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591-04295B-10

Proposed Committee Substitute by the Committee on Criminal
Justice

A bill to be entitled

An act relating to controlled substances; amending s.
456.037, F.S.; providing that pain-management clinics
that are required to be registered with the Department
of Health are business establishments; amending s.
456.057, F.S.; providing that the Department of Health
is not required to attempt to obtain authorization
from a patient for the release of the patient's
medical records under certain circumstances;
authorizing the department to obtain patient records
without authorization or subpoena if the department
has probable cause to believe that certain violations
have occurred or are occurring; repealing s.
458.309(4), (5), and (6), F.S., relating to pain-
management clinics; creating s. 458.3265, F.S.;
requiring all privately owned pain-management clinics,
or offices that primarily engage in the treatment of
pain by prescribing or dispensing controlled substance
medications or by employing a physician who is
primarily engaged in the treatment of pain by
prescribing or dispensing controlled substance
medications, to register with the Department of
Health; providing exceptions; requiring each location
of a pain-management clinic to register separately;
requiring a clinic to designate a physician who is
responsible for complying with requirements related to
registration and operation of the clinic; requiring



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28 the department to deny registration or revoke the
29 registration of a pain-management clinic for certain
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



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57 document corrective action; requiring the department
58 and the Board of Medicine to adopt rules; authorizing
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



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86 certificate of registration and prohibit osteopathic
87 physicians associated with the clinic from practicing
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



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115 fines, deny a clinic's registration, or revoke a
116 clinic's registration; amending s. 459.013, F.S.;
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. 893.055, F.S.;
124 providing for the prescription drug monitoring
125 program's database to report certain information
126 directly to applicable law enforcement agencies for
127 investigation; requiring the department to adopt
128 rules; amending s. 893.0551, F.S.; providing for
129 disclosure of confidential and exempt information to
130 applicable law enforcement; providing an effective
131 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



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144 required to be registered under s. 458.3265 or s. 459.0137.

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



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173 or the issuance of a subpoena would jeopardize the
174 investigation.

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.



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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
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. Subsections (4), (5), and (6) of section
216 458.309, Florida Statutes, are repealed.

217 Section 4. Section 458.3265, Florida Statutes, is created
218 to read:

219 458.3265 Pain-management clinics.-

220 (1) REGISTRATION.-

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

227 1. That clinic is licensed as a facility pursuant to
228 chapter 395;

229 2. The majority of the physicians who provide services in
230 the clinic primarily provide surgical services;



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

235 4. The clinic is affiliated with an accredited medical
236 school at which training is provided for medical students,
237 residents, or fellows;

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

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

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

245 (c) As a part of registration, a clinic must designate a
246 physician who is responsible for complying with all requirements
247 related to registration and operation of the clinic in
248 compliance with this section. Within 10 days after termination
249 of a designated physician, the clinic must notify the department
250 of the identity of another designated physician for that clinic.
251 The designated physician shall have a full, active, and
252 unencumbered license under this chapter or chapter 459 and shall
253 practice at the clinic location for which the physician has
254 assumed responsibility. Failing to have a licensed designated
255 physician practicing at the location of the registered clinic
256 may be the basis for a summary suspension of the clinic
257 registration certificate as described in s. 456.073(8) for a
258 license or s. 120.60(6).

259 (d) The department shall deny registration to any clinic



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260 that is not fully owned by a physician licensed under this
261 chapter or chapter 459 or a group of physicians, each of whom is
262 licensed under this chapter or chapter 459; or that is not a
263 health care clinic licensed under part X of chapter 400.

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

267 1. Whose Drug Enforcement Administration number has ever
268 been revoked.

269 2. Whose application for a license to prescribe, dispense,
270 or administer a controlled substance has been denied by any
271 jurisdiction.

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

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



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

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

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

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

313 (k) If the clinic's registration is revoked, any person
314 named in the registration documents of the pain-management
315 clinic, including persons owning or operating the pain-
316 management clinic, may not, as an individual or as a part of a
317 group, apply to operate a pain-management clinic for 5 years



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318 after the date the registration is revoked.

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

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

324 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
325 apply to any physician who provides professional services in a
326 pain-management clinic that is required to be registered in
327 subsection (1).

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

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

332 2. Effective July 1, 2012, the physician has not
333 successfully completed a pain medicine fellowship that is
334 accredited by the Accreditation Council for Graduate Medical
335 Education or a pain medicine residency that is accredited by the
336 Accreditation Council for Graduate Medical Education unless
337 recognized as a specialist in pain medicine by an organization
338 approved by the Board of Medicine.

339
340 A physician who violates this paragraph is subject to
341 disciplinary action by his or her appropriate medical regulatory
342 board.

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



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347 (c) A physician must perform a physical examination of a
348 patient on the same day that he or she dispenses or prescribes a
349 controlled substance to a patient at a pain-management clinic.
350 If the physician prescribes or dispenses more than a 72-hour
351 dose of controlled substances for the treatment of chronic
352 nonmalignant pain, the physician must document in the patient's
353 record the reason for prescribing or dispensing that quantity.

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

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

370 (3) INSPECTION.—

371 (a) The department shall inspect the pain-management clinic
372 annually, including a review of the patient records, to ensure
373 that it complies with this section and the rules of the Board of
374 Medicine adopted pursuant to subsection (4) unless the clinic is
375 accredited by a nationally recognized accrediting agency



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376 approved by the Board of Medicine.

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

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

385 (4) RULEMAKING.—

386 (a) The department shall adopt rules necessary to
387 administer the registration and inspection of pain-management
388 clinics which establish the specific requirements, procedures,
389 forms, and fees.

390 (b) The department shall adopt a rule defining what
391 constitutes practice by a designated physician at the clinic
392 location for which the physician has assumed responsibility, as
393 set forth in subsection (1). When adopting the rule, the
394 department shall consider the number of clinic employees, the
395 location of the pain-management clinic, the clinic's hours of
396 operation, and the amount of controlled substances being
397 prescribed, dispensed, or administered at the pain-management
398 clinic.

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

404 (d) The Board of Medicine shall adopt rules setting forth



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405 standards of practice for physicians practicing in privately
406 owned pain-management clinics that primarily engage in the
407 treatment of pain by prescribing or dispensing controlled
408 substance medications. Such rules shall address, but need not be
409 limited to:

- 410 1. Facility operations;
- 411 2. Physical operations;
- 412 3. Infection control requirements;
- 413 4. Health and safety requirements;
- 414 5. Quality assurance requirements;
- 415 6. Patient records;
- 416 7. Training requirements for all facility health care
417 practitioners who are not regulated by another board;
- 418 8. Inspections; and
- 419 9. Data collection and reporting requirements.

420
421 A physician is primarily engaged in the treatment of pain by
422 prescribing or dispensing controlled substance medications when
423 the majority of the patients seen are prescribed or dispensed
424 controlled substance medications for the treatment of chronic
425 nonmalignant pain. Chronic nonmalignant pain is pain unrelated
426 to cancer which persists beyond the usual course of the disease
427 or the injury that is the cause of the pain or more than 90 days
428 after surgery.

429 (5) PENALTIES; ENFORCEMENT.-

430 (a) The department may impose an administrative fine on the
431 clinic of up to \$5,000 per violation for violating the
432 requirements of this section; chapter 499, the Florida Drug and
433 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and



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434 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
435 Abuse Prevention and Control Act; chapter 893, the Florida
436 Comprehensive Drug Abuse Prevention and Control Act; or the
437 rules of the department. In determining whether a penalty is to
438 be imposed, and in fixing the amount of the fine, the department
439 shall consider the following factors:

440 1. The gravity of the violation, including the probability
441 that death or serious physical or emotional harm to a patient
442 has resulted, or could have resulted, from the pain-management
443 clinic's actions or the actions of the physician, the severity
444 of the action or potential harm, and the extent to which the
445 provisions of the applicable laws or rules were violated.

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

448 3. Whether there were any previous violations at the pain-
449 management clinic.

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

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

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

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



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

467 Section 5. Section 458.327, Florida Statutes, is amended to
468 read:

469 458.327 Penalty for violations.-

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

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

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

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

479 (d) Attempting to obtain or obtaining a position as a
480 medical practitioner or medical resident in a clinic or hospital
481 through knowing misrepresentation of education, training, or
482 experience.

483 (e) Knowingly operating, owning, or managing a
484 nonregistered pain-management clinic that is required to be
485 registered with the Department of Health pursuant to s.
486 458.3265(1).

487 (2) Each of the following acts constitutes a misdemeanor of
488 the first degree, punishable as provided in s. 775.082 or s.
489 775.083:

490 (a) Knowingly concealing information relating to violations
491 of this chapter.



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

494 (c) Referring any patient, for health care goods or
495 services, to a partnership, firm, corporation, or other business
496 entity in which the physician or the physician's employer has an
497 equity interest of 10 percent or more unless, prior to such
498 referral, the physician notifies the patient of his or her
499 financial interest and of the patient's right to obtain such
500 goods or services at the location of the patient's choice. This
501 section does not apply to the following types of equity
502 interest:

503 1. The ownership of registered securities issued by a
504 publicly held corporation or the ownership of securities issued
505 by a publicly held corporation, the shares of which are traded
506 on a national exchange or the over-the-counter market;

507 2. A physician's own practice, whether he or she is a sole
508 practitioner or part of a group, when the health care good or
509 service is prescribed or provided solely for the physician's own
510 patients and is provided or performed by the physician or under
511 the physician's supervision; or

512 3. An interest in real property resulting in a landlord-
513 tenant relationship between the physician and the entity in
514 which the equity interest is held, unless the rent is
515 determined, in whole or in part, by the business volume or
516 profitability of the tenant or is otherwise unrelated to fair
517 market value.

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



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521 (e) Practicing medicine or attempting to practice medicine
522 with an inactive or delinquent license.

523 (f) Knowingly prescribing or dispensing, or causing to be
524 prescribed or dispensed, controlled substances in a
525 nonregistered pain-management clinic that is required to be
526 registered with the Department of Health pursuant to s.
527 458.3265(1).

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

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

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

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

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

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

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

547 4. Being convicted or found guilty of, regardless of
548 adjudication to, a felony or any other crime involving moral
549 turpitude, fraud, dishonesty, or deceit in any jurisdiction of



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550 the courts of this state, of any other state, or of the United
551 States;

552 5. Being convicted of, or disciplined by a regulatory
553 agency of the Federal Government or a regulatory agency of
554 another state for any offense that would constitute a violation
555 of this chapter;

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

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

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

570 9. Failing to timely notify the board of the date of his or
571 her termination from a pain-management clinic as required by s.
572 458.3265(2).

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

577 Section 7. Subsections (3), (4), and (5) of section
578 459.005, Florida Statutes, are repealed.



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579 Section 8. Section 459.0137, Florida Statutes, is created
580 to read:

581 459.0137 Pain-management clinics.-

582 (1) REGISTRATION.-

583 (a) All privately owned pain-management clinics,
584 facilities, or offices, hereinafter referred to as "clinics,"
585 which advertise in any medium for any type of pain-management
586 services, or employ an osteopathic physician who is primarily
587 engaged in the treatment of pain by prescribing or dispensing
588 controlled substance medications, must register with the
589 department unless:

590 1. That clinic is licensed as a facility pursuant to
591 chapter 395;

592 2. The majority of the physicians who provide services in
593 the clinic primarily provide surgical services;

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

598 4. The clinic is affiliated with an accredited medical
599 school at which training is provided for medical students,
600 residents, or fellows;

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

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

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



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608 (c) As a part of registration, a clinic must designate an
609 osteopathic physician who is responsible for complying with all
610 requirements related to registration and operation of the clinic
611 in compliance with this section. Within 10 days after
612 termination of a designated osteopathic physician, the clinic
613 must notify the department of the identity of another designated
614 physician for that clinic. The designated physician shall have a
615 full, active, and unencumbered license under chapter 458 or this
616 chapter and shall practice at the clinic location for which the
617 physician has assumed responsibility. Failing to have a licensed
618 designated osteopathic physician practicing at the location of
619 the registered clinic may be the basis for a summary suspension
620 of the clinic registration certificate as described in s.
621 456.073(8) for a license or s. 120.60(6).

622 (d) The department shall deny registration to any clinic
623 that is not fully owned by a physician licensed under chapter
624 458 or this chapter or a group of physicians, each of whom is
625 licensed under chapter 458 or this chapter; or that is not a
626 health care clinic licensed under part X of chapter 400.

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

630 1. Whose Drug Enforcement Administration number has ever
631 been revoked.

632 2. Whose application for a license to prescribe, dispense,
633 or administer a controlled substance has been denied by any
634 jurisdiction.

635 3. Who has been convicted of or plead guilty or nolo
636 contendere to, regardless of adjudication, an offense that



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637 constitutes a felony for receipt of illicit and diverted drugs,
638 including a controlled substance listed in Schedule I, Schedule
639 II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in
640 this state, any other state, or the United States.

641 (f) If the department finds that a pain-management clinic
642 does not meet the requirement of paragraph (d) or is owned,
643 directly or indirectly, by a person meeting any criteria listed
644 in paragraph (e), the department shall revoke the certificate of
645 registration previously issued by the department. As determined
646 by rule, the department may grant an exemption to denying a
647 registration or revoking a previously issued registration if
648 more than 10 years have elapsed since adjudication. As used in
649 this subsection, the term "convicted" includes an adjudication
650 of guilt following a plea of guilty or nolo contendere or the
651 forfeiture of a bond when charged with a crime.

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

657 (h) If the registration of a pain-management clinic is
658 revoked or suspended, the designated physician of the pain-
659 management clinic, the owner or lessor of the pain-management
660 clinic property, the manager, and the proprietor shall cease to
661 operate the facility as a pain-management clinic as of the
662 effective date of the suspension or revocation.

663 (i) If a pain-management clinic registration is revoked or
664 suspended, the designated physician of the pain-management
665 clinic, the owner or lessor of the clinic property, the manager,



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666 or the proprietor is responsible for removing all signs and
667 symbols identifying the premises as a pain-management clinic.

668 (j) Upon the effective date of the suspension or
669 revocation, the designated physician of the pain-management
670 clinic shall advise the department of the disposition of the
671 medicinal drugs located on the premises. The disposition is
672 subject to the supervision and approval of the department.
673 Medicinal drugs that are purchased or held by a pain-management
674 clinic that is not registered may be deemed adulterated pursuant
675 to s. 499.006.

676 (k) If the clinic's registration is revoked, any person
677 named in the registration documents of the pain-management
678 clinic, including persons owning or operating the pain-
679 management clinic, may not as an individual or as a part of a
680 group, make application for a permit to operate a pain-
681 management clinic for 5 years after the date the registration is
682 revoked.

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

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

688 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
689 apply to any osteopathic physician who provides professional
690 services in a pain-management clinic that is required to be
691 registered in subsection (1).

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

694 1. The pain-management clinic is not registered with the



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695 department as required by this section; or

696 2. Effective July 1, 2012, the physician has not
697 successfully completed a pain medicine fellowship that is
698 accredited by the Accreditation Council for Graduate Medical
699 Education or the American Osteopathic Association or a pain
700 medicine residency that is accredited by the Accreditation
701 Council for Graduate Medical Education or the American
702 Osteopathic Association unless recognized as a specialist in
703 pain medicine by an organization approved by the Board of
704 Osteopathic Medicine.

705
706 An osteopathic physician who violates this paragraph is subject
707 to disciplinary action by his or her appropriate medical
708 regulatory board.

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

713 (c) An osteopathic physician must perform a physical
714 examination of a patient on the same day that he or she
715 dispenses or prescribes a controlled substance to a patient at a
716 pain-management clinic. If the osteopathic physician prescribes
717 or dispenses more than a 72-hour dose of controlled substances
718 for the treatment of chronic nonmalignant pain, the osteopathic
719 physician must document in the patient's record the reason for
720 prescribing or dispensing that quantity.

721 (d) An osteopathic physician authorized to prescribe
722 controlled substances who practices at a pain-management clinic
723 is responsible for maintaining the control and security of his



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

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

737 (3) INSPECTION.—

738 (a) The department shall inspect the pain-management clinic
739 annually, including a review of the patient records, to ensure
740 that it complies with this section and the rules of the Board of
741 Osteopathic Medicine adopted pursuant to subsection (4) unless
742 the clinic is accredited by a nationally recognized accrediting
743 agency approved by the Board of Osteopathic Medicine.

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

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

752 (4) RULEMAKING.—



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753 (a) The department shall adopt rules necessary to
754 administer the registration and inspection of pain-management
755 clinics which establish the specific requirements, procedures,
756 forms, and fees.

757 (b) The department shall adopt a rule defining what
758 constitutes practice by a designated osteopathic physician at
759 the clinic location for which the physician has assumed
760 responsibility, as set forth in subsection (1). When adopting
761 the rule, the department shall consider the number of clinic
762 employees, the location of the pain-management clinic, the
763 clinic's hours of operation, and the amount of controlled
764 substances being prescribed, dispensed, or administered at the
765 pain-management clinic.

766 (c) The Board of Osteopathic Medicine shall adopt a rule
767 establishing the maximum number of prescriptions for Schedule II
768 or Schedule III controlled substances or the controlled
769 substance Alprazolam which may be written at any one registered
770 pain-management clinic during any 24-hour period.

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

- 777 1. Facility operations;
778 2. Physical operations;
779 3. Infection control requirements;
780 4. Health and safety requirements;
781 5. Quality assurance requirements;



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- 782 6. Patient records;
783 7. Training requirements for all facility health care
784 practitioners who are not regulated by another board;
785 8. Inspections; and
786 9. Data collection and reporting requirements.
787

788 An osteopathic physician is primarily engaged in the treatment
789 of pain by prescribing or dispensing controlled substance
790 medications when the majority of the patients seen are
791 prescribed or dispensed controlled substance medications for the
792 treatment of chronic nonmalignant pain. Chronic nonmalignant
793 pain is pain unrelated to cancer which persists beyond the usual
794 course of the disease or the injury that is the cause of the
795 pain or more than 90 days after surgery.

796 (5) PENALTIES; ENFORCEMENT.—

797 (a) The department may impose an administrative fine on the
798 clinic of up to \$5,000 per violation for violating the
799 requirements of this section; chapter 499, the Florida Drug and
800 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
801 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
802 Abuse Prevention and Control Act; chapter 893, the Florida
803 Comprehensive Drug Abuse Prevention and Control Act; or the
804 rules of the department. In determining whether a penalty is to
805 be imposed, and in fixing the amount of the fine, the department
806 shall consider the following factors:

- 807 1. The gravity of the violation, including the probability
808 that death or serious physical or emotional harm to a patient
809 has resulted, or could have resulted, from the pain-management
810 clinic's actions or the actions of the osteopathic physician,



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811 the severity of the action or potential harm, and the extent to
812 which the provisions of the applicable laws or rules were
813 violated.

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

816 3. Whether there were any previous violations at the pain-
817 management clinic.

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

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

823 (c) The department may impose a fine and, in the case of an
824 owner-operated pain-management clinic, revoke or deny a pain-
825 management clinic's registration, if the clinic's designated
826 osteopathic physician knowingly and intentionally misrepresents
827 actions taken to correct a violation.

828 (d) An owner or designated osteopathic physician of a pain-
829 management clinic who concurrently operates an unregistered
830 pain-management clinic is subject to an administrative fine of
831 \$5,000 per day.

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

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

838 459.013 Penalty for violations.—

839 (1) Each of the following acts constitutes a felony of the



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840 third degree, punishable as provided in s. 775.082, s. 775.083,
841 or s. 775.084:

842 (a) The practice of osteopathic medicine, or an attempt to
843 practice osteopathic medicine, without an active license or
844 certificate issued pursuant to this chapter.

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

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

851 (d) Attempting to obtain or obtaining a position as an
852 osteopathic medical practitioner or osteopathic medical resident
853 in a clinic or hospital through knowing misrepresentation of
854 education, training, or experience.

855 (e) Knowingly operating, owning, or managing a
856 nonregistered pain-management clinic that is required to be
857 registered with the Department of Health pursuant to s.
858 459.0137(1).

859 (2) Each of the following acts constitutes a misdemeanor of
860 the first degree, punishable as provided in s. 775.082 or s.
861 775.083:

862 (a) Knowingly concealing information relating to violations
863 of this chapter.

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

866 (c) The practice of medicine as a resident or intern
867 without holding a valid current registration pursuant to s.
868 459.021.



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869 (d) Knowingly prescribing or dispensing, or causing to be
870 prescribed or dispensed, controlled substances in a
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 Section 10. Paragraphs (qq) and (rr) are added to
875 subsection (1) of section 459.015, Florida Statutes, to read:
876 459.015 Grounds for disciplinary action; action by the
877 board and department.—

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

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

883 1. Registering a pain-management clinic through
884 misrepresentation or fraud;

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

888 3. Failing to comply with any requirement of chapter 499,
889 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
890 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
891 the Drug Abuse Prevention and Control Act; or chapter 893, the
892 Florida Comprehensive Drug Abuse Prevention and Control Act;

893 4. Being convicted or found guilty of, regardless of
894 adjudication to, a felony or any other crime involving moral
895 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
896 the courts of this state, of any other state, or of the United
897 States;



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898 5. Being convicted of, or disciplined by a regulatory
899 agency of the Federal Government or a regulatory agency of
900 another state for any offense that would constitute a violation
901 of this chapter;

902 6. Being convicted of, or entering a plea of guilty or nolo
903 contendere to, regardless of adjudication, a crime in any
904 jurisdiction of the courts of this state, of any other state, or
905 of the United States which relates to the practice of, or the
906 ability to practice, a licensed health care profession;

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

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

916 9. Failing to timely notify the board of the date of his or
917 her termination from a pain-management clinic as required by s.
918 459.0137(2).

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

923 Section 11. Paragraph (b) of subsection (7) of section
924 893.055, Florida Statutes, is amended to read:

925 893.055 Prescription drug monitoring program.—

926 (7)



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927 (b)1. A pharmacy, prescriber, or dispenser shall have
928 access to information in the prescription drug monitoring
929 program's database which relates to a patient of that pharmacy,
930 prescriber, or dispenser in a manner established by the
931 department as needed for the purpose of reviewing the patient's
932 controlled substance prescription history.

933 2. The prescription drug monitoring program's database
934 shall report information directly to applicable law enforcement
935 agencies to investigate whether any violation of s.
936 893.13(7)(a)8., s. 893.13(8)(a), or s. 893.13(8)(b), has
937 occurred regarding controlled substances in Schedule II,
938 Schedule III, or Schedule IV. The department shall adopt rules
939 to identify the factors that might be indicative of a violation
940 of s. 893.13(7)(a)8., s. 893.13(8)(a), or s. 893.13(8)(b), based
941 on input from the Department of Law Enforcement and
942 representatives of local law enforcement, the Florida Medical
943 Association, the Florida Osteopathic Medical Association, the
944 Florida Pharmacy Association, and other relevant stakeholders.

945 3. Other access to the program's database shall be limited
946 to the program's manager and to the designated program and
947 support staff, who may act only at the direction of the program
948 manager or, in the absence of the program manager, as
949 authorized. Access by the program manager or such designated
950 staff is for prescription drug program management only or for
951 management of the program's database and its system in support
952 of the requirements of this section and in furtherance of the
953 prescription drug monitoring program. Confidential and exempt
954 information in the database shall be released only as provided
955 in paragraph (c) and s. 893.0551.



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956 Section 12. Subsections (4), (5), and (6) of section
957 893.0551, Florida Statutes, are renumbered as subsections (5),
958 (6), and (7), respectively, and subsection (4) is added to that
959 section, to read:

960 893.0551 Public records exemption for the prescription drug
961 monitoring program.—

962 (4) The department shall disclose such confidential and
963 exempt information to the applicable law enforcement agency in
964 accordance with s. 893.055(7)(b)2. The law enforcement agency
965 may disclose the confidential and exempt information received
966 from the department to a criminal justice agency as defined in
967 s. 119.011 as part of an active investigation that is specific
968 to a violation of s. 893.13(7)(a)8., s. 893.13(8)(a), or s.
969 893.13(8)(b).

970 Section 13. This act shall take effect October 1, 2010.