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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/26/2010	.	
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The Committee on Health Regulation (Bennett) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (5) of section 456.037, Florida Statutes, is amended, and subsection (6) is added to that section, to read:

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

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



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13 to, dental laboratories, electrology facilities, massage
14 establishments, ~~and~~ pharmacies, and pain-management clinics
15 required to be registered under s. 458.309 or s. 459.005.

16 (6) A licensee authorized to prescribe controlled
17 substances who practices at a pain-management clinic is
18 responsible for maintaining the control and security of his or
19 her prescription blanks and any other method used for
20 prescribing controlled substance pain medication. The licensee
21 shall comply with the requirements for counterfeit-resistant
22 prescription blanks in s. 893.065 and the rules adopted pursuant
23 to that section. The licensee shall notify in writing:

24 (a) The department within 24 hours following any theft or
25 loss of a prescription blank or breach of any other method for
26 prescribing pain medication.

27 (b) The applicable board of the date of termination of
28 employment within 10 days after terminating his or her
29 employment with a pain-management clinic required to be
30 registered under s. 458.309.

31 Section 2. Paragraph (a) of subsection (9) of section
32 456.057, Florida Statutes, is amended to read:

33 456.057 Ownership and control of patient records; report or
34 copies of records to be furnished.—

35 (9) (a) 1. The department may obtain patient records pursuant
36 to a subpoena without written authorization from the patient if
37 the department and the probable cause panel of the appropriate
38 board, if any, find reasonable cause to believe that a health
39 care practitioner has excessively or inappropriately prescribed
40 any controlled substance specified in chapter 893 in violation
41 of this chapter or any professional practice act or that a



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42 health care practitioner has practiced his or her profession
43 below that level of care, skill, and treatment required as
44 defined by this chapter or any professional practice act and
45 also find that appropriate, reasonable attempts were made to
46 obtain a patient release. Notwithstanding the foregoing, the
47 department need not attempt to obtain a patient release when
48 investigating an offense involving the inappropriate
49 prescribing, overprescribing, or diversion of controlled
50 substances and the offense involves a pain-management clinic.

51 2. The department may obtain patient records and insurance
52 information pursuant to a subpoena without written authorization
53 from the patient if the department and the probable cause panel
54 of the appropriate board, if any, find reasonable cause to
55 believe that a health care practitioner has provided inadequate
56 medical care based on termination of insurance and also find
57 that appropriate, reasonable attempts were made to obtain a
58 patient release.

59 3. The department may obtain patient records, billing
60 records, insurance information, provider contracts, and all
61 attachments thereto pursuant to a subpoena without written
62 authorization from the patient if the department and probable
63 cause panel of the appropriate board, if any, find reasonable
64 cause to believe that a health care practitioner has submitted a
65 claim, statement, or bill using a billing code that would result
66 in payment greater in amount than would be paid using a billing
67 code that accurately describes the services performed, requested
68 payment for services that were not performed by that health care
69 practitioner, used information derived from a written report of
70 an automobile accident generated pursuant to chapter 316 to



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71 solicit or obtain patients personally or through an agent
72 regardless of whether the information is derived directly from
73 the report or a summary of that report or from another person,
74 solicited patients fraudulently, received a kickback as defined
75 in s. 456.054, violated the patient brokering provisions of s.
76 817.505, or presented or caused to be presented a false or
77 fraudulent insurance claim within the meaning of s.
78 817.234(1)(a), and also find that, within the meaning of s.
79 817.234(1)(a), patient authorization cannot be obtained because
80 the patient cannot be located or is deceased, incapacitated, or
81 suspected of being a participant in the fraud or scheme, and if
82 the subpoena is issued for specific and relevant records.

83 4. Notwithstanding subparagraphs 1.-3., when the department
84 investigates a professional liability claim or undertakes action
85 pursuant to s. 456.049 or s. 627.912, the department may obtain
86 patient records pursuant to a subpoena without written
87 authorization from the patient if the patient refuses to
88 cooperate or if the department attempts to obtain a patient
89 release and the failure to obtain the patient records would be
90 detrimental to the investigation.

91 Section 3. Section 456.069, Florida Statutes, is amended to
92 read:

93 456.069 Authority to inspect.—In addition to the authority
94 specified in s. 465.017, duly authorized agents and employees of
95 the department may ~~shall have the power to~~ inspect in a lawful
96 manner at all reasonable hours:

97 (1) Any pharmacy; ~~or~~

98 (2) Any establishment at which the services of a licensee
99 authorized to prescribe controlled substances specified in



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100 chapter 893 are offered; or

101 (3) Any facility offering services that require the
102 facility to be registered as a pain-management clinic pursuant
103 to s. 458.309(4) or s. 459.005(3),

104
105 for the purpose of determining if any of the provisions of this
106 chapter or any practice act of a profession or any rule adopted
107 thereunder is being violated; or for the purpose of securing
108 such other evidence as may be needed for prosecution. Such
109 evidence may include, but is not limited to, patient records.
110 The department may obtain patient records without patient
111 authorization or subpoena from any pain-management clinic
112 required to be licensed if the department has probable cause to
113 believe that a violation of any provision of s. 456.072 is
114 occurring or has occurred and reasonably believes that obtaining
115 such authorization is not feasible due to the volume of the
116 dispensing and prescribing activity involving controlled
117 substances and that obtaining patient authorization or the
118 issuance of a subpoena would jeopardize the investigation.

119 Section 4. Section 456.071, Florida Statutes, is amended to
120 read:

121 456.071 Power to administer oaths, take depositions, and
122 issue subpoenas.—For the purpose of any investigation or
123 proceeding conducted by the department, the department shall
124 have the power to administer oaths, take depositions, make
125 inspections when authorized by statute, issue subpoenas which
126 shall be supported by affidavit, serve subpoenas and other
127 process, and compel the attendance of witnesses and the
128 production of books, papers, documents, and other evidence. The



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129 department shall exercise this power on its own initiative or
130 whenever requested by a board or the probable cause panel of any
131 board. Challenges to, and enforcement of, the subpoenas and
132 orders shall be handled as provided in s. 120.569, except that
133 venue is in the Circuit Court for the Second Judicial Circuit,
134 in the county where the examination, investigation, or hearing
135 is conducted, or in the county in which the person resides.

136 Section 5. Paragraphs (mm), (nn), and (oo) are added to
137 subsection (1) of section 456.072, Florida Statutes, to read:

138 456.072 Grounds for discipline; penalties; enforcement.—

139 (1) The following acts shall constitute grounds for which
140 the disciplinary actions specified in subsection (2) may be
141 taken:

142 (mm) Applicable to a licensee who serves as the designated
143 physician of a pain-management clinic as defined in s. 458.309
144 or s. 459.005:

145 1. Registering a pain-management clinic through
146 misrepresentation or fraud;

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

150 3. Failing to comply with any requirement of chapter 499,
151 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
152 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
153 the Drug Abuse Prevention and Control Act; or chapter 893, the
154 Florida Comprehensive Drug Abuse Prevention and Control Act;

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



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158 the courts of this state, of any other state, or of the United
159 States;

160 5. Being convicted of, or disciplined by a regulatory
161 agency of the Federal Government or a regulatory agency of
162 another state for, any offense that would constitute a violation
163 of this chapter;

164 6. Being convicted of, or entering a plea of guilty or nolo
165 contendere to, regardless of adjudication, a crime in any
166 jurisdiction which relates to the practice of, or the ability to
167 practice, a licensed health care profession;

168 7. Being convicted of, or entering a plea of guilty or nolo
169 contendere to, regardless of adjudication, a crime in any
170 jurisdiction which relates to health care fraud;

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

176 9. Failing to have a licensed medical director employed or
177 under contract with the clinic as required by chapter 400 or
178 failing to practice at the location of the registered clinic for
179 which the professional is the designated physician. A violation
180 of this paragraph may be the basis for a summary suspension as
181 described in s. 456.073(8) or s. 120.60(6).

182 (nn) Failing to timely notify the department of the theft
183 of prescription blanks from a pain-management clinic or a breach
184 of other methods for prescribing within 24 hours as required by
185 s. 456.037(6).

186 (oo) Failing to timely notify the applicable board



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187 governing his or her prescribing privileges of the date of his
188 or her termination from a pain-management clinic as required by
189 s. 456.037(6).

190 Section 6. Section 458.309, Florida Statutes, is amended to
191 read:

192 458.309 Rulemaking authority.—

193 (1) The board has authority to adopt rules pursuant to ss.
194 120.536(1) and 120.54 to implement the provisions of this
195 chapter conferring duties upon it.

196 (2) (a) Any rules which the board adopts relating to the
197 classroom phase of medical education shall not apply to any
198 person who is enrolled in the classroom phase of medical
199 education or has graduated prior to or at the time the rule
200 becomes effective, so long as such person does not interrupt his
201 or her medical education.

202 (b) 1. Any rules which the board adopts relating to the
203 clinical clerkship phase of medical education shall not apply to
204 any person who is enrolled in the clinical clerkship phase of
205 medical education prior to or at the time the rule becomes
206 effective, so long as such person does not interrupt his or her
207 medical education.

208 2. Rules adopted by the Florida Board of Medical Examiners
209 prior to October 1, 1986, and relating to clinical clerkships
210 for graduates of foreign medical schools do not apply to any
211 such graduate who:

212 a. Had completed a clinical clerkship prior to the
213 effective date of the rule; or

214 b. Had begun a clinical clerkship but had not completed the
215 clinical clerkship prior to the effective date of the rule, so



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216 long as the clinical clerkship took no longer than 3 years to
217 complete.

218 (c) Any rules which the board adopts relating to residency
219 shall not apply to any person who has begun his or her residency
220 prior to or at the time the rule becomes effective, so long as
221 such person does not interrupt the residency.

222 (3) All physicians who perform level 2 procedures lasting
223 more than 5 minutes and all level 3 surgical procedures in an
224 office setting must register the office with the department
225 unless that office is licensed as a facility pursuant to chapter
226 395. The department shall inspect the physician's office
227 annually unless the office is accredited by a nationally
228 recognized accrediting agency or an accrediting organization
229 subsequently approved by the Board of Medicine. The actual costs
230 for registration and inspection or accreditation shall be paid
231 by the person seeking to register and operate the office setting
232 in which office surgery is performed.

233 (4) Effective January 4, 2010, all privately owned pain-
234 management clinics, facilities, or offices, hereinafter referred
235 to as "clinics," which advertise in any medium for any type of
236 pain-management services, or employ a physician who is primarily
237 engaged in the treatment of pain by prescribing or dispensing
238 controlled substance medications, must register with the
239 department ~~by January 4, 2010~~, unless that clinic is licensed as
240 a facility pursuant to chapter 395. A physician may not practice
241 medicine in a pain-management clinic that is required to but has
242 not registered with the department. Each clinic location shall
243 be registered separately regardless of whether the clinic is
244 operated under the same business name or management as another



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245 clinic. ~~If the clinic is licensed as a health care clinic under~~
246 ~~chapter 400, the medical director is responsible for registering~~
247 ~~the facility with the department.~~ If the clinic is not
248 registered pursuant to chapter 395 ~~or chapter 400~~, the clinic
249 shall, upon registration with the department, designate a
250 physician who is responsible for complying with all requirements
251 related to registration of the clinic. The designated physician
252 shall have a full, active, and unencumbered license ~~be licensed~~
253 under this chapter or chapter 459 and shall practice at the
254 office location for which the physician has assumed
255 responsibility. The department shall inspect the clinic
256 annually, including a review of the patient records, to ensure
257 that it complies with rules of the Board of Medicine adopted
258 pursuant to this subsection and subsection (6) ~~(5)~~ unless the
259 office is accredited by a nationally recognized accrediting
260 agency approved by the Board of Medicine. The actual costs for
261 registration and inspection or accreditation shall be paid by
262 the physician seeking to register the clinic.

263 (5) (a) The department may deny an application for
264 registering a pain-management clinic or revoke or suspend a
265 current registration. The department may impose an
266 administrative fine on the clinic of up to \$5,000 per violation
267 for violating the requirements of this section, chapter 499, the
268 Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
269 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
270 the Drug Abuse Prevention and Control Act; or chapter 893, the
271 Florida Comprehensive Drug Abuse Prevention and Control Act; or
272 the rules of the department. In determining whether a penalty is
273 to be imposed, and in fixing the amount of the fine, the



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274 department shall consider the following factors:

275 1. The gravity of the violation, including the probability
276 that death or serious physical or emotional harm to a patient
277 has resulted, or could have resulted, from a licensee's actions,
278 the severity of the action or potential harm, and the extent to
279 which the provisions of the applicable laws or rules were
280 violated.

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

283 3. Whether there were any previous violations at the pain-
284 management clinic.

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

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

290 (c) Any action taken to correct a violation shall be
291 documented in writing by the owner or designated physician of
292 the pain-management clinic and verified by followup visits by
293 departmental personnel. The department may impose a fine and, in
294 the case of an owner-operated pain-management clinic may revoke
295 or deny a clinic's registration, if the clinic's designated
296 physician knowingly and intentionally misrepresents actions
297 taken to correct a violation.

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

301 (e) If the owner of a pain-management clinic fails to apply
302 for a change-of-ownership registration and operates the clinic



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303 under the new ownership, the owner is subject to a fine of
304 \$5,000.

305 (f) During an onsite inspection, the department shall make
306 a reasonable attempt to discuss each violation with the owner or
307 designated physician of the pain-management clinic before
308 issuing a formal written notification.

309 (g)1. If the registration of a pain-management clinic is
310 revoked or suspended, the designated physician of the pain-
311 management clinic, the owner or lessor of the pain-management
312 clinic property, and the owner, manager, or proprietor shall
313 cease to operate the facility as a pain-management clinic as of
314 the effective date of the suspension or revocation.

315 2. If a pain-management clinic registration is revoked or
316 suspended, the designated physician of the pain-management
317 clinic, the owner or lessor of the clinic property, or the
318 owner, manager, or proprietor is responsible for removing all
319 signs and symbols identifying the premises as a pain-management
320 clinic.

321 3. If the clinic's registration is revoked, any person
322 named in the registration documents of the pain-management
323 clinic, including persons owning or operating the pain-
324 management clinic, may not, as an individual or as a part of a
325 group, apply to operate a pain-management clinic for 5 years
326 after the date the registration is revoked.

327 4. Upon the effective date of the suspension or revocation,
328 the pain-management clinic shall advise the department of the
329 disposition of the medicinal drugs located on the premises. The
330 disposition is subject to the supervision and approval of the
331 department. Medicinal drugs that are purchased or held by a



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332 pain-management clinic that is not registered may be deemed
333 adulterated pursuant to s. 499.006.

334 5. The period of the suspension shall be prescribed by the
335 department, but may not exceed 1 year.

336 (6)~~(5)~~ The Board of Medicine shall adopt rules setting
337 forth standards of practice for physicians practicing in
338 privately owned pain-management clinics that primarily engage in
339 the treatment of pain by prescribing or dispensing controlled
340 substance medications. Such rules shall address, but need not be
341 limited to, the following subjects:

- 342 (a) Facility operations;
- 343 (b) Physical operations;
- 344 (c) Infection control requirements;
- 345 (d) Health and safety requirements;
- 346 (e) Quality assurance requirements;
- 347 (f) Patient records;
- 348 (g) Training requirements for all facility health care
349 practitioners who are not regulated by another board;
- 350 (h) Inspections; and
- 351 (i) Data collection and reporting requirements.

352
353 A physician is primarily engaged in the treatment of pain by
354 prescribing or dispensing controlled substance medications when
355 the majority of the patients seen are prescribed or dispensed
356 controlled substance medications for the treatment of chronic
357 nonmalignant pain. Chronic nonmalignant pain is pain unrelated
358 to cancer which persists beyond the usual course of the disease
359 or the injury that is the cause of the pain or more than 90 days
360 after surgery.



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361 ~~(7)-(6)~~ A privately owned clinic, facility, or office that
362 advertises in any medium for any type of pain-management
363 services or employs one or more physicians who are primarily
364 engaged in the treatment of pain by prescribing or dispensing
365 controlled substances is exempt from the registration provisions
366 in subsection (4) if:

367 (a) The majority of the physicians who provide services in
368 the clinic, facility, or office primarily provide surgical
369 services;

370 (b) The clinic, facility or office is owned by a publicly
371 held corporation whose shares are traded on a national exchange
372 or on the over-the-counter market and whose total assets at the
373 end of corporation's most recent fiscal quarter exceeded \$50
374 million;

375 (c) The clinic, facility or office is affiliated with an
376 accredited medical school at which training is provided for
377 medical students, residents, or fellows;

378 (d) If the clinic does not prescribe or dispense controlled
379 substances for the treatment of pain; or

380 (e) The clinic, facility or office is owned by a corporate
381 entity exempt from federal taxation under 26 U.S.C. s.
382 501(c)(3).

383 (8) The department shall adopt rules necessary to
384 administer the registration and inspection of pain-management
385 clinics establishing the specific requirements, procedures,
386 forms, and fees.

387 (9) The department shall adopt a rule defining what
388 constitutes practice by a designated physician at the office
389 location for which the physician has assumed responsibility, as



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390 set forth in subsections (3) and (4). When adopting the rule,
391 the department shall consider the number of clinic employees,
392 the location of the pain-management clinic, its hours of
393 operation, and the amount of controlled substances being
394 prescribed, dispensed, or administered at the pain-management
395 clinic.

396 (10) The Boards of Medicine and Osteopathic Medicine shall
397 adopt a rule establishing the maximum number of prescriptions
398 for Schedule II or Schedule III controlled substances which may
399 be written at any one registered pain-management clinic during
400 any 24-hour period.

401 Section 7. Section 458.3265, Florida Statutes, is created
402 to read:

403 458.3265 Pain-management clinics.-

404 (1) (a) A physician may not practice medicine in a pain-
405 management clinic, as described in s. 458.309(4), if:

406 1. Effective July 1, 2010, the physician has not
407 successfully completed a pain medicine fellowship that is
408 accredited by the Accreditation Council for Graduate Medical
409 Education or a pain medicine residency that is accredited by the
410 Accreditation Council for Graduate Medical Education unless
411 previously registered and qualified as a pain medicine physician
412 with the Board of Medicine; or

413 2. The pain-management clinic is not registered with the
414 department as required by s. 458.309. As provided in s.
415 458.309(4), each location of a pain-management clinic must be
416 registered separately regardless of whether the clinic is
417 operated under the same business name or management as another
418 clinic.



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419
420 The department may revoke the clinic's certificate of
421 registration and prohibit all physicians associated with that
422 pain-management clinic from practicing at that office location
423 based upon an annual inspection and evaluation of the factors
424 described in s. 458.309(5) (a). A physician who violates this
425 paragraph is subject to review by his or her appropriate medical
426 regulatory board.

427 (b) The department shall deny registration to any clinic
428 not fully owned by a physician licensed pursuant to this chapter
429 or chapter 459, a group of physicians licensed pursuant to this
430 chapter or chapter 459, or a health care clinic licensed under
431 part X of chapter 400.

432 (c) The department shall deny registration to any pain-
433 management clinic owned by or with any contractual or employment
434 relationship with a physician:

435 1. Whose Drug Enforcement Administration number has ever
436 been revoked.

437 2. Whose application for a license to prescribe, dispense,
438 or administer a controlled substance has been denied by any
439 jurisdiction.

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

446 (d) If the department finds that a pain-management clinic
447 is owned , directly or indirectly, by a person meeting any



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448 criteria listed in paragraph (b) or paragraph (c), the
449 department shall refuse to register the pain-management clinic
450 or shall revoke the certificate of registration previously
451 issued by the department. As determined by rule, the department
452 may grant an exemption if more than 10 years have elapsed since
453 adjudication. As used in this subsection, the term "convicted"
454 includes an adjudication of guilt following a plea of guilty or
455 nolo contendere or the forfeiture of a bond when charged with a
456 crime.

457 (2) A person may not dispense any medication, including a
458 controlled substance, on the premises of a registered pain-
459 management clinic unless he or she is a physician licensed under
460 this chapter or chapter 459.

461 (3) After a physical examination of the patient the same
462 day of dispensing a controlled substance, a physician must
463 document in the patient's record the reason for prescribing or
464 dispensing more than a 72-hour dose of a controlled substance
465 for the treatment of chronic nonmalignant pain.

466 Section 8. Section 458.327, Florida Statutes, is amended to
467 read:

468 458.327 Penalty for violations.—

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

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

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

476 (c) Attempting to obtain or obtaining a license to practice



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477 medicine by knowing misrepresentation.

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

482 (e) Knowingly operating, owning, or managing a
483 nonregistered pain-management clinic that is required to be
484 registered with the Department of Health pursuant to
485 s.458.309(4).

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

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

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

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

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



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

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

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

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

522 (f) Knowingly prescribing or dispensing, or causing to be
523 prescribed or dispensed, controlled substances in a
524 nonregistered pain-management clinic that is required to be
525 registered with the Department of Health pursuant to s.
526 458.309(4).

527 Section 9. Section 459.005, Florida Statutes, is amended to
528 read:

529 459.005 Rulemaking authority.—

530 (1) The board has authority to adopt rules pursuant to ss.
531 120.536(1) and 120.54 to implement the provisions of this
532 chapter conferring duties upon it.

533 (2) All physicians who perform level 2 procedures lasting
534 more than 5 minutes and all level 3 surgical procedures in an



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535 office setting must register the office with the department
536 unless that office is licensed as a facility pursuant to chapter
537 395. The department shall inspect the physician's office
538 annually unless the office is accredited by a nationally
539 recognized accrediting agency or an accrediting organization
540 subsequently approved by the Board of Osteopathic Medicine. The
541 actual costs for registration and inspection or accreditation
542 shall be paid by the person seeking to register and operate the
543 office setting in which office surgery is performed.

544 (3) Effective January 4, 2010, all privately owned pain-
545 management clinics, facilities, or offices, hereinafter referred
546 to as "clinics," which advertise in any medium for any type of
547 pain-management services, or employ a physician who is licensed
548 under this chapter and who is primarily engaged in the treatment
549 of pain by prescribing or dispensing controlled substance
550 medications, must register with the department ~~by January 4,~~
551 ~~2010,~~ unless that clinic is licensed as a facility under chapter
552 395. A physician may not practice osteopathic medicine in a
553 pain-management clinic that is required to but has not
554 registered with the department. Each clinic location shall be
555 registered separately regardless of whether the clinic is
556 operated under the same business name or management as another
557 clinic. ~~If the clinic is licensed as a health care clinic under~~
558 ~~chapter 400, the medical director is responsible for registering~~
559 ~~the facility with the department.~~ If the clinic is not
560 registered under chapter 395 ~~or chapter 400,~~ the clinic shall,
561 upon registration with the department, designate a physician who
562 is responsible for complying with all requirements related to
563 registration of the clinic. The designated physician shall have



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564 a full, active, and unencumbered license ~~be licensed~~ under
565 chapter 458 or this chapter and shall practice at the office
566 location for which the physician has assumed responsibility. The
567 department shall inspect the clinic annually, including a review
568 of the patient records, to ensure that it complies with rules of
569 the Board of Osteopathic Medicine adopted pursuant to this
570 subsection and subsection (4) unless the office is accredited by
571 a nationally recognized accrediting agency approved by the Board
572 of Osteopathic Medicine. The actual costs for registration and
573 inspection or accreditation shall be paid by the physician
574 seeking to register the clinic.

575 (4) The Board of Osteopathic Medicine shall adopt rules
576 setting forth standards of practice for physicians who practice
577 in privately owned pain-management clinics that primarily engage
578 in the treatment of pain by prescribing or dispensing controlled
579 substance medications. Such rules shall address, but need not be
580 limited to, the following subjects:

- 581 (a) Facility operations;
- 582 (b) Physical operations;
- 583 (c) Infection control requirements;
- 584 (d) Health and safety requirements;
- 585 (e) Quality assurance requirements;
- 586 (f) Patient records;
- 587 (g) Training requirements for all facility health care
588 practitioners who are not regulated by another board;
- 589 (h) Inspections; and
- 590 (i) Data collection and reporting requirements.

591
592 A physician is primarily engaged in the treatment of pain by



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593 prescribing or dispensing controlled substance medications when
594 the majority of the patients seen are prescribed or dispensed
595 controlled substance medications for the treatment of chronic
596 nonmalignant pain. Chronic nonmalignant pain is pain unrelated
597 to cancer which persists beyond the usual course of the disease
598 or the injury that is the cause of the pain or more than 90 days
599 after surgery.

600 (5) A privately owned clinic, facility, or office that
601 advertises in any medium for any type of pain-management
602 services or employs one or more physicians who are primarily
603 engaged in the treatment of pain by prescribing or dispensing
604 controlled substances is exempt from the registration provisions
605 in subsection (3) if:

606 (a) The majority of the physicians who provide services in
607 the clinic, facility, or office primarily provide surgical
608 services;

609 (b) The clinic, facility or office is owned by a publicly
610 held corporation whose shares are traded on a national exchange
611 or on the over-the-counter market and whose total assets at the
612 end of corporation's most recent fiscal quarter exceeded \$50
613 million;

614 (c) The clinic, facility or office is affiliated with an
615 accredited medical school at which training is provided for
616 medical students, residents, or fellows;

617 (d) If the clinic does not prescribe or dispense controlled
618 substances for the treatment of pain; or

619 (e) The clinic, facility or office is owned by a corporate
620 entity exempt from federal taxation under 26 U.S.C. s.
621 501(c)(3).



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622 (6) (a) The department may deny an application for
623 registering a pain-management clinic or revoke or suspend a
624 current registration. The department may impose an
625 administrative fine on the clinic of up to \$5,000 per violation
626 for violating the requirements of this section, chapter 499, the
627 Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
628 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
629 the Drug Abuse Prevention and Control Act; or chapter 893, the
630 Florida Comprehensive Drug Abuse Prevention and Control Act; or
631 the rules of the department. In determining whether a penalty is
632 to be imposed, and in fixing the amount of the fine, the
633 department shall consider the following factors:

634 1. The gravity of the violation, including the probability
635 that death or serious physical or emotional harm to a patient
636 has resulted, or could have resulted, from a licensee's actions,
637 the severity of the action or potential harm, and the extent to
638 which the provisions of the applicable laws or rules were
639 violated.

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

642 3. Whether there were any previous violations at the pain-
643 management clinic.

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

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

649 (c) Any action taken to correct a violation shall be
650 documented in writing by the owner or designated physician of



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651 the pain-management clinic and verified by followup visits by
652 departmental personnel. The department may impose a fine and, in
653 the case of an owner-operated pain-management clinic may revoke
654 or deny a clinic's registration, if the clinic's designated
655 physician knowingly and intentionally misrepresents actions
656 taken to correct a violation.

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

660 (e) If the owner of a pain-management clinic fails to apply
661 for a change-of-ownership registration and operates the clinic
662 under the new ownership, the owner is subject to a fine of
663 \$5,000.

664 (f) During an onsite inspection, the department shall make
665 a reasonable attempt to discuss each violation with the owner or
666 designated physician of the pain-management clinic before
667 issuing a formal written notification.

668 (g)1. If the registration of a pain-management clinic is
669 revoked or suspended, the designated physician of the pain-
670 management clinic, the owner or lessor of the pain-management
671 clinic property, and the owner, manager, or proprietor shall
672 cease to operate the facility as a pain-management clinic as of
673 the effective date of the suspension or revocation.

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



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680 3. If the clinic's registration is revoked, any person
681 named in the registration documents of the pain-management
682 clinic, including persons owning or operating the pain-
683 management clinic, may not, as an individual or as a part of a
684 group, apply to operate a pain-management clinic for 5 years
685 after the date the registration is revoked.

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

693 5. The period of the suspension shall be prescribed by the
694 department, but may not exceed 1 year.

695 (7) The department shall adopt rules necessary to
696 administer the registration and inspection of pain-management
697 clinics establishing the specific requirements, procedures,
698 forms, and fees.

699 (8) The department shall adopt a rule defining what
700 constitutes practice by a designated physician at the office
701 location for which the physician has assumed responsibility, as
702 set forth in subsections (3) and (4). When adopting the rule,
703 the department shall consider the number of clinic employees,
704 the location of the pain-management clinic, its hours of
705 operation, and the amount of controlled substances being
706 prescribed, dispensed, or administered at the pain-management
707 clinic.

708 (9) The Boards of Medicine and Osteopathic Medicine shall



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709 adopt a rule establishing the maximum number of prescriptions
710 for Schedule II or Schedule III controlled substances which may
711 can be written at any one registered pain-management clinic
712 during any 24-hour period.

713 Section 10. Section 459.0137, Florida Statutes, is created
714 to read:

715 459.0137 Pain-management clinics.-

716 (1) (a) An osteopathic physician may not practice
717 osteopathic medicine in a pain-management clinic, as described
718 in s. 459.005(3), if:

719 1. Effective July 1, 2010, the physician has not
720 successfully completed a pain medicine fellowship that is
721 accredited by the Accreditation Council for Graduate Medical
722 Education or a pain medicine residency that is accredited by the
723 Accreditation Council for Graduate Medical Education unless
724 previously registered and qualified as a pain medicine physician
725 with the Board of Osteopathic Medicine; or

726 2. The pain-management clinic is not registered with the
727 department as required by s. 459.005. As provided in s.
728 459.005(3), each location of a pain-management clinic must be
729 registered separately regardless of whether the clinic is
730 operated under the same business name or management as another
731 clinic.

732
733 The department may revoke the clinic's certificate of
734 registration and prohibit all physicians associated with that
735 pain-management clinic from practicing at that office location
736 based upon an annual inspection and evaluation of the factors
737 described in s. 459.005(6) (a). A physician who violates this



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738 paragraph is subject to review by his or her appropriate medical
739 regulatory board.

740 (b) The department shall deny registration to any clinic
741 not fully owned by a physician licensed pursuant to chapter 458
742 or this chapter, a group of physicians licensed pursuant to
743 chapter 458 or this chapter, or a health care clinic licensed
744 under part X of chapter 400.

745 (c) The department shall deny registration to any pain-
746 management clinic owned by or with any contractual or employment
747 relationship with a physician:

748 1. Whose Drug Enforcement Administration number has ever
749 been revoked;

750 2. Whose application for a license to prescribe, dispense,
751 or administer a controlled substance has been denied by any
752 jurisdiction; or

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

759 (d) If the department finds that a pain-management clinic
760 is owned, directly or indirectly, by a person meeting any
761 criteria listed in paragraph (b) or paragraph (c), the
762 department shall refuse to register the pain-management clinic
763 or shall revoke the certificate of registration previously
764 issued by the department. As determined by rule, the department
765 may grant an exemption if more than 10 years have elapsed since
766 adjudication. As used in this subsection, the term "convicted"



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767 includes an adjudication of guilt following a plea of guilty or
768 nolo contendere or the forfeiture of a bond when charged with a
769 crime.

770 (2) A person may not dispense any medication, including a
771 controlled substance, on the premises of a registered pain-
772 management clinic unless he or she is a physician licensed under
773 this chapter or chapter 458.

774 (3) After a physical examination of the patient the same
775 day of dispensing a controlled substance, a physician must
776 document in the patient's record the reason for prescribing or
777 dispensing more than a 72-hour dose of a controlled substance
778 for the treatment of chronic nonmalignant pain.

779 Section 11. Subsections (1) and (2) of section 459.013,
780 Florida Statutes, are amended to read:

781 459.013 Penalty for violations.—

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

785 (a) The practice of osteopathic medicine, or an attempt to
786 practice osteopathic medicine, without an active license or
787 certificate issued pursuant to this chapter.

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

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

794 (d) Attempting to obtain or obtaining a position as an
795 osteopathic medical practitioner or osteopathic medical resident



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796 in a clinic or hospital through knowing misrepresentation of
797 education, training, or experience.

798 (e) Knowingly operating, owning, or managing a
799 nonregistered pain-management clinic that is required to be
800 registered with the Department of Health pursuant to s.
801 459.005(3).

802 (2) Each of the following acts constitutes a misdemeanor of
803 the first degree, punishable as provided in s. 775.082 or s.
804 775.083:

805 (a) Knowingly concealing information relating to violations
806 of this chapter.

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

809 (c) The practice of medicine as a resident or intern
810 without holding a valid current registration pursuant to s.
811 459.021.

812 (d) Knowingly prescribing or dispensing, or causing to be
813 prescribed or dispensed, controlled substances in a
814 nonregistered pain-management clinic that is required to be
815 registered with the Department of Health pursuant to s.
816 459.005(3).

817 Section 12. This act shall take effect July 1, 2010.

818
819 ===== T I T L E A M E N D M E N T =====

820 And the title is amended as follows:

821 Delete everything before the enacting clause
822 and insert:

823 A bill to be entitled

824 An act relating to pain management; amending s.



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825 456.037, F.S.; providing that pain-management clinics
826 are business establishments subject to licensure by
827 the Department of Health; requiring a health
828 professional licensee who works at a pain-management
829 clinic that prescribes controlled substances to be
830 responsible for maintaining control and security over
831 his or her blank prescription pads and any other
832 method used to prescribe controlled substance pain
833 medication; requiring the health professional licensee
834 to notify the department within a specified time of
835 the theft or loss of the blank prescription pads;
836 requiring a health professional licensee to give
837 written notice to the applicable board within a
838 specified period after the health professional
839 licensee's termination of employment at the pain-
840 management clinic; amending s. 456.057, F.S.;
841 providing that the Department of Health is not
842 required to attempt to obtain authorization from a
843 patient for the release of the patient's medical
844 records under certain circumstances; amending s.
845 456.069, F.S.; authorizing the Department of Health to
846 inspect a pain-management clinic in a lawful manner at
847 all reasonable hours for the purpose of determining if
848 any provision of ch. 456, F.S., or any rule adopted by
849 the department has been violated; authorizing the
850 department to obtain patient records without
851 authorization or subpoena if the department has
852 probable cause to believe that a violation of s.
853 456.072, F.S., has occurred or is occurring; amending



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854 s. 456.071, F.S.; providing venue for judicial
855 challenges to any subpoena or order issued by the
856 Department of Health during its investigations;
857 amending s. 456.072, F.S.; providing additional acts
858 that constitute grounds for disciplinary actions
859 against health professional licensees; amending s.
860 458.309, F.S.; requiring all privately owned pain-
861 management clinics, or offices that primarily engage
862 in the treatment of pain by prescribing or dispensing
863 controlled substance medications or employ a physician
864 who is primarily engaged in the treatment of pain by
865 prescribing or dispensing controlled substance
866 medications, to register with the Department of Health
867 within a specified time; providing an exception;
868 authorizing the department to deny an application for
869 registering a pain-management clinic or to revoke or
870 suspend the current registration certificate of a
871 pain-management clinic for certain reasons;
872 authorizing the department to impose fines for certain
873 violations of law; requiring the department to
874 consider certain factors when calculating the amount
875 of the fine; providing that each day a violation
876 continues constitutes an separate violation; requiring
877 the pain-management clinic to document in writing all
878 efforts undertaken by the pain-management clinic to
879 correct a violation; providing that the owner or
880 designated physician of a pain-management clinic is
881 subject to an administrative fine; providing that the
882 owner of a pain-management clinic that does not apply



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883 for a change-of-ownership license and operates the
884 clinic under a new ownership is subject to a fine;
885 requiring the department to discuss each violation
886 with the owner or designated physician of the pain-
887 management clinic before a formal written
888 notification; requiring a pain-management clinic to
889 cease operating if its registration certificate is
890 revoked or suspended; requiring certain named persons
891 to remove all signs and symbols identifying the
892 premises as a pain-management clinic; prohibiting any
893 person acting as an individual or as part of a group
894 from applying for a certificate to operate a pain-
895 management clinic for a certain period after the date
896 the person's registration certificate is revoked;
897 providing for disposition of drugs at the former pain-
898 management clinic; providing that certain clinics,
899 facilities, and offices that advertises any type of
900 pain-management services are exempt from the
901 registration provisions under certain conditions;
902 requiring the department and the Boards of Medicine
903 and Osteopathic Medicine to adopt rules; creating ss.
904 458.3265 and 459.0137, F.S.; providing for
905 requirements for the registration of pain-management
906 clinics; prohibiting a physician or an osteopathic
907 physician from practicing medicine in a pain-
908 management clinic under certain conditions; requiring
909 each location of a pain-management clinic to be
910 registered separately regardless of whether the clinic
911 is operated under the same business name or management



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912 as another clinic; prohibiting a pain-management
913 clinic from being owned by or having any contractual
914 relationship with certain specified persons; providing
915 that if the department finds that a privately owned
916 pain-management clinic is owned by a person possessing
917 disqualifying criteria, the department shall refuse to
918 register the pain-management clinic or revoke a
919 previously issued certificate of registration;
920 prohibiting a person from dispensing medication on the
921 premises of a registered pain-management clinic unless
922 he or she is a physician licensed under ch. 458 or ch.
923 459, F.S.; requiring a physician to document in the
924 patient's record why the physician is prescribing or
925 dispensing more than a specified amount of a
926 controlled substances for the treatment of chronic
927 nonmalignant pain; amending s. 458.327, F.S.;

928 providing that committing certain specified acts while
929 managing a pain-management clinic constitutes a felony
930 of the third degree or a misdemeanor of the first
931 degree; amending s. 459.005, F.S.; requiring all
932 privately owned pain-management clinics, or offices
933 that primarily engage in the treatment of pain by
934 prescribing or dispensing controlled substance
935 medications or employ a physician who is primarily
936 engaged in the treatment of pain by prescribing or
937 dispensing controlled substance medications, to
938 register with the Department of Health within a
939 specified time; providing an exception; providing that
940 certain clinics, facilities, and offices that



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941 advertises any type of pain-management services are
942 exempt from the registration provisions under certain
943 conditions; authorizing the department to deny an
944 application for registering a pain-management clinic
945 or to revoke or suspend the current registration
946 certificate of a pain-management clinic for certain
947 reasons; authorizing the department to impose fines
948 for certain violations of law; requiring the
949 department to consider certain factors when
950 calculating the amount of the fine; providing that
951 each day a violation continues constitutes a separate
952 violation; requiring the pain-management clinic to
953 document in writing all efforts undertaken by the
954 pain-management clinic to correct a violation;
955 providing that the owner or designated physician of a
956 pain-management clinic is subject to an administrative
957 fine; providing that the owner of a pain-management
958 clinic that does not apply for a change-of-ownership
959 license and operates the clinic under a new ownership
960 is subject to a fine; requiring the department to
961 discuss each violation with the owner or designated
962 physician of the pain-management clinic before a
963 formal written notification; requiring a pain-
964 management clinic to cease operating if its
965 registration certificate is revoked or suspended;
966 requiring certain named persons to remove all signs
967 and symbols identifying the premises as a pain-
968 management clinic; prohibiting any person acting as an
969 individual or as part of a group from applying for a



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970 certificate to operate a pain-management clinic for a
971 certain period after the date the person's
972 registration certificate is revoked; providing for
973 disposition of drugs at the former pain-management
974 clinic; requiring the department and the Boards of
975 Medicine and Osteopathic Medicine to adopt rules;
976 amending s. 459.013, F.S.; providing that committing
977 certain specified acts while managing a pain-
978 management clinic constitutes a felony of the third
979 degree or a misdemeanor of the first degree; providing
980 an effective date.