms, and fees.

398 (b) The department shall adopt a rule defining what  
399 constitutes practice by a designated physician at the clinic  
400 location for which the physician has assumed responsibility, as  
401 set forth in subsection (1). When adopting the rule, the  
402 department shall consider the number of clinic employees, the  
403 location of the pain-management clinic, the clinic's hours of  
404 operation, and the amount of controlled substances being  
405 prescribed, dispensed, or administered at the pain-management  
406 clinic.

20102272er

407 (c) The Board of Medicine shall adopt a rule establishing  
408 the maximum number of prescriptions for Schedule II or Schedule  
409 III controlled substances or the controlled substance Alprazolam  
410 which may be written at any one registered pain-management  
411 clinic during any 24-hour period.

412 (d) The Board of Medicine shall adopt rules setting forth  
413 standards of practice for physicians practicing in privately  
414 owned pain-management clinics that primarily engage in the  
415 treatment of pain by prescribing or dispensing controlled  
416 substance medications. Such rules shall address, but need not be  
417 limited to:

418 1. Facility operations;

419 2. Physical operations;

420 3. Infection control requirements;

421 4. Health and safety requirements;

422 5. Quality assurance requirements;

423 6. Patient records;

424 7. Training requirements for all facility health care  
425 practitioners who are not regulated by another board;

426 8. Inspections; and

427 9. Data collection and reporting requirements.

428  
429 A physician is primarily engaged in the treatment of pain by  
430 prescribing or dispensing controlled substance medications when  
431 the majority of the patients seen are prescribed or dispensed  
432 controlled substance medications for the treatment of chronic  
433 nonmalignant pain. Chronic nonmalignant pain is pain unrelated  
434 to cancer which persists beyond the usual course of the disease  
435 or the injury that is the cause of the pain or more than 90 days

20102272er

436 after surgery.

437 (5) PENALTIES; ENFORCEMENT.—

438 (a) The department may impose an administrative fine on the  
439 clinic of up to \$5,000 per violation for violating the  
440 requirements of this section; chapter 499, the Florida Drug and  
441 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and  
442 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug  
443 Abuse Prevention and Control Act; chapter 893, the Florida  
444 Comprehensive Drug Abuse Prevention and Control Act; or the  
445 rules of the department. In determining whether a penalty is to  
446 be imposed, and in fixing the amount of the fine, the department  
447 shall consider the following factors:

448 1. The gravity of the violation, including the probability  
449 that death or serious physical or emotional harm to a patient  
450 has resulted, or could have resulted, from the pain-management  
451 clinic's actions or the actions of the physician, the severity  
452 of the action or potential harm, and the extent to which the  
453 provisions of the applicable laws or rules were violated.

454 2. What actions, if any, the owner or designated physician  
455 took to correct the violations.

456 3. Whether there were any previous violations at the pain-  
457 management clinic.

458 4. The financial benefits that the pain-management clinic  
459 derived from committing or continuing to commit the violation.

460 (b) Each day a violation continues after the date fixed for  
461 termination of the violation as ordered by the department  
462 constitutes an additional, separate, and distinct violation.

463 (c) The department may impose a fine and, in the case of an  
464 owner-operated pain-management clinic, revoke or deny a pain-

20102272er

465 management clinic's registration, if the clinic's designated  
466 physician knowingly and intentionally misrepresents actions  
467 taken to correct a violation.

468 (d) An owner or designated physician of a pain-management  
469 clinic who concurrently operates an unregistered pain-management  
470 clinic is subject to an administrative fine of \$5,000 per day.

471 (e) If the owner of a pain-management clinic that requires  
472 registration fails to apply to register the clinic upon a  
473 change-of-ownership and operates the clinic under the new  
474 ownership, the owner is subject to a fine of \$5,000.

475 Section 5. Section 458.327, Florida Statutes, is amended to  
476 read:

477 458.327 Penalty for violations.—

478 (1) Each of the following acts constitutes a felony of the  
479 third degree, punishable as provided in s. 775.082, s. 775.083,  
480 or s. 775.084:

481 (a) The practice of medicine or an attempt to practice  
482 medicine without a license to practice in Florida.

483 (b) The use or attempted use of a license which is  
484 suspended or revoked to practice medicine.

485 (c) Attempting to obtain or obtaining a license to practice  
486 medicine by knowing misrepresentation.

487 (d) Attempting to obtain or obtaining a position as a  
488 medical practitioner or medical resident in a clinic or hospital  
489 through knowing misrepresentation of education, training, or  
490 experience.

491 (e) Knowingly operating, owning, or managing a  
492 nonregistered pain-management clinic that is required to be  
493 registered with the Department of Health pursuant to s.

20102272er

494 458.3265(1).

495 (2) Each of the following acts constitutes a misdemeanor of  
496 the first degree, punishable as provided in s. 775.082 or s.  
497 775.083:

498 (a) Knowingly concealing information relating to violations  
499 of this chapter.

500 (b) Making any willfully false oath or affirmation whenever  
501 an oath or affirmation is required by this chapter.

502 (c) Referring any patient, for health care goods or  
503 services, to a partnership, firm, corporation, or other business  
504 entity in which the physician or the physician's employer has an  
505 equity interest of 10 percent or more unless, prior to such  
506 referral, the physician notifies the patient of his or her  
507 financial interest and of the patient's right to obtain such  
508 goods or services at the location of the patient's choice. This  
509 section does not apply to the following types of equity  
510 interest:

511 1. The ownership of registered securities issued by a  
512 publicly held corporation or the ownership of securities issued  
513 by a publicly held corporation, the shares of which are traded  
514 on a national exchange or the over-the-counter market;

515 2. A physician's own practice, whether he or she is a sole  
516 practitioner or part of a group, when the health care good or  
517 service is prescribed or provided solely for the physician's own  
518 patients and is provided or performed by the physician or under  
519 the physician's supervision; or

520 3. An interest in real property resulting in a landlord-  
521 tenant relationship between the physician and the entity in  
522 which the equity interest is held, unless the rent is

20102272er

523 determined, in whole or in part, by the business volume or  
524 profitability of the tenant or is otherwise unrelated to fair  
525 market value.

526 (d) Leading the public to believe that one is licensed as a  
527 medical doctor, or is engaged in the licensed practice of  
528 medicine, without holding a valid, active license.

529 (e) Practicing medicine or attempting to practice medicine  
530 with an inactive or delinquent license.

531 (f) Knowingly prescribing or dispensing, or causing to be  
532 prescribed or dispensed, controlled substances in a  
533 nonregistered pain-management clinic that is required to be  
534 registered with the Department of Health pursuant to s.  
535 458.3265(1).

536 Section 6. Paragraphs (oo), (pp), and (qq) are added to  
537 subsection (1) of section 458.331, Florida Statutes, to read:

538 458.331 Grounds for disciplinary action; action by the  
539 board and department.—

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

542 (oo) Applicable to a licensee who serves as the designated  
543 physician of a pain-management clinic as defined in s. 458.3265  
544 or s. 459.0137:

545 1. Registering a pain-management clinic through  
546 misrepresentation or fraud;

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

550 3. Failing to comply with any requirement of chapter 499,  
551 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the

20102272er

552 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,  
553 the Drug Abuse Prevention and Control Act; or chapter 893, the  
554 Florida Comprehensive Drug Abuse Prevention and Control Act;

555 4. Being convicted or found guilty of, regardless of  
556 adjudication to, a felony or any other crime involving moral  
557 turpitude, fraud, dishonesty, or deceit in any jurisdiction of  
558 the courts of this state, of any other state, or of the United  
559 States;

560 5. Being convicted of, or disciplined by a regulatory  
561 agency of the Federal Government or a regulatory agency of  
562 another state for any offense that would constitute a violation  
563 of this chapter;

564 6. Being convicted of, or entering a plea of guilty or nolo  
565 contendere to, regardless of adjudication, a crime in any  
566 jurisdiction of the courts of this state, of any other state, or  
567 of the United States which relates to the practice of, or the  
568 ability to practice, a licensed health care profession;

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

573 8. Dispensing any medicinal drug based upon a communication  
574 that purports to be a prescription as defined in s. 465.003(14)  
575 or s. 893.02 if the dispensing practitioner knows or has reason  
576 to believe that the purported prescription is not based upon a  
577 valid practitioner-patient relationship; or

578 9. Failing to timely notify the board of the date of his or  
579 her termination from a pain-management clinic as required by s.  
580 458.3265(2).

20102272er

581 (pp) Failing to timely notify the department of the theft  
582 of prescription blanks from a pain-management clinic or a breach  
583 of other methods for prescribing within 24 hours as required by  
584 s. 458.3265(2).

585 (qq) Promoting or advertising through any communication  
586 media the use, sale, or dispensing of any controlled substance  
587 appearing on any schedule in chapter 893.

588 Section 7. Subsections (3), (4), and (5) of section  
589 459.005, Florida Statutes, are repealed.

590 Section 8. Section 459.0137, Florida Statutes, is created  
591 to read:

592 459.0137 Pain-management clinics.-

593 (1) REGISTRATION.-

594 (a) All privately owned pain-management clinics,  
595 facilities, or offices, hereinafter referred to as "clinics,"  
596 which advertise in any medium for any type of pain-management  
597 services, or employ an osteopathic physician who is primarily  
598 engaged in the treatment of pain by prescribing or dispensing  
599 controlled substance medications, must register with the  
600 department unless:

601 1. That clinic is licensed as a facility pursuant to  
602 chapter 395;

603 2. The majority of the physicians who provide services in  
604 the clinic primarily provide surgical services;

605 3. The clinic is owned by a publicly held corporation whose  
606 shares are traded on a national exchange or on the over-the-  
607 counter market and whose total assets at the end of the  
608 corporation's most recent fiscal quarter exceeded \$50 million;

609 4. The clinic is affiliated with an accredited medical

20102272er

610 school at which training is provided for medical students,  
611 residents, or fellows;

612 5. The clinic does not prescribe or dispense controlled  
613 substances for the treatment of pain; or

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

616 (b) Each clinic location shall be registered separately  
617 regardless of whether the clinic is operated under the same  
618 business name or management as another clinic.

619 (c) As a part of registration, a clinic must designate an  
620 osteopathic physician who is responsible for complying with all  
621 requirements related to registration and operation of the clinic  
622 in compliance with this section. Within 10 days after  
623 termination of a designated osteopathic physician, the clinic  
624 must notify the department of the identity of another designated  
625 physician for that clinic. The designated physician shall have a  
626 full, active, and unencumbered license under chapter 458 or this  
627 chapter and shall practice at the clinic location for which the  
628 physician has assumed responsibility. Failing to have a licensed  
629 designated osteopathic physician practicing at the location of  
630 the registered clinic may be the basis for a summary suspension  
631 of the clinic registration certificate as described in s.  
632 456.073(8) for a license or s. 120.60(6).

633 (d) The department shall deny registration to any clinic  
634 that is not fully owned by a physician licensed under chapter  
635 458 or this chapter or a group of physicians, each of whom is  
636 licensed under chapter 458 or this chapter; or that is not a  
637 health care clinic licensed under part X of chapter 400.

638 (e) The department shall deny registration to any pain-

20102272er

639 management clinic owned by or with any contractual or employment  
640 relationship with a physician:

641 1. Whose Drug Enforcement Administration number has ever  
642 been revoked.

643 2. Whose application for a license to prescribe, dispense,  
644 or administer a controlled substance has been denied by any  
645 jurisdiction.

646 3. Who has been convicted of or plead guilty or nolo  
647 contendere to, regardless of adjudication, an offense that  
648 constitutes a felony for receipt of illicit and diverted drugs,  
649 including a controlled substance listed in Schedule I, Schedule  
650 II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in  
651 this state, any other state, or the United States.

652 (f) If the department finds that a pain-management clinic  
653 does not meet the requirement of paragraph (d) or is owned,  
654 directly or indirectly, by a person meeting any criteria listed  
655 in paragraph (e), the department shall revoke the certificate of  
656 registration previously issued by the department. As determined  
657 by rule, the department may grant an exemption to denying a  
658 registration or revoking a previously issued registration if  
659 more than 10 years have elapsed since adjudication. As used in  
660 this subsection, the term "convicted" includes an adjudication  
661 of guilt following a plea of guilty or nolo contendere or the  
662 forfeiture of a bond when charged with a crime.

663 (g) The department may revoke the clinic's certificate of  
664 registration and prohibit all physicians associated with that  
665 pain-management clinic from practicing at that clinic location  
666 based upon an annual inspection and evaluation of the factors  
667 described in subsection (3).

20102272er

668       (h) If the registration of a pain-management clinic is  
669 revoked or suspended, the designated physician of the pain-  
670 management clinic, the owner or lessor of the pain-management  
671 clinic property, the manager, and the proprietor shall cease to  
672 operate the facility as a pain-management clinic as of the  
673 effective date of the suspension or revocation.

674       (i) If a pain-management clinic registration is revoked or  
675 suspended, the designated physician of the pain-management  
676 clinic, the owner or lessor of the clinic property, the manager,  
677 or the proprietor is responsible for removing all signs and  
678 symbols identifying the premises as a pain-management clinic.

679       (j) Upon the effective date of the suspension or  
680 revocation, the designated physician of the pain-management  
681 clinic shall advise the department of the disposition of the  
682 medicinal drugs located on the premises. The disposition is  
683 subject to the supervision and approval of the department.  
684 Medicinal drugs that are purchased or held by a pain-management  
685 clinic that is not registered may be deemed adulterated pursuant  
686 to s. 499.006.

687       (k) If the clinic's registration is revoked, any person  
688 named in the registration documents of the pain-management  
689 clinic, including persons owning or operating the pain-  
690 management clinic, may not as an individual or as a part of a  
691 group, make application for a permit to operate a pain-  
692 management clinic for 5 years after the date the registration is  
693 revoked.

694       (l) The period of suspension for the registration of a pain  
695 management clinic shall be prescribed by the department, but may  
696 not exceed 1 year.

20102272er

697 (m) A change of ownership of a registered pain-management  
698 clinic requires submission of a new registration application.

699 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities  
700 apply to any osteopathic physician who provides professional  
701 services in a pain-management clinic that is required to be  
702 registered in subsection (1).

703 (a) An osteopathic physician may not practice medicine in a  
704 pain-management clinic, as described in subsection (4), if:

705 1. The pain-management clinic is not registered with the  
706 department as required by this section; or

707 2. Effective July 1, 2012, the physician has not  
708 successfully completed a pain medicine fellowship that is  
709 accredited by the Accreditation Council for Graduate Medical  
710 Education or the American Osteopathic Association or a pain  
711 medicine residency that is accredited by the Accreditation  
712 Council for Graduate Medical Education or the American  
713 Osteopathic Association or, prior to July 1, 2012, does not  
714 comply with rules adopted by the board.

715  
716 Any physician who qualifies to practice medicine in a pain-  
717 management clinic pursuant to rules adopted by the Board of  
718 Osteopathic Medicine as of July 1, 2012, may continue to  
719 practice medicine in a pain-management clinic as long as the  
720 physician continues to meet the qualifications set forth in the  
721 board rules. An osteopathic physician who violates this  
722 paragraph is subject to disciplinary action by his or her  
723 appropriate medical regulatory board.

724 (b) A person may not dispense any medication, including a  
725 controlled substance, on the premises of a registered pain-

20102272er

726 management clinic unless he or she is a physician licensed under  
727 this chapter or chapter 458.

728 (c) An osteopathic physician must perform a physical  
729 examination of a patient on the same day that he or she  
730 dispenses or prescribes a controlled substance to a patient at a  
731 pain-management clinic. If the osteopathic physician prescribes  
732 or dispenses more than a 72-hour dose of controlled substances  
733 for the treatment of chronic nonmalignant pain, the osteopathic  
734 physician must document in the patient's record the reason for  
735 prescribing or dispensing that quantity.

736 (d) An osteopathic physician authorized to prescribe  
737 controlled substances who practices at a pain-management clinic  
738 is responsible for maintaining the control and security of his  
739 or her prescription blanks and any other method used for  
740 prescribing controlled substance pain medication. The  
741 osteopathic physician shall comply with the requirements for  
742 counterfeit-resistant prescription blanks in s. 893.065 and the  
743 rules adopted pursuant to that section. The osteopathic  
744 physician shall notify in writing the department within 24 hours  
745 following any theft or loss of a prescription blank or breach of  
746 any other method for prescribing pain medication.

747 (e) The designated osteopathic physician of a pain-  
748 management clinic shall notify the applicable board in writing  
749 of the date of termination of employment within 10 days after  
750 terminating his or her employment with a pain-management clinic  
751 that is required to be registered under subsection (1).

752 (3) INSPECTION.—

753 (a) The department shall inspect the pain-management clinic  
754 annually, including a review of the patient records, to ensure

20102272er

755 that it complies with this section and the rules of the Board of  
756 Osteopathic Medicine adopted pursuant to subsection (4) unless  
757 the clinic is accredited by a nationally recognized accrediting  
758 agency approved by the Board of Osteopathic Medicine.

759 (b) During an onsite inspection, the department shall make  
760 a reasonable attempt to discuss each violation with the owner or  
761 designated physician of the pain-management clinic before  
762 issuing a formal written notification.

763 (c) Any action taken to correct a violation shall be  
764 documented in writing by the owner or designated physician of  
765 the pain-management clinic and verified by followup visits by  
766 departmental personnel.

767 (4) RULEMAKING.—

768 (a) The department shall adopt rules necessary to  
769 administer the registration and inspection of pain-management  
770 clinics which establish the specific requirements, procedures,  
771 forms, and fees.

772 (b) The department shall adopt a rule defining what  
773 constitutes practice by a designated osteopathic physician at  
774 the clinic location for which the physician has assumed  
775 responsibility, as set forth in subsection (1). When adopting  
776 the rule, the department shall consider the number of clinic  
777 employees, the location of the pain-management clinic, the  
778 clinic's hours of operation, and the amount of controlled  
779 substances being prescribed, dispensed, or administered at the  
780 pain-management clinic.

781 (c) The Board of Osteopathic Medicine shall adopt a rule  
782 establishing the maximum number of prescriptions for Schedule II  
783 or Schedule III controlled substances or the controlled

20102272er

784 substance Alprazolam which may be written at any one registered  
785 pain-management clinic during any 24-hour period.

786 (d) The Board of Osteopathic Medicine shall adopt rules  
787 setting forth standards of practice for osteopathic physicians  
788 practicing in privately owned pain-management clinics that  
789 primarily engage in the treatment of pain by prescribing or  
790 dispensing controlled substance medications. Such rules shall  
791 address, but need not be limited to:

- 792 1. Facility operations;
- 793 2. Physical operations;
- 794 3. Infection control requirements;
- 795 4. Health and safety requirements;
- 796 5. Quality assurance requirements;
- 797 6. Patient records;
- 798 7. Training requirements for all facility health care  
799 practitioners who are not regulated by another board;
- 800 8. Inspections; and
- 801 9. Data collection and reporting requirements.

802

803 An osteopathic physician is primarily engaged in the treatment  
804 of pain by prescribing or dispensing controlled substance  
805 medications when the majority of the patients seen are  
806 prescribed or dispensed controlled substance medications for the  
807 treatment of chronic nonmalignant pain. Chronic nonmalignant  
808 pain is pain unrelated to cancer which persists beyond the usual  
809 course of the disease or the injury that is the cause of the  
810 pain or more than 90 days after surgery.

811 (5) PENALTIES; ENFORCEMENT.—

812 (a) The department may impose an administrative fine on the

20102272er

813 clinic of up to \$5,000 per violation for violating the  
814 requirements of this section; chapter 499, the Florida Drug and  
815 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and  
816 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug  
817 Abuse Prevention and Control Act; chapter 893, the Florida  
818 Comprehensive Drug Abuse Prevention and Control Act; or the  
819 rules of the department. In determining whether a penalty is to  
820 be imposed, and in fixing the amount of the fine, the department  
821 shall consider the following factors:

822 1. The gravity of the violation, including the probability  
823 that death or serious physical or emotional harm to a patient  
824 has resulted, or could have resulted, from the pain-management  
825 clinic's actions or the actions of the osteopathic physician,  
826 the severity of the action or potential harm, and the extent to  
827 which the provisions of the applicable laws or rules were  
828 violated.

829 2. What actions, if any, the owner or designated  
830 osteopathic physician took to correct the violations.

831 3. Whether there were any previous violations at the pain-  
832 management clinic.

833 4. The financial benefits that the pain-management clinic  
834 derived from committing or continuing to commit the violation.

835 (b) Each day a violation continues after the date fixed for  
836 termination of the violation as ordered by the department  
837 constitutes an additional, separate, and distinct violation.

838 (c) The department may impose a fine and, in the case of an  
839 owner-operated pain-management clinic, revoke or deny a pain-  
840 management clinic's registration, if the clinic's designated  
841 osteopathic physician knowingly and intentionally misrepresents

20102272er

842 actions taken to correct a violation.

843 (d) An owner or designated osteopathic physician of a pain-  
844 management clinic who concurrently operates an unregistered  
845 pain-management clinic is subject to an administrative fine of  
846 \$5,000 per day.

847 (e) If the owner of a pain-management clinic that requires  
848 registration fails to apply to register the clinic upon a  
849 change-of-ownership and operates the clinic under the new  
850 ownership, the owner is subject to a fine of \$5,000.

851 Section 9. Subsections (1) and (2) of section 459.013,  
852 Florida Statutes, are amended to read:

853 459.013 Penalty for violations.—

854 (1) Each of the following acts constitutes a felony of the  
855 third degree, punishable as provided in s. 775.082, s. 775.083,  
856 or s. 775.084:

857 (a) The practice of osteopathic medicine, or an attempt to  
858 practice osteopathic medicine, without an active license or  
859 certificate issued pursuant to this chapter.

860 (b) The practice of osteopathic medicine by a person  
861 holding a limited license, osteopathic faculty certificate, or  
862 other certificate issued under this chapter beyond the scope of  
863 practice authorized for such licensee or certificateholder.

864 (c) Attempting to obtain or obtaining a license to practice  
865 osteopathic medicine by knowing misrepresentation.

866 (d) Attempting to obtain or obtaining a position as an  
867 osteopathic medical practitioner or osteopathic medical resident  
868 in a clinic or hospital through knowing misrepresentation of  
869 education, training, or experience.

870 (e) Knowingly operating, owning, or managing a

20102272er

871 nonregistered pain-management clinic that is required to be  
872 registered with the Department of Health pursuant to s.  
873 459.0137(1).

874 (2) Each of the following acts constitutes a misdemeanor of  
875 the first degree, punishable as provided in s. 775.082 or s.  
876 775.083:

877 (a) Knowingly concealing information relating to violations  
878 of this chapter.

879 (b) Making any willfully false oath or affirmation whenever  
880 an oath or affirmation is required by this chapter.

881 (c) The practice of medicine as a resident or intern  
882 without holding a valid current registration pursuant to s.  
883 459.021.

884 (d) Knowingly prescribing or dispensing, or causing to be  
885 prescribed or dispensed, controlled substances in a  
886 nonregistered pain-management clinic that is required to be  
887 registered with the Department of Health pursuant to s.  
888 459.0137(1).

889 Section 10. Paragraphs (qq), (rr), and (ss) are added to  
890 subsection (1) of section 459.015, Florida Statutes, to read:

891 459.015 Grounds for disciplinary action; action by the  
892 board and department.—

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

895 (qq) Applicable to a licensee who serves as the designated  
896 physician of a pain-management clinic as defined in s. 458.3265  
897 or s. 459.0137:

898 1. Registering a pain-management clinic through  
899 misrepresentation or fraud;

20102272er

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

903       3. Failing to comply with any requirement of chapter 499,  
904 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the  
905 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,  
906 the Drug Abuse Prevention and Control Act; or chapter 893, the  
907 Florida Comprehensive Drug Abuse Prevention and Control Act;

908       4. Being convicted or found guilty of, regardless of  
909 adjudication to, a felony or any other crime involving moral  
910 turpitude, fraud, dishonesty, or deceit in any jurisdiction of  
911 the courts of this state, of any other state, or of the United  
912 States;

913       5. Being convicted of, or disciplined by a regulatory  
914 agency of the Federal Government or a regulatory agency of  
915 another state for any offense that would constitute a violation  
916 of this chapter;

917       6. Being convicted of, or entering a plea of guilty or nolo  
918 contendere to, regardless of adjudication, a crime in any  
919 jurisdiction of the courts of this state, of any other state, or  
920 of the United States which relates to the practice of, or the  
921 ability to practice, a licensed health care profession;

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

926       8. Dispensing any medicinal drug based upon a communication  
927 that purports to be a prescription as defined in s. 465.003(14)  
928 or s. 893.02 if the dispensing practitioner knows or has reason

20102272er

929 to believe that the purported prescription is not based upon a  
930 valid practitioner-patient relationship; or

931 9. Failing to timely notify the board of the date of his or  
932 her termination from a pain-management clinic as required by s.  
933 459.0137(2).

934 (rr) Failing to timely notify the department of the theft  
935 of prescription blanks from a pain-management clinic or a breach  
936 of other methods for prescribing within 24 hours as required by  
937 s. 459.0137(2).

938 (ss) Promoting or advertising through any communication  
939 media the use, sale, or dispensing of any controlled substance  
940 appearing on any schedule in chapter 893.

941 Section 11. Subsection (1) of section 465.0276, Florida  
942 Statutes, is amended to read:

943 465.0276 Dispensing practitioner.-

944 (1) (a) A person may not dispense medicinal drugs unless  
945 licensed as a pharmacist or otherwise authorized under this  
946 chapter to do so, except that a practitioner authorized by law  
947 to prescribe drugs may dispense such drugs to her or his  
948 patients in the regular course of her or his practice in  
949 compliance with this section.

950 (b) A practitioner registered under this section may not  
951 dispense more than a 72-hour supply of a controlled substance  
952 listed in Schedule II, Schedule III, Schedule IV, or Schedule V  
953 of s. 893.03 for any patient who pays for the medication by  
954 cash, check, or credit card in a clinic registered under s.  
955 458.3265 or s. 459.0137. A practitioner who violates this  
956 paragraph commits a felony of the third degree, punishable as  
957 provided in s. 775.082, s. 775.083, or s. 775.084. This

20102272er

958 paragraph does not apply to:

959 1. A practitioner who dispenses medication to a workers'  
960 compensation patient pursuant to chapter 440.

961 2. A practitioner who dispenses medication to an insured  
962 patient who pays by cash, check, or credit card to cover any  
963 applicable copayment or deductible.

964 3. The dispensing of complimentary packages of medicinal  
965 drugs to the practitioner's own patients in the regular course  
966 of her or his practice without the payment of a fee or  
967 remuneration of any kind, whether direct or indirect, as  
968 provided in subsection (5).

969 Section 12. Paragraph (j) is added to subsection (1),  
970 paragraph (d) is added to subsection (2), and paragraph (f) is  
971 added to subsection (7) of section 893.055, Florida Statutes, to  
972 read:

973 893.055 Prescription drug monitoring program.—

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

975 (j) "Program manager" means an employee of or a person  
976 contracted by the Department of Health who is designated to  
977 ensure the integrity of the prescription drug monitoring program  
978 in accordance with the requirements established in paragraphs  
979 (2) (a) and (b).

980 (2)

981 (d) The program manager shall work with professional health  
982 care licensure boards and the stakeholders listed in paragraph  
983 (b) to develop rules appropriate for identifying indicators of  
984 controlled substance abuse.

985 (7)

986 (f) The program manager, upon determining a pattern

20102272er

987 consistent with the rules established under paragraph (2)(c) and  
988 having cause to believe a violation of s. 893.13(7)(a)8.,  
989 (8)(a), or (8)(b) has occurred, may provide relevant information  
990 to the applicable law enforcement agency.

991 Section 13. Subsections (4), (5), and (6) of section  
992 893.0551, Florida Statutes, are renumbered as subsections (5),  
993 (6), and (7), respectively, and subsection (4) is added to that  
994 section, to read:

995 893.0551 Public records exemption for the prescription drug  
996 monitoring program.—

997 (4) The department shall disclose such confidential and  
998 exempt information to the applicable law enforcement agency in  
999 accordance with s. 893.055(7)(b)2. The law enforcement agency  
1000 may disclose the confidential and exempt information received  
1001 from the department to a criminal justice agency as defined in  
1002 s. 119.011 as part of an active investigation that is specific  
1003 to a violation of s. 893.13(7)(a)8., s. 893.13(8)(a), or s.  
1004 893.13(8)(b).

1005 Section 14. This act shall take effect October 1, 2010.