

By the Committee on Health Regulation; and Senators Gardiner, Aronberg, and Gelber

588-03762-10

20102722c1

1 A bill to be entitled
2 An act relating to pain management; amending s.
3 456.037, F.S.; providing that pain-management clinics
4 are business establishments that are required to be
5 registered with the Department of Health; 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; amending s. 456.071,
14 F.S.; providing for venue of judicial challenges to
15 any subpoena or order issued by the Department of
16 Health during its investigations; repealing s.
17 458.309(5), (6), and (7), F.S., relating to pain-
18 management clinics; creating s. 458.3265, F.S.;
19 requiring all privately owned pain-management clinics,
20 or offices that primarily engage in the treatment of
21 pain by prescribing or dispensing controlled substance
22 medications or by employing a physician who is
23 primarily engaged in the treatment of pain by
24 prescribing or dispensing controlled substance
25 medications, to register with the Department of Health
26 by a specified date; providing exceptions; requiring
27 each location of a pain-management clinic to register
28 separately; requiring a clinic to designate a
29 physician who is responsible for complying with

588-03762-10

20102722c1

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

588-03762-10

20102722c1

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

588-03762-10

20102722c1

88 clinic; requiring the department to deny registration
89 or revoke the registration of a pain-management clinic
90 for certain conditions; authorizing the department to
91 revoke a clinic's certificate of registration and
92 prohibit osteopathic physicians associated with the
93 clinic from practicing at the clinic's office
94 location; requiring a pain-management clinic to cease
95 operating if its registration certificate is revoked
96 or suspended; requiring certain named persons to
97 remove all signs and symbols identifying the premises
98 as a pain-management clinic; requiring a pain-
99 management clinic that has had its registration
100 revoked or suspended to advise the department of the
101 disposition of the medicinal drugs located on the
102 premises; providing that medicinal drugs that are
103 purchased or held by a pain-management clinic that is
104 not registered may be deemed adulterated; prohibiting
105 any person acting as an individual or as part of a
106 group from applying for a certificate to operate a
107 pain-management clinic for a certain period after the
108 date the person's registration certificate is revoked;
109 providing that a change of ownership of a registered
110 pain-management clinic requires submission of a new
111 registration application; providing the
112 responsibilities of an osteopathic physician who
113 provides professional services at a pain-management
114 clinic; prohibiting certain practitioners from
115 dispensing a specified dosage of certain controlled
116 substances to patients who pay by cash, check, or

588-03762-10

20102722c1

117 credit card; providing an exception; providing a
118 criminal penalty; providing for nonapplication;
119 requiring the department to inspect pain-management
120 clinics and its patient records; requiring the
121 department and the Board of Osteopathic Medicine to
122 adopt rules; authorizing the department to impose
123 fines, deny a clinic's registration, or revoke a
124 clinic's registration; amending s. 459.013, F.S.;
125 providing that the commission of certain specified
126 acts involving a nonregistered pain-management clinic
127 constitutes a felony of the third degree or a
128 misdemeanor of the first degree; amending s. 459.015,
129 F.S.; providing additional acts that constitute
130 grounds for disciplinary actions against health
131 professional licensees; providing an effective date.
132

133 Be It Enacted by the Legislature of the State of Florida:
134

135 Section 1. Subsection (5) of section 456.037, Florida
136 Statutes, is amended to read:

137 456.037 Business establishments; requirements for active
138 status licenses; delinquency; discipline; applicability.-

139 (5) This section applies to any business establishment
140 registered, permitted, or licensed by the department to do
141 business. Business establishments include, but are not limited
142 to, dental laboratories, electrology facilities, massage
143 establishments, ~~and~~ pharmacies, and pain-management clinics
144 required to be registered under s. 458.3265 or s. 459.0137.

145 Section 2. Paragraph (a) of subsection (9) of section

588-03762-10

20102722c1

146 456.057, Florida Statutes, is amended to read:

147 456.057 Ownership and control of patient records; report or
148 copies of records to be furnished.—

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

588-03762-10

20102722c1

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

183 3. The department may obtain patient records, billing
184 records, insurance information, provider contracts, and all
185 attachments thereto pursuant to a subpoena without written
186 authorization from the patient if the department and probable
187 cause panel of the appropriate board, if any, find reasonable
188 cause to believe that a health care practitioner has submitted a
189 claim, statement, or bill using a billing code that would result
190 in payment greater in amount than would be paid using a billing
191 code that accurately describes the services performed, requested
192 payment for services that were not performed by that health care
193 practitioner, used information derived from a written report of
194 an automobile accident generated pursuant to chapter 316 to
195 solicit or obtain patients personally or through an agent
196 regardless of whether the information is derived directly from
197 the report or a summary of that report or from another person,
198 solicited patients fraudulently, received a kickback as defined
199 in s. 456.054, violated the patient brokering provisions of s.
200 817.505, or presented or caused to be presented a false or
201 fraudulent insurance claim within the meaning of s.
202 817.234(1)(a), and also find that, within the meaning of s.
203 817.234(1)(a), patient authorization cannot be obtained because

588-03762-10

20102722c1

204 the patient cannot be located or is deceased, incapacitated, or
205 suspected of being a participant in the fraud or scheme, and if
206 the subpoena is issued for specific and relevant records.

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

215 Section 3. Section 456.071, Florida Statutes, is amended to
216 read:

217 456.071 Power to administer oaths, take depositions, and
218 issue subpoenas.—For the purpose of any investigation or
219 proceeding conducted by the department, the department shall
220 have the power to administer oaths, take depositions, make
221 inspections when authorized by statute, issue subpoenas which
222 shall be supported by affidavit, serve subpoenas and other
223 process, and compel the attendance of witnesses and the
224 production of books, papers, documents, and other evidence. The
225 department shall exercise this power on its own initiative or
226 whenever requested by a board or the probable cause panel of any
227 board. Challenges to, and enforcement of, the subpoenas and
228 orders shall be handled as provided in s. 120.569, except that
229 venue is in the Circuit Court for the Second Judicial Circuit,
230 in the county where the examination, investigation, or hearing
231 is conducted, or in the county in which the person resides.

232 Section 4. Subsections (4), (5), and (6) of section

588-03762-10

20102722c1

233 458.309, Florida Statutes, are repealed.

234 Section 5. Section 458.3265, Florida Statutes, is created
235 to read:

236 458.3265 Pain-management clinics.-

237 (1) REGISTRATION.-

238 (a) Effective January 4, 2010, all privately owned pain-
239 management clinics, facilities, or offices, hereinafter referred
240 to as "clinics," which advertise in any medium for any type of
241 pain-management services, or employ a physician who is primarily
242 engaged in the treatment of pain by prescribing or dispensing
243 controlled substance medications, must register with the
244 department unless:

245 1. That clinic is licensed as a facility pursuant to
246 chapter 395;

247 2. The majority of the physicians who provide services in
248 the clinic, facility, or office primarily provide surgical
249 services;

250 3. The clinic, facility, or office is owned by a publicly
251 held corporation whose shares are traded on a national exchange
252 or on the over-the-counter market and whose total assets at the
253 end of corporation's most recent fiscal quarter exceeded \$50
254 million;

255 4. The clinic, facility, or office is affiliated with an
256 accredited medical school at which training is provided for
257 medical students, residents, or fellows;

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

260 6. The clinic, facility, or office is owned by a corporate
261 entity exempt from federal taxation under 26 U.S.C. s.

588-03762-10

20102722c1

262 501(c)(3).

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

266 (c) As a part of registration, a clinic must designate a
267 physician who is responsible for complying with all requirements
268 related to registration of the clinic. The designated physician
269 shall have a full, active, and unencumbered license under this
270 chapter or chapter 459 and shall practice at the office location
271 for which the physician has assumed responsibility.

272 (d) The department shall deny registration to any clinic
273 not fully owned by a physician licensed under this chapter or
274 chapter 459 or a group of physicians licensed under this chapter
275 or chapter 459.

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

279 1. Whose Drug Enforcement Administration number has ever
280 been revoked.

281 2. Whose application for a license to prescribe, dispense,
282 or administer a controlled substance has been denied by any
283 jurisdiction.

284 3. Who has been convicted of or plead guilty or nolo
285 contender to, regardless of adjudication, an offense that
286 constitutes a felony for receipt of illicit and diverted drugs,
287 including a controlled substance listed in Schedule I, Schedule
288 II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in
289 this state, any other state, or the United States.

290 (f) If the department finds that a pain-management clinic

588-03762-10

20102722c1

291 is owned, directly or indirectly, by a person meeting any
292 criteria listed in paragraph (d) or paragraph (e), the
293 department shall revoke the certificate of registration
294 previously issued by the department. As determined by rule, the
295 department may grant an exemption to denying a registration or
296 revoking a previously issued registration if more than 10 years
297 have elapsed since adjudication. As used in this subsection, the
298 term "convicted" includes an adjudication of guilt following a
299 plea of guilty or nolo contendere or the forfeiture of a bond
300 when charged with a crime.

301 (g) The department may revoke the clinic's certificate of
302 registration and prohibit all physicians associated with that
303 pain-management clinic from practicing at that office location
304 based upon an annual inspection and evaluation of the factors
305 described in subsection (3).

306 (h) If the registration of a pain-management clinic is
307 revoked or suspended, the designated physician of the pain-
308 management clinic, the owner or lessor of the pain-management
309 clinic property, the manager, and the proprietor shall cease to
310 operate the facility as a pain-management clinic as of the
311 effective date of the suspension or revocation.

312 (i) If a pain-management clinic registration is revoked or
313 suspended, the designated physician of the pain-management
314 clinic, the owner or lessor of the clinic property, the manager,
315 or the proprietor is responsible for removing all signs and
316 symbols identifying the premises as a pain-management clinic.

317 (j) Upon the effective date of the suspension or
318 revocation, the designated physician of the pain-management
319 clinic shall advise the department of the disposition of the

588-03762-10

20102722c1

320 medicinal drugs located on the premises. The disposition is
321 subject to the supervision and approval of the department.
322 Medicinal drugs that are purchased or held by a pain-management
323 clinic that is not registered may be deemed adulterated pursuant
324 to s. 499.006.

325 (k) If the clinic's registration is revoked, any person
326 named in the registration documents of the pain-management
327 clinic, including persons owning or operating the pain-
328 management clinic, may not, as an individual or as a part of a
329 group, apply to operate a pain-management clinic for 5 years
330 after the date the registration is revoked.

331 (l) The period of the suspension shall be prescribed by the
332 department, but may not exceed 1 year.

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

335 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
336 apply to any physician who provides professional services in a
337 pain-management clinic that is required to be registered in
338 subsection (1).

339 (a) A physician may not practice medicine in a pain-
340 management clinic, as described in subsection (4), if the pain-
341 management clinic is not registered with the department as
342 required by this section. A physician who violates this
343 paragraph is subject to review by his or her appropriate medical
344 regulatory board.

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

588-03762-10

20102722c1

349 (c) After a physical examination of the patient, a
350 physician, on the same day of dispensing or prescribing a
351 controlled substance, must document in the patient's record the
352 reason for prescribing or dispensing more than a 72-hour dose of
353 a controlled substance for the treatment of chronic nonmalignant
354 pain.

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

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

370 (f) A practitioner registered under s. 465.0276 who
371 practices at a pain-management clinic that is required to be
372 registered under this section or s. 459.0137, may not dispense
373 more than a 72-hour supply of a controlled substance listed in
374 Schedule II or Schedule III, as provided in s. 893.03, to
375 patients who pay by cash, check, or credit card for such
376 medications. This limitation does not apply to patients who have
377 insurance coverage for the medications and are using cash,

588-03762-10

20102722c1

378 check, or a credit card to meet a required copayment or
379 deductible. A practitioner who knowingly violates this paragraph
380 commits a felony of the third degree, punishable as provided in
381 s. 775.082, s. 775.083, or s. 775.084. This paragraph does not
382 apply to practitioners who dispense medications to
383 workers' compensation patients pursuant to chapter 440. This
384 paragraph does not apply to the dispensing of complimentary
385 packages of medicinal drugs to the practitioner's own patients
386 in the regular course of his or her practice without the payment
387 of fee or remuneration of any kind, whether direct or indirect,
388 and in conformity with the requirements of this subsection. This
389 paragraph does not apply to controlled substances dispensed in
390 the health care system of the Department of Corrections.

391 (3) INSPECTION.—

392 (a) The department shall inspect the clinic annually,
393 including a review of the patient records, to ensure that it
394 complies with this section and the rules of the Board of
395 Medicine adopted pursuant to subsection (4) unless the office is
396 accredited by a nationally recognized accrediting agency
397 approved by the Board of Medicine.

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

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

406 (4) RULEMAKING.—

588-03762-10

20102722c1

407 (a) The department shall adopt rules necessary to
408 administer the registration and inspection of pain-management
409 clinics which establish the specific requirements, procedures,
410 forms, and fees.

411 (b) The department shall adopt a rule defining what
412 constitutes practice by a designated physician at the office
413 location for which the physician has assumed responsibility, as
414 set forth in subsection (1). When adopting the rule, the
415 department shall consider the number of clinic employees, the
416 location of the pain-management clinic, its hours of operation,
417 and the amount of controlled substances being prescribed,
418 dispensed, or administered at the pain-management clinic.

419 (c) The Board of Medicine shall adopt a rule establishing
420 the maximum number of prescriptions for Schedule II or Schedule
421 III controlled substances which may be written at any one
422 registered pain-management clinic during any 24-hour period.

423 (d) The Board of Medicine shall adopt rules setting forth
424 standards of practice for physicians practicing in privately
425 owned pain-management clinics that primarily engage in the
426 treatment of pain by prescribing or dispensing controlled
427 substance medications. Such rules shall address, but need not be
428 limited to:

- 429 1. Facility operations;
- 430 2. Physical operations;
- 431 3. Infection control requirements;
- 432 4. Health and safety requirements;
- 433 5. Quality assurance requirements;
- 434 6. Patient records;
- 435 7. Training requirements for all facility health care

588-03762-10

20102722c1

436 practitioners who are not regulated by another board;

437 8. Inspections; and

438 9. Data collection and reporting requirements.

439

440 A physician is primarily engaged in the treatment of pain by
441 prescribing or dispensing controlled substance medications when
442 the majority of the patients seen are prescribed or dispensed
443 controlled substance medications for the treatment of chronic
444 nonmalignant pain. Chronic nonmalignant pain is pain unrelated
445 to cancer which persists beyond the usual course of the disease
446 or the injury that is the cause of the pain or more than 90 days
447 after surgery.

448 (5) PENALTIES; ENFORCEMENT.—

449 (a) The department may impose an administrative fine on the
450 clinic of up to \$5,000 per violation for violating the
451 requirements of this section, chapter 499, the Florida Drug and
452 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
453 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
454 Abuse Prevention and Control Act; chapter 893, the Florida
455 Comprehensive Drug Abuse Prevention and Control Act; or the
456 rules of the department. In determining whether a penalty is to
457 be imposed, and in fixing the amount of the fine, the department
458 shall consider the following factors:

459 1. The gravity of the violation, including the probability
460 that death or serious physical or emotional harm to a patient
461 has resulted, or could have resulted, from the pain-management
462 clinic's actions, the severity of the action or potential harm,
463 and the extent to which the provisions of the applicable laws or
464 rules were violated.

588-03762-10

20102722c1

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

467 3. Whether there were any previous violations at the pain-
468 management clinic.

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

471 (b) Each day a violation continues after the date fixed for
472 termination as ordered by the department constitutes an
473 additional, separate, and distinct violation.

474 (c) The department may impose a fine and, in the case of an
475 owner-operated pain-management clinic revoke or deny a clinic's
476 registration, if the clinic's designated physician knowingly and
477 intentionally misrepresents actions taken to correct a
478 violation.

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

482 (e) If the owner of a pain-management clinic fails to apply
483 to register the clinic upon a change-of-ownership and operates
484 the clinic under the new ownership, the owner is subject to a
485 fine of \$5,000.

486 Section 6. Section 458.327, Florida Statutes, is amended to
487 read:

488 458.327 Penalty for violations.—

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

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

588-03762-10

20102722c1

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

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

498 (d) Attempting to obtain or obtaining a position as a
499 medical practitioner or medical resident in a clinic or hospital
500 through knowing misrepresentation of education, training, or
501 experience.

502 (e) Knowingly operating, owning, or managing a
503 nonregistered pain-management clinic that is required to be
504 registered with the Department of Health pursuant to s.
505 458.3265(1).

506 (2) Each of the following acts constitutes a misdemeanor of
507 the first degree, punishable as provided in s. 775.082 or s.
508 775.083:

509 (a) Knowingly concealing information relating to violations
510 of this chapter.

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

513 (c) Referring any patient, for health care goods or
514 services, to a partnership, firm, corporation, or other business
515 entity in which the physician or the physician's employer has an
516 equity interest of 10 percent or more unless, prior to such
517 referral, the physician notifies the patient of his or her
518 financial interest and of the patient's right to obtain such
519 goods or services at the location of the patient's choice. This
520 section does not apply to the following types of equity
521 interest:

522 1. The ownership of registered securities issued by a

588-03762-10

20102722c1

523 publicly held corporation or the ownership of securities issued
524 by a publicly held corporation, the shares of which are traded
525 on a national exchange or the over-the-counter market;

526 2. A physician's own practice, whether he or she is a sole
527 practitioner or part of a group, when the health care good or
528 service is prescribed or provided solely for the physician's own
529 patients and is provided or performed by the physician or under
530 the physician's supervision; or

531 3. An interest in real property resulting in a landlord-
532 tenant relationship between the physician and the entity in
533 which the equity interest is held, unless the rent is
534 determined, in whole or in part, by the business volume or
535 profitability of the tenant or is otherwise unrelated to fair
536 market value.

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

540 (e) Practicing medicine or attempting to practice medicine
541 with an inactive or delinquent license.

542 (f) Knowingly prescribing or dispensing, or causing to be
543 prescribed or dispensed, controlled substances in a
544 nonregistered pain-management clinic that is required to be
545 registered with the Department of Health pursuant to s.
546 458.3265(1).

547 Section 7. Paragraphs (oo), (pp), and (qq) are added to
548 subsection (1) of section 458.331, Florida Statutes, to read:

549 458.331 Grounds for disciplinary action; action by the
550 board and department.—

551 (1) The following acts constitute grounds for denial of a

588-03762-10

20102722c1

552 license or disciplinary action, as specified in s. 456.072(2):

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

556 1. Registering a pain-management clinic through
557 misrepresentation or fraud;

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

561 3. Failing to comply with any requirement of chapter 499,
562 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
563 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
564 the Drug Abuse Prevention and Control Act; or chapter 893, the
565 Florida Comprehensive Drug Abuse Prevention and Control Act;

566 4. Being convicted or found guilty of, regardless of
567 adjudication to, a felony or any other crime involving moral
568 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
569 the courts of this state, of any other state, or of the United
570 States;

571 5. Being convicted of, or disciplined by a regulatory
572 agency of the Federal Government or a regulatory agency of
573 another state for any offense that would constitute a violation
574 of this chapter;

575 6. Being convicted of, or entering a plea of guilty or nolo
576 contendere to, regardless of adjudication, a crime in any
577 jurisdiction which relates to the practice of, or the ability to
578 practice, a licensed health care profession;

579 7. Being convicted of, or entering a plea of guilty or nolo
580 contendere to, regardless of adjudication, a crime in any

588-03762-10

20102722c1

581 jurisdiction which relates to health care fraud;

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

587 9. Failing to have a licensed designated physician
588 practicing at the location of the registered clinic. A violation
589 of this paragraph may be the basis for a summary suspension as
590 described in s. 456.073(8) or s. 120.60(6).

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

595 (qq) Failing to timely notify the applicable board
596 governing his or her prescribing privileges of the date of his
597 or her termination from a pain-management clinic as required by
598 s. 458.3265(2).

599 Section 8. Subsections (3), (4), and (5) of section
600 459.005, Florida Statutes, are repealed.

601 Section 9. Section 459.0137, Florida Statutes, is created
602 to read:

603 459.0137 Pain-management clinics.—

604 (1) REGISTRATION.—

605 (a) Effective January 4, 2010, all privately owned pain-
606 management clinics, facilities, or offices, hereinafter referred
607 to as "clinics," which advertise in any medium for any type of
608 pain-management services, or employ an osteopathic physician who
609 is primarily engaged in the treatment of pain by prescribing or

588-03762-10

20102722c1

610 dispensing controlled substance medications, must register with
611 the department unless:

612 1. That clinic is licensed as a facility pursuant to
613 chapter 395;

614 2. The majority of the physicians who provide services in
615 the clinic, facility, or office primarily provide surgical
616 services;

617 3. The clinic, facility, or office is owned by a publicly
618 held corporation whose shares are traded on a national exchange
619 or on the over-the-counter market and whose total assets at the
620 end of corporation's most recent fiscal quarter exceeded \$50
621 million;

622 4. The clinic, facility, or office is affiliated with an
623 accredited medical school at which training is provided for
624 medical students, residents, or fellows;

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

627 6. The clinic, facility, or office is owned by a corporate
628 entity exempt from federal taxation under 26 U.S.C. s.
629 501(c) (3).

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

633 (c) As a part of registration, a clinic must designate an
634 osteopathic physician who is responsible for complying with all
635 requirements related to registration of the clinic. The
636 designated physician shall have a full, active, and unencumbered
637 license under chapter 458 or this chapter and shall practice at
638 the office location for which the physician has assumed

588-03762-10

20102722c1

639 responsibility.

640 (d) The department shall deny registration to any clinic
641 not fully owned by a physician licensed under chapter 458 or
642 this chapter or a group of physicians under to chapter 458 or
643 this chapter.

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

647 1. Whose Drug Enforcement Administration number has ever
648 been revoked.

649 2. Whose application for a license to prescribe, dispense,
650 or administer a controlled substance has been denied by any
651 jurisdiction.

652 3. Who has been convicted of or plead guilty or nolo
653 contender to, regardless of adjudication, an offense that
654 constitutes a felony for receipt of illicit and diverted drugs,
655 including a controlled substance listed in Schedule I, Schedule
656 II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in
657 this state, any other state, or the United States.

658 (f) If the department finds that a pain-management clinic
659 is owned, directly or indirectly, by a person meeting any
660 criteria listed in paragraph (d) or paragraph (e), the
661 department shall revoke the certificate of registration
662 previously issued by the department. As determined by rule, the
663 department may grant an exemption to denying a registration or
664 revoking a previously issued registration if more than 10 years
665 have elapsed since adjudication. As used in this subsection, the
666 term "convicted" includes an adjudication of guilt following a
667 plea of guilty or nolo contendere or the forfeiture of a bond

588-03762-10

20102722c1

668 when charged with a crime.

669 (g) The department may revoke the clinic's certificate of
670 registration and prohibit all physicians associated with that
671 pain-management clinic from practicing at that office location
672 based upon an annual inspection and evaluation of the factors
673 described in subsection (3).

674 (h) If the registration of a pain-management clinic is
675 revoked or suspended, the designated physician of the pain-
676 management clinic, the owner or lessor of the pain-management
677 clinic property, the manager, and the proprietor shall cease to
678 operate the facility as a pain-management clinic as of the
679 effective date of the suspension or revocation.

680 (i) If a pain-management clinic registration is revoked or
681 suspended, the designated physician of the pain-management
682 clinic, the owner or lessor of the clinic property, the manager,
683 or the proprietor is responsible for removing all signs and
684 symbols identifying the premises as a pain-management clinic.

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

693 (k) If the clinic's registration is revoked, any person
694 named in the registration documents of the pain-management
695 clinic, including persons owning or operating the pain-
696 management clinic, may not as an individual or as a part of a

588-03762-10

20102722c1

697 group, make application for a permit to operate a pain-
698 management clinic for 5 years after the date the registration is
699 revoked.

700 (1) The period of the suspension shall be prescribed by the
701 department, but may not exceed 1 year.

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

704 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
705 apply to any osteopathic physician who provides professional
706 services in a pain-management clinic that is required to be
707 registered in subsection (1).

708 (a) An osteopathic physician may not practice medicine in a
709 pain-management clinic, as described in subsection (4), if the
710 pain-management clinic is not registered with the department as
711 required by this section. An osteopathic physician who violates
712 this paragraph is subject to review by his or her appropriate
713 medical regulatory board.

714 (b) A person may not dispense any medication, including a
715 controlled substance, on the premises of a registered pain-
716 management clinic unless he or she is a physician licensed under
717 this chapter or chapter 458.

718 (c) After a physical examination of the patient, an
719 osteopathic physician, on the same day of dispensing or
720 prescribing a controlled substance, must document in the
721 patient's record the reason for prescribing or dispensing more
722 than a 72-hour dose of a controlled substance for the treatment
723 of chronic nonmalignant pain.

724 (d) An osteopathic physician authorized to prescribe
725 controlled substances who practices at a pain-management clinic

588-03762-10

20102722c1

726 is responsible for maintaining the control and security of his
727 or her prescription blanks and any other method used for
728 prescribing controlled substance pain medication. The
729 osteopathic physician shall comply with the requirements for
730 counterfeit-resistant prescription blanks in s. 893.065 and the
731 rules adopted pursuant to that section. The osteopathic
732 physician shall notify in writing the department within 24 hours
733 following any theft or loss of a prescription blank or breach of
734 any other method for prescribing pain medication.

735 (e) The osteopathic physician shall notify the applicable
736 board in writing of the date of termination of employment within
737 10 days after terminating his or her employment with a pain-
738 management clinic that is required to be registered under
739 subsection (1).

740 (f) An osteopathic practitioner registered under s.
741 465.0276 who practices at a pain-management clinic that is
742 required to be registered under s. 458.3265 or this section may
743 not dispense more than a 72-hour supply of a controlled
744 substance listed in Schedule II or Schedule III, as provided in
745 s. 893.03, to patients who pay by cash, check, or credit card
746 for such medications. This limitation does not apply to patients
747 who have insurance coverage for the medications and are using
748 cash, check, or a credit card to meet a required copayment or
749 deductible. A practitioner who knowingly violates this provision
750 commits a felony of the third degree, punishable as provided in
751 s. 775.082, s. 775.083, or s. 775.084. This paragraph does not
752 apply to practitioners who dispense medications to
753 workers' compensation patients pursuant to chapter 440. This
754 paragraph does not apply to the dispensing of complimentary

588-03762-10

20102722c1

755 packages of medicinal drugs to the practitioner's own patients
756 in the regular course of his or her practice, without the
757 payment of fee or remuneration of any kind, whether direct or
758 indirect, and in conformity with the requirements of this
759 subsection. This paragraph does not apply to controlled
760 substances dispensed in the health care system of the Department
761 of Corrections.

762 (3) INSPECTION.—

763 (a) The department shall inspect the clinic annually,
764 including a review of the patient records, to ensure that it
765 complies with this section and the rules of the Board of
766 Osteopathic Medicine adopted pursuant to subsection (4) unless
767 the office is accredited by a nationally recognized accrediting
768 agency approved by the Board of Osteopathic Medicine.

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

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

777 (4) RULEMAKING.—

778 (a) The department shall adopt rules necessary to
779 administer the registration and inspection of pain-management
780 clinics which establish the specific requirements, procedures,
781 forms, and fees.

782 (b) The department shall adopt a rule defining what
783 constitutes practice by a designated physician at the office

588-03762-10

20102722c1

784 location for which the physician has assumed responsibility, as
785 set forth in subsection (1). When adopting the rule, the
786 department shall consider the number of clinic employees, the
787 location of the pain-management clinic, its hours of operation,
788 and the amount of controlled substances being prescribed,
789 dispensed, or administered at the pain-management clinic.

790 (c) The Board of Osteopathic Medicine shall adopt a rule
791 establishing the maximum number of prescriptions for Schedule II
792 or Schedule III controlled substances which may be written at
793 any one registered pain-management clinic during any 24-hour
794 period.

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

- 801 1. Facility operations;
- 802 2. Physical operations;
- 803 3. Infection control requirements;
- 804 4. Health and safety requirements;
- 805 5. Quality assurance requirements;
- 806 6. Patient records;
- 807 7. Training requirements for all facility health care
808 practitioners who are not regulated by another board;
- 809 8. Inspections; and
- 810 9. Data collection and reporting requirements.

811
812 An osteopathic physician is primarily engaged in the treatment

588-03762-10

20102722c1

813 of pain by prescribing or dispensing controlled substance
814 medications when the majority of the patients seen are
815 prescribed or dispensed controlled substance medications for the
816 treatment of chronic nonmalignant pain. Chronic nonmalignant
817 pain is pain unrelated to cancer which persists beyond the usual
818 course of the disease or the injury that is the cause of the
819 pain or more than 90 days after surgery.

820 (5) PENALTIES; ENFORCEMENT.—

821 (a) The department may impose an administrative fine on the
822 clinic of up to \$5,000 per violation for violating the
823 requirements of this section, chapter 499, the Florida Drug and
824 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
825 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
826 Abuse Prevention and Control Act; chapter 893, the Florida
827 Comprehensive Drug Abuse Prevention and Control Act; or the
828 rules of the department. In determining whether a penalty is to
829 be imposed, and in fixing the amount of the fine, the department
830 shall consider the following factors:

831 1. The gravity of the violation, including the probability
832 that death or serious physical or emotional harm to a patient
833 has resulted, or could have resulted, from the pain-management
834 clinic's actions, the severity of the action or potential harm,
835 and the extent to which the provisions of the applicable laws or
836 rules were violated.

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

839 3. Whether there were any previous violations at the pain-
840 management clinic.

841 4. The financial benefits that the pain-management clinic

588-03762-10

20102722c1

842 derived from committing or continuing to commit the violation.

843 (b) Each day a violation continues after the date fixed for
844 termination as ordered by the department constitutes an
845 additional, separate, and distinct violation.

846 (c) The department may impose a fine and, in the case of an
847 owner-operated pain-management clinic revoke or deny a clinic's
848 registration, if the clinic's designated physician knowingly and
849 intentionally misrepresents actions taken to correct a
850 violation.

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

854 (e) If the owner of a pain-management clinic fails to apply
855 to register the clinic upon a change-of-ownership and operates
856 the clinic under the new ownership, the owner is subject to a
857 fine of \$5,000.

858 Section 10. Subsections (1) and (2) of section 459.013,
859 Florida Statutes, are amended to read:

860 459.013 Penalty for violations.—

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

864 (a) The practice of osteopathic medicine, or an attempt to
865 practice osteopathic medicine, without an active license or
866 certificate issued pursuant to this chapter.

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

588-03762-10

20102722c1

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

873 (d) Attempting to obtain or obtaining a position as an
874 osteopathic medical practitioner or osteopathic medical resident
875 in a clinic or hospital through knowing misrepresentation of
876 education, training, or experience.

877 (e) Knowingly operating, owning, or managing a
878 nonregistered pain-management clinic that is required to be
879 registered with the Department of Health pursuant to s.
880 459.0137(1).

881 (2) Each of the following acts constitutes a misdemeanor of
882 the first degree, punishable as provided in s. 775.082 or s.
883 775.083:

884 (a) Knowingly concealing information relating to violations
885 of this chapter.

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

888 (c) The practice of medicine as a resident or intern
889 without holding a valid current registration pursuant to s.
890 459.021.

891 (d) Knowingly prescribing or dispensing, or causing to be
892 prescribed or dispensed, controlled substances in a
893 nonregistered pain-management clinic that is required to be
894 registered with the Department of Health pursuant to s.
895 459.0137(1).

896 Section 11. Paragraphs (qq), (rr), and (ss) are added to
897 subsection (1) of section 459.015, Florida Statutes, to read:

898 459.015 Grounds for disciplinary action; action by the
899 board and department.-

588-03762-10

20102722c1

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

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

905 1. Registering a pain-management clinic through
906 misrepresentation or fraud;

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

910 3. Failing to comply with any requirement of chapter 499,
911 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
912 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
913 the Drug Abuse Prevention and Control Act; or chapter 893, the
914 Florida Comprehensive Drug Abuse Prevention and Control Act;

915 4. Being convicted or found guilty of, regardless of
916 adjudication to, a felony or any other crime involving moral
917 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
918 the courts of this state, of any other state, or of the United
919 States;

920 5. Being convicted of, or disciplined by a regulatory
921 agency of the Federal Government or a regulatory agency of
922 another state for any offense that would constitute a violation
923 of this chapter;

924 6. Being convicted of, or entering a plea of guilty or nolo
925 contendere to, regardless of adjudication, a crime in any
926 jurisdiction which relates to the practice of, or the ability to
927 practice, a licensed health care profession;

928 7. Being convicted of, or entering a plea of guilty or nolo

588-03762-10

20102722c1

929 contendere to, regardless of adjudication, a crime in any
930 jurisdiction which relates to health care fraud;

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

936 9. Failing to have a licensed designated physician
937 practicing at the location of the registered clinic. A violation
938 of this paragraph may be the basis for a summary suspension as
939 described in s. 456.073(8) or s. 120.60(6).

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

944 (ss) Failing to timely notify the applicable board
945 governing his or her prescribing privileges of the date of his
946 or her termination from a pain-management clinic as required by
947 s. 459.0137(2).

948 Section 12. This act shall take effect October 1, 2010.