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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/26/2010	.	
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The Committee on Health Regulation (Gardiner) 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 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  
to, dental laboratories, electrology facilities, massage



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13 establishments, ~~and~~ pharmacies, and pain-management clinics  
14 required to be registered under s. 458.3265 or s. 459.0137.

15 Section 2. Paragraph (a) of subsection (9) of section  
16 456.057, Florida Statutes, is amended to read:

17 456.057 Ownership and control of patient records; report or  
18 copies of records to be furnished.—

19 (9) (a) 1. The department may obtain patient records pursuant  
20 to a subpoena without written authorization from the patient if  
21 the department and the probable cause panel of the appropriate  
22 board, if any, find reasonable cause to believe that a health  
23 care practitioner has excessively or inappropriately prescribed  
24 any controlled substance specified in chapter 893 in violation  
25 of this chapter or any professional practice act or that a  
26 health care practitioner has practiced his or her profession  
27 below that level of care, skill, and treatment required as  
28 defined by this chapter or any professional practice act and  
29 also find that appropriate, reasonable attempts were made to  
30 obtain a patient release. Notwithstanding the foregoing, the  
31 department need not attempt to obtain a patient release when  
32 investigating an offense involving the inappropriate  
33 prescribing, overprescribing, or diversion of controlled  
34 substances and the offense involves a pain-management clinic.  
35 The department may obtain patient records without patient  
36 authorization or subpoena from any pain-management clinic  
37 required to be licensed if the department has probable cause to  
38 believe that a violation of any provision of s. 458.3265 or s.  
39 459.0137 is occurring or has occurred and reasonably believes  
40 that obtaining such authorization is not feasible due to the  
41 volume of the dispensing and prescribing activity involving



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42 controlled substances and that obtaining patient authorization  
43 or the issuance of a subpoena would jeopardize the  
44 investigation.

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

53         3. The department may obtain patient records, billing  
54 records, insurance information, provider contracts, and all  
55 attachments thereto pursuant to a subpoena without written  
56 authorization from the patient if the department and probable  
57 cause panel of the appropriate board, if any, find reasonable  
58 cause to believe that a health care practitioner has submitted a  
59 claim, statement, or bill using a billing code that would result  
60 in payment greater in amount than would be paid using a billing  
61 code that accurately describes the services performed, requested  
62 payment for services that were not performed by that health care  
63 practitioner, used information derived from a written report of  
64 an automobile accident generated pursuant to chapter 316 to  
65 solicit or obtain patients personally or through an agent  
66 regardless of whether the information is derived directly from  
67 the report or a summary of that report or from another person,  
68 solicited patients fraudulently, received a kickback as defined  
69 in s. 456.054, violated the patient brokering provisions of s.  
70 817.505, or presented or caused to be presented a false or



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71 fraudulent insurance claim within the meaning of s.  
72 817.234(1)(a), and also find that, within the meaning of s.  
73 817.234(1)(a), patient authorization cannot be obtained because  
74 the patient cannot be located or is deceased, incapacitated, or  
75 suspected of being a participant in the fraud or scheme, and if  
76 the subpoena is issued for specific and relevant records.

77 4. Notwithstanding subparagraphs 1.-3., when the department  
78 investigates a professional liability claim or undertakes action  
79 pursuant to s. 456.049 or s. 627.912, the department may obtain  
80 patient records pursuant to a subpoena without written  
81 authorization from the patient if the patient refuses to  
82 cooperate or if the department attempts to obtain a patient  
83 release and the failure to obtain the patient records would be  
84 detrimental to the investigation.

85 Section 3. Section 456.071, Florida Statutes, is amended to  
86 read:

87 456.071 Power to administer oaths, take depositions, and  
88 issue subpoenas.—For the purpose of any investigation or  
89 proceeding conducted by the department, the department shall  
90 have the power to administer oaths, take depositions, make  
91 inspections when authorized by statute, issue subpoenas which  
92 shall be supported by affidavit, serve subpoenas and other  
93 process, and compel the attendance of witnesses and the  
94 production of books, papers, documents, and other evidence. The  
95 department shall exercise this power on its own initiative or  
96 whenever requested by a board or the probable cause panel of any  
97 board. Challenges to, and enforcement of, the subpoenas and  
98 orders shall be handled as provided in s. 120.569, except that  
99 venue is in the Circuit Court for the Second Judicial Circuit,



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100 in the county where the examination, investigation, or hearing  
101 is conducted, or in the county in which the person resides.

102 Section 4. Subsections (4), (5), and (6) of section  
103 458.309, Florida Statutes, are repealed.

104 Section 5. Section 458.3265, Florida Statutes, is created  
105 to read:

106 458.3265 Pain-management clinics.-

107 (1) REGISTRATION.-

108 (a) Effective January 4, 2010, all privately owned pain-  
109 management clinics, facilities, or offices, hereinafter referred  
110 to as "clinics," which advertise in any medium for any type of  
111 pain-management services, or employ a physician who is primarily  
112 engaged in the treatment of pain by prescribing or dispensing  
113 controlled substance medications, must register with the  
114 department unless:

115 1. That clinic is licensed as a facility pursuant to  
116 chapter 395;

117 2. The majority of the physicians who provide services in  
118 the clinic, facility, or office primarily provide surgical  
119 services;

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

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

128 5. The clinic does not prescribe or dispense controlled



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129 substances for the treatment of pain; or

130 6. The clinic, facility, or office is owned by a corporate  
131 entity exempt from federal taxation under 26 U.S.C. s.  
132 501(c) (3).

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

136 (c) As a part of registration, a clinic must designate a  
137 physician who is responsible for complying with all requirements  
138 related to registration of the clinic. The designated physician  
139 shall have a full, active, and unencumbered license under this  
140 chapter or chapter 459 and shall practice at the office location  
141 for which the physician has assumed responsibility.

142 (d) The department shall deny registration to any clinic  
143 not fully owned by a physician licensed under this chapter or  
144 chapter 459 or a group of physicians licensed under this chapter  
145 or chapter 459.

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

149 1. Whose Drug Enforcement Administration number has ever  
150 been revoked.

151 2. Whose application for a license to prescribe, dispense,  
152 or administer a controlled substance has been denied by any  
153 jurisdiction.

154 3. Who has been convicted of or plead guilty or nolo  
155 contender to, regardless of adjudication, an offense that  
156 constitutes a felony for receipt of illicit and diverted drugs,  
157 including a controlled substance listed in Schedule I, Schedule



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158 II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in  
159 this state, any other state, or the United States.

160 (f) If the department finds that a pain-management clinic  
161 is owned, directly or indirectly, by a person meeting any  
162 criteria listed in paragraph (d) or paragraph (e), the  
163 department shall revoke the certificate of registration  
164 previously issued by the department. As determined by rule, the  
165 department may grant an exemption to denying a registration or  
166 revoking a previously issued registration if more than 10 years  
167 have elapsed since adjudication. As used in this subsection, the  
168 term "convicted" includes an adjudication of guilt following a  
169 plea of guilty or nolo contendere or the forfeiture of a bond  
170 when charged with a crime.

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

176 (h) If the registration of a pain-management clinic is  
177 revoked or suspended, the designated physician of the pain-  
178 management clinic, the owner or lessor of the pain-management  
179 clinic property, the manager, and the proprietor shall cease to  
180 operate the facility as a pain-management clinic as of the  
181 effective date of the suspension or revocation.

182 (i) If a pain-management clinic registration is revoked or  
183 suspended, the designated physician of the pain-management  
184 clinic, the owner or lessor of the clinic property, the manager,  
185 or the proprietor is responsible for removing all signs and  
186 symbols identifying the premises as a pain-management clinic.



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187       (j) Upon the effective date of the suspension or  
188 revocation, the designated physician of the pain-management  
189 clinic shall advise the department of the disposition of the  
190 medicinal drugs located on the premises. The disposition is  
191 subject to the supervision and approval of the department.  
192 Medicinal drugs that are purchased or held by a pain-management  
193 clinic that is not registered may be deemed adulterated pursuant  
194 to s. 499.006.

195       (k) If the clinic's registration is revoked, any person  
196 named in the registration documents of the pain-management  
197 clinic, including persons owning or operating the pain-  
198 management clinic, may not, as an individual or as a part of a  
199 group, apply to operate a pain-management clinic for 5 years  
200 after the date the registration is revoked.

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

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

205       (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities  
206 apply to any physician who provides professional services in a  
207 pain-management clinic that is required to be registered in  
208 subsection (1).

209       (a) A physician may not practice medicine in a pain-  
210 management clinic, as described in subsection (4), if the pain-  
211 management clinic is not registered with the department as  
212 required by this section. A physician who violates this  
213 paragraph is subject to review by his or her appropriate medical  
214 regulatory board.

215       (b) A person may not dispense any medication, including a





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216 controlled substance, on the premises of a registered pain-  
217 management clinic unless he or she is a physician licensed under  
218 this chapter or chapter 459.

219 (c) After a physical examination of the patient, a  
220 physician, on the same day of dispensing or prescribing a  
221 controlled substance, must document in the patient's record the  
222 reason for prescribing or dispensing more than a 72-hour dose of  
223 a controlled substance for the treatment of chronic nonmalignant  
224 pain.

225 (d) A physician authorized to prescribe controlled  
226 substances who practices at a pain-management clinic is  
227 responsible for maintaining the control and security of his or  
228 her prescription blanks and any other method used for  
229 prescribing controlled substance pain medication. The physician  
230 shall comply with the requirements for counterfeit-resistant  
231 prescription blanks in s. 893.065 and the rules adopted pursuant  
232 to that section. The physician shall notify in writing the  
233 department within 24 hours following any theft or loss of a  
234 prescription blank or breach of any other method for prescribing  
235 pain medication.

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

240 (f) A practitioner registered under s. 465.0276 who  
241 practices at a pain-management clinic that is required to be  
242 registered under this section or s. 459.0137, may not dispense  
243 more than a 72-hour supply of a controlled substance listed in  
244 Schedule II or Schedule III, as provided in s. 893.03, to



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245 patients who pay by cash, check, or credit card for such  
246 medications. This limitation does not apply to patients who have  
247 insurance coverage for the medications and are using cash,  
248 check, or a credit card to meet a required copayment or  
249 deductible. A practitioner who knowingly violates this paragraph  
250 commits a felony of the third degree, punishable as provided in  
251 s. 775.082, s. 775.083, or s. 775.084. This paragraph does not  
252 apply to practitioners who dispense medications to  
253 workers' compensation patients pursuant to chapter 440. This  
254 paragraph does not apply to the dispensing of complimentary  
255 packages of medicinal drugs to the practitioner's own patients  
256 in the regular course of his or her practice without the payment  
257 of fee or remuneration of any kind, whether direct or indirect,  
258 and in conformity with the requirements of this subsection. This  
259 paragraph does not apply to controlled substances dispensed in  
260 the health care system of the Department of Corrections.

261 (3) INSPECTION.—

262 (a) The department shall inspect the clinic annually,  
263 including a review of the patient records, to ensure that it  
264 complies with this section and the rules of the Board of  
265 Medicine adopted pursuant to subsection (4) unless the office is  
266 accredited by a nationally recognized accrediting agency  
267 approved by the Board of Medicine.

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

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



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274 the pain-management clinic and verified by followup visits by  
275 departmental personnel.

276 (4) RULEMAKING.—

277 (a) The department shall adopt rules necessary to  
278 administer the registration and inspection of pain-management  
279 clinics which establish the specific requirements, procedures,  
280 forms, and fees.

281 (b) The department shall adopt a rule defining what  
282 constitutes practice by a designated physician at the office  
283 location for which the physician has assumed responsibility, as  
284 set forth in subsection (1). When adopting the rule, the  
285 department shall consider the number of clinic employees, the  
286 location of the pain-management clinic, its hours of operation,  
287 and the amount of controlled substances being prescribed,  
288 dispensed, or administered at the pain-management clinic.

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

293 (d) The Board of Medicine shall adopt rules setting forth  
294 standards of practice for physicians practicing in privately  
295 owned pain-management clinics that primarily engage in the  
296 treatment of pain by prescribing or dispensing controlled  
297 substance medications. Such rules shall address, but need not be  
298 limited to:

- 299 1. Facility operations;
- 300 2. Physical operations;
- 301 3. Infection control requirements;
- 302 4. Health and safety requirements;



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303 5. Quality assurance requirements;

304 6. Patient records;

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

307 8. Inspections; and

308 9. Data collection and reporting requirements.

309  
310 A physician is primarily engaged in the treatment of pain by  
311 prescribing or dispensing controlled substance medications when  
312 the majority of the patients seen are prescribed or dispensed  
313 controlled substance medications for the treatment of chronic  
314 nonmalignant pain. Chronic nonmalignant pain is pain unrelated  
315 to cancer which persists beyond the usual course of the disease  
316 or the injury that is the cause of the pain or more than 90 days  
317 after surgery.

318 (5) PENALTIES; ENFORCEMENT.-

319 (a) The department may impose an administrative fine on the  
320 clinic of up to \$5,000 per violation for violating the  
321 requirements of this section, chapter 499, the Florida Drug and  
322 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and  
323 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug  
324 Abuse Prevention and Control Act; chapter 893, the Florida  
325 Comprehensive Drug Abuse Prevention and Control Act; or the  
326 rules of the department. In determining whether a penalty is to  
327 be imposed, and in fixing the amount of the fine, the department  
328 shall consider the following factors:

329 1. The gravity of the violation, including the probability  
330 that death or serious physical or emotional harm to a patient  
331 has resulted, or could have resulted, from the pain-management



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332 clinic's actions, the severity of the action or potential harm,  
333 and the extent to which the provisions of the applicable laws or  
334 rules were violated.

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

337 3. Whether there were any previous violations at the pain-  
338 management clinic.

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

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

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

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

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

356 Section 6. Section 458.327, Florida Statutes, is amended to  
357 read:

358 458.327 Penalty for violations.—

359 (1) Each of the following acts constitutes a felony of the  
360 third degree, punishable as provided in s. 775.082, s. 775.083,



361 or s. 775.084:

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

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

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

368 (d) Attempting to obtain or obtaining a position as a  
369 medical practitioner or medical resident in a clinic or hospital  
370 through knowing misrepresentation of education, training, or  
371 experience.

372 (e) Knowingly operating, owning, or managing a  
373 nonregistered pain-management clinic that is required to be  
374 registered with the Department of Health pursuant to s.  
375 458.3265(1).

376 (2) Each of the following acts constitutes a misdemeanor of  
377 the first degree, punishable as provided in s. 775.082 or s.  
378 775.083:

379 (a) Knowingly concealing information relating to violations  
380 of this chapter.

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

383 (c) Referring any patient, for health care goods or  
384 services, to a partnership, firm, corporation, or other business  
385 entity in which the physician or the physician's employer has an  
386 equity interest of 10 percent or more unless, prior to such  
387 referral, the physician notifies the patient of his or her  
388 financial interest and of the patient's right to obtain such  
389 goods or services at the location of the patient's choice. This



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390 section does not apply to the following types of equity  
391 interest:

392 1. The ownership of registered securities issued by a  
393 publicly held corporation or the ownership of securities issued  
394 by a publicly held corporation, the shares of which are traded  
395 on a national exchange or the over-the-counter market;

396 2. A physician's own practice, whether he or she is a sole  
397 practitioner or part of a group, when the health care good or  
398 service is prescribed or provided solely for the physician's own  
399 patients and is provided or performed by the physician or under  
400 the physician's supervision; or

401 3. An interest in real property resulting in a landlord-  
402 tenant relationship between the physician and the entity in  
403 which the equity interest is held, unless the rent is  
404 determined, in whole or in part, by the business volume or  
405 profitability of the tenant or is otherwise unrelated to fair  
406 market value.

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

410 (e) Practicing medicine or attempting to practice medicine  
411 with an inactive or delinquent license.

412 (f) Knowingly prescribing or dispensing, or causing to be  
413 prescribed or dispensed, controlled substances in a  
414 nonregistered pain-management clinic that is required to be  
415 registered with the Department of Health pursuant to s.  
416 458.3265(1).

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



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419           458.331 Grounds for disciplinary action; action by the  
420 board and department.—  
421           (1) The following acts constitute grounds for denial of a  
422 license or disciplinary action, as specified in s. 456.072(2):  
423           (oo) Applicable to a licensee who serves as the designated  
424 physician of a pain-management clinic as defined in s. 458.3265  
425 or s. 459.0137:  
426           1. Registering a pain-management clinic through  
427 misrepresentation or fraud;  
428           2. Procuring, or attempting to procure, the registration of  
429 a pain-management clinic for any other person by making or  
430 causing to be made, any false representation;  
431           3. Failing to comply with any requirement of chapter 499,  
432 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the  
433 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,  
434 the Drug Abuse Prevention and Control Act; or chapter 893, the  
435 Florida Comprehensive Drug Abuse Prevention and Control Act;  
436           4. Being convicted or found guilty of, regardless of  
437 adjudication to, a felony or any other crime involving moral  
438 turpitude, fraud, dishonesty, or deceit in any jurisdiction of  
439 the courts of this state, of any other state, or of the United  
440 States;  
441           5. Being convicted of, or disciplined by a regulatory  
442 agency of the Federal Government or a regulatory agency of  
443 another state for any offense that would constitute a violation  
444 of this chapter;  
445           6. Being convicted of, or entering a plea of guilty or nolo  
446 contendere to, regardless of adjudication, a crime in any  
447 jurisdiction which relates to the practice of, or the ability to





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448 practice, a licensed health care profession;  
449 7. Being convicted of, or entering a plea of guilty or nolo  
450 contendere to, regardless of adjudication, a crime in any  
451 jurisdiction which relates to health care fraud;  
452 8. Dispensing any medicinal drug based upon a communication  
453 that purports to be a prescription as defined in s. 465.003(14)  
454 or s. 893.02 if the dispensing practitioner knows or has reason  
455 to believe that the purported prescription is not based upon a  
456 valid practitioner-patient relationship; or  
457 9. Failing to have a licensed designated physician  
458 practicing at the location of the registered clinic. A violation  
459 of this paragraph may be the basis for a summary suspension as  
460 described in s. 456.073(8) or s. 120.60(6).  
461 (pp) Failing to timely notify the department of the theft  
462 of prescription blanks from a pain-management clinic or a breach  
463 of other methods for prescribing within 24 hours as required by  
464 s. 458.3265(2).  
465 (qq) Failing to timely notify the applicable board  
466 governing his or her prescribing privileges of the date of his  
467 or her termination from a pain-management clinic as required by  
468 s. 458.3265(2).  
469 Section 8. Subsections (3), (4), and (5) of section  
470 459.005, Florida Statutes, are repealed.  
471 Section 9. Section 459.0137, Florida Statutes, is created  
472 to read:  
473 459.0137 Pain-management clinics.—  
474 (1) REGISTRATION.—  
475 (a) Effective January 4, 2010, all privately owned pain-  
476 management clinics, facilities, or offices, hereinafter referred



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477 to as "clinics," which advertise in any medium for any type of  
478 pain-management services, or employ an osteopathic physician who  
479 is primarily engaged in the treatment of pain by prescribing or  
480 dispensing controlled substance medications, must register with  
481 the department unless:

482 1. That clinic is licensed as a facility pursuant to  
483 chapter 395;

484 2. The majority of the physicians who provide services in  
485 the clinic, facility, or office primarily provide surgical  
486 services;

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

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

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

497 6. The clinic, facility, or office is owned by a corporate  
498 entity exempt from federal taxation under 26 U.S.C. s.  
499 501(c)(3).

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

503 (c) As a part of registration, a clinic must designate an  
504 osteopathic physician who is responsible for complying with all  
505 requirements related to registration of the clinic. The



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506 designated physician shall have a full, active, and unencumbered  
507 license under chapter 458 or this chapter and shall practice at  
508 the office location for which the physician has assumed  
509 responsibility.

510 (d) The department shall deny registration to any clinic  
511 not fully owned by a physician licensed under chapter 458 or  
512 this chapter or a group of physicians under to chapter 458 or  
513 this chapter.

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

517 1. Whose Drug Enforcement Administration number has ever  
518 been revoked.

519 2. Whose application for a license to prescribe, dispense,  
520 or administer a controlled substance has been denied by any  
521 jurisdiction.

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

528 (f) If the department finds that a pain-management clinic  
529 is owned, directly or indirectly, by a person meeting any  
530 criteria listed in paragraph (d) or paragraph (e), the  
531 department shall revoke the certificate of registration  
532 previously issued by the department. As determined by rule, the  
533 department may grant an exemption to denying a registration or  
534 revoking a previously issued registration if more than 10 years



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535 have elapsed since adjudication. As used in this subsection, the  
536 term "convicted" includes an adjudication of guilt following a  
537 plea of guilty or nolo contendere or the forfeiture of a bond  
538 when charged with a crime.

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

544 (h) If the registration of a pain-management clinic is  
545 revoked or suspended, the designated physician of the pain-  
546 management clinic, the owner or lessor of the pain-management  
547 clinic property, the manager, and the proprietor shall cease to  
548 operate the facility as a pain-management clinic as of the  
549 effective date of the suspension or revocation.

550 (i) If a pain-management clinic registration is revoked or  
551 suspended, the designated physician of the pain-management  
552 clinic, the owner or lessor of the clinic property, the manager,  
553 or the proprietor is responsible for removing all signs and  
554 symbols identifying the premises as a pain-management clinic.

555 (j) Upon the effective date of the suspension or  
556 revocation, the designated physician of the pain-management  
557 clinic shall advise the department of the disposition of the  
558 medicinal drugs located on the premises. The disposition is  
559 subject to the supervision and approval of the department.  
560 Medicinal drugs that are purchased or held by a pain-management  
561 clinic that is not registered may be deemed adulterated pursuant  
562 to s. 499.006.

563 (k) If the clinic's registration is revoked, any person



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564 named in the registration documents of the pain-management  
565 clinic, including persons owning or operating the pain-  
566 management clinic, may not as an individual or as a part of a  
567 group, make application for a permit to operate a pain-  
568 management clinic for 5 years after the date the registration is  
569 revoked.

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

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

574 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities  
575 apply to any osteopathic physician who provides professional  
576 services in a pain-management clinic that is required to be  
577 registered in subsection (1).

578 (a) An osteopathic physician may not practice medicine in a  
579 pain-management clinic, as described in subsection (4), if the  
580 pain-management clinic is not registered with the department as  
581 required by this section. An osteopathic physician who violates  
582 this paragraph is subject to review by his or her appropriate  
583 medical regulatory board.

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

588 (c) After a physical examination of the patient, an  
589 osteopathic physician, on the same day of dispensing or  
590 prescribing a controlled substance, must document in the  
591 patient's record the reason for prescribing or dispensing more  
592 than a 72-hour dose of a controlled substance for the treatment



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593 of chronic nonmalignant pain.

594 (d) An osteopathic physician authorized to prescribe  
595 controlled substances who practices at a pain-management clinic  
596 is responsible for maintaining the control and security of his  
597 or her prescription blanks and any other method used for  
598 prescribing controlled substance pain medication. The  
599 osteopathic physician shall comply with the requirements for  
600 counterfeit-resistant prescription blanks in s. 893.065 and the  
601 rules adopted pursuant to that section. The osteopathic  
602 physician shall notify in writing the department within 24 hours  
603 following any theft or loss of a prescription blank or breach of  
604 any other method for prescribing pain medication.

605 (e) The osteopathic physician shall notify the applicable  
606 board in writing of the date of termination of employment within  
607 10 days after terminating his or her employment with a pain-  
608 management clinic that is required to be registered under  
609 subsection (1).

610 (f) An osteopathic practitioner registered under s.  
611 465.0276 who practices at a pain-management clinic that is  
612 required to be registered under s. 458.3265 or this section may  
613 not dispense more than a 72-hour supply of a controlled  
614 substance listed in Schedule II or Schedule III, as provided in  
615 s. 893.03, to patients who pay by cash, check, or credit card  
616 for such medications. This limitation does not apply to patients  
617 who have insurance coverage for the medications and are using  
618 cash, check, or a credit card to meet a required copayment or  
619 deductible. A practitioner who knowingly violates this provision  
620 commits a felony of the third degree, punishable as provided in  
621 s. 775.082, s. 775.083, or s. 775.084. This paragraph does not



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622 apply to practitioners who dispense medications to  
623 workers' compensation patients pursuant to chapter 440. This  
624 paragraph does not apply to the dispensing of complimentary  
625 packages of medicinal drugs to the practitioner's own patients  
626 in the regular course of his or her practice, without the  
627 payment of fee or remuneration of any kind, whether direct or  
628 indirect, and in conformity with the requirements of this  
629 subsection. This paragraph does not apply to controlled  
630 substances dispensed in the health care system of the Department  
631 of Corrections.

632 (3) INSPECTION.—

633 (a) The department shall inspect the clinic annually,  
634 including a review of the patient records, to ensure that it  
635 complies with this section and the rules of the Board of  
636 Osteopathic Medicine adopted pursuant to subsection (4) unless  
637 the office is accredited by a nationally recognized accrediting  
638 agency approved by the Board of Osteopathic Medicine.

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

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

647 (4) RULEMAKING.—

648 (a) The department shall adopt rules necessary to  
649 administer the registration and inspection of pain-management  
650 clinics which establish the specific requirements, procedures,



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651 forms, and fees.

652 (b) The department shall adopt a rule defining what  
653 constitutes practice by a designated physician at the office  
654 location for which the physician has assumed responsibility, as  
655 set forth in subsection (1). When adopting the rule, the  
656 department shall consider the number of clinic employees, the  
657 location of the pain-management clinic, its hours of operation,  
658 and the amount of controlled substances being prescribed,  
659 dispensed, or administered at the pain-management clinic.

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

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

- 671 1. Facility operations;
- 672 2. Physical operations;
- 673 3. Infection control requirements;
- 674 4. Health and safety requirements;
- 675 5. Quality assurance requirements;
- 676 6. Patient records;
- 677 7. Training requirements for all facility health care  
678 practitioners who are not regulated by another board;
- 679 8. Inspections; and





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680           9. Data collection and reporting requirements.

681  
682   An osteopathic physician is primarily engaged in the treatment  
683   of pain by prescribing or dispensing controlled substance  
684   medications when the majority of the patients seen are  
685   prescribed or dispensed controlled substance medications for the  
686   treatment of chronic nonmalignant pain. Chronic nonmalignant  
687   pain is pain unrelated to cancer which persists beyond the usual  
688   course of the disease or the injury that is the cause of the  
689   pain or more than 90 days after surgery.

690           (5) PENALTIES; ENFORCEMENT.—

691           (a) The department may impose an administrative fine on the  
692   clinic of up to \$5,000 per violation for violating the  
693   requirements of this section, chapter 499, the Florida Drug and  
694   Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and  
695   Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug  
696   Abuse Prevention and Control Act; chapter 893, the Florida  
697   Comprehensive Drug Abuse Prevention and Control Act; or the  
698   rules of the department. In determining whether a penalty is to  
699   be imposed, and in fixing the amount of the fine, the department  
700   shall consider the following factors:

701           1. The gravity of the violation, including the probability  
702   that death or serious physical or emotional harm to a patient  
703   has resulted, or could have resulted, from the pain-management  
704   clinic's actions, the severity of the action or potential harm,  
705   and the extent to which the provisions of the applicable laws or  
706   rules were violated.

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



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709           3. Whether there were any previous violations at the pain-  
710 management clinic.

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

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

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

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

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

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

730           459.013 Penalty for violations.—

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

734           (a) The practice of osteopathic medicine, or an attempt to  
735 practice osteopathic medicine, without an active license or  
736 certificate issued pursuant to this chapter.

737           (b) The practice of osteopathic medicine by a person



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738 holding a limited license, osteopathic faculty certificate, or  
739 other certificate issued under this chapter beyond the scope of  
740 practice authorized for such licensee or certificateholder.

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

743 (d) Attempting to obtain or obtaining a position as an  
744 osteopathic medical practitioner or osteopathic medical resident  
745 in a clinic or hospital through knowing misrepresentation of  
746 education, training, or experience.

747 (e) Knowingly operating, owning, or managing a  
748 nonregistered pain-management clinic that is required to be  
749 registered with the Department of Health pursuant to s.  
750 459.0137(1).

751 (2) Each of the following acts constitutes a misdemeanor of  
752 the first degree, punishable as provided in s. 775.082 or s.  
753 775.083:

754 (a) Knowingly concealing information relating to violations  
755 of this chapter.

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

758 (c) The practice of medicine as a resident or intern  
759 without holding a valid current registration pursuant to s.  
760 459.021.

761 (d) Knowingly prescribing or dispensing, or causing to be  
762 prescribed or dispensed, controlled substances in a  
763 nonregistered pain-management clinic that is required to be  
764 registered with the Department of Health pursuant to s.  
765 459.0137(1).

766 Section 11. Paragraphs (qq), (rr), and (ss) are added to



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767 subsection (1) of section 459.015, Florida Statutes, to read:  
768 459.015 Grounds for disciplinary action; action by the  
769 board and department.—

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

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

775 1. Registering a pain-management clinic through  
776 misrepresentation or fraud;

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

780 3. Failing to comply with any requirement of chapter 499,  
781 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the  
782 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,  
783 the Drug Abuse Prevention and Control Act; or chapter 893, the  
784 Florida Comprehensive Drug Abuse Prevention and Control Act;

785 4. Being convicted or found guilty of, regardless of  
786 adjudication to, a felony or any other crime involving moral  
787 turpitude, fraud, dishonesty, or deceit in any jurisdiction of  
788 the courts of this state, of any other state, or of the United  
789 States;

790 5. Being convicted of, or disciplined by a regulatory  
791 agency of the Federal Government or a regulatory agency of  
792 another state for any offense that would constitute a violation  
793 of this chapter;

794 6. Being convicted of, or entering a plea of guilty or nolo  
795 contendere to, regardless of adjudication, a crime in any



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796 jurisdiction which relates to the practice of, or the ability to  
797 practice, a licensed health care profession;

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

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

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

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

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

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

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

821 And the title is amended as follows:

822 Delete everything before the enacting clause  
823 and insert:

824 A bill to be entitled



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825 An act relating to pain management; amending s.  
826 456.037, F.S.; providing that pain-management clinics  
827 are business establishments that are required to be  
828 registered with the Department of Health; amending s.  
829 456.057, F.S.; providing that the Department of Health  
830 is not required to attempt to obtain authorization  
831 from a patient for the release of the patient's  
832 medical records under certain circumstances;  
833 authorizing the department to obtain patient records  
834 without authorization or subpoena if the department  
835 has probable cause to believe that certain violations  
836 have occurred or are occurring; amending s. 456.071,  
837 F.S.; providing for venue of judicial challenges to  
838 any subpoena or order issued by the Department of  
839 Health during its investigations; repealing s.  
840 458.309(5), (6), and (7), F.S., relating to pain-  
841 management clinics; creating s. 458.3265, F.S.;  
842 requiring all privately owned pain-management clinics,  
843 or offices that primarily engage in the treatment of  
844 pain by prescribing or dispensing controlled substance  
845 medications or by employing a physician who is  
846 primarily engaged in the treatment of pain by  
847 prescribing or dispensing controlled substance  
848 medications, to register with the Department of Health  
849 by a specified date; providing an exceptions;  
850 requiring each location of a pain-management clinic to  
851 register separately; requiring a clinic to designate a  
852 physician who is responsible for complying with  
853 requirements related to registration of the clinic;



854 requiring the department to deny registration or  
855 revoke the registration of a pain-management clinic  
856 for certain conditions; authorizing the department to  
857 revoke a clinic's certificate of registration and  
858 prohibit physicians associated with the clinic from  
859 practicing at the clinic's office location; requiring  
860 a pain-management clinic to cease operating if its  
861 registration certificate is revoked or suspended;  
862 requiring certain named persons to remove all signs  
863 and symbols identifying the premises as a pain-  
864 management clinic; requiring a pain-management clinic  
865 that has had its registration revoked or suspended to  
866 advise the department of the disposition of the  
867 medicinal drugs located on the premises; providing  
868 that medicinal drugs that are purchased or held by a  
869 pain-management clinic that is not registered may be  
870 deemed adulterated; prohibiting any person acting as  
871 an individual or as part of a group from applying for  
872 a certificate to operate a pain-management clinic for  
873 a certain period after the date the person's  
874 registration certificate is revoked; providing that a  
875 change of ownership of a registered pain-management  
876 clinic requires submission of a new registration  
877 application; providing the responsibilities of a  
878 physician that provides professional services at a  
879 pain-management clinic; prohibiting certain  
880 practitioners from dispensing a specified dosage of  
881 certain controlled substances to patients who pay by  
882 cash, check, or credit card; providing an exception;



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883 providing a criminal penalty; providing for  
884 nonapplication; requiring the department to inspect  
885 pain-management clinics and its patient records;  
886 requiring the department and the Board of Medicine to  
887 adopt rules; authorizing the department to impose  
888 fines, deny a clinic's registration, or revoke a  
889 clinic's registration; amending s. 458.327, F.S.;  
890 providing that committing certain specified acts  
891 involving a nonregistered pain-management clinic  
892 constitutes a felony of the third degree or a  
893 misdemeanor of the first degree; amending s. 458.331,  
894 F.S.; providing additional acts that constitute  
895 grounds for disciplinary actions against health  
896 professional licensees; repealing s. 459.005(3), (4),  
897 and (5), F.S., relating to pain-management clinics;  
898 creating s. 459.0137, F.S.; requiring all privately  
899 owned pain-management clinics, or offices that  
900 primarily engage in the treatment of pain by  
901 prescribing or dispensing controlled substance  
902 medications or by employing an osteopathic physician  
903 who is primarily engaged in the treatment of pain by  
904 prescribing or dispensing controlled substance  
905 medications, to register with the department by a  
906 specified date; providing an exceptions; requiring  
907 each location of a pain-management clinic to register  
908 separately; requiring a clinic to designate an  
909 osteopathic physician who is responsible for complying  
910 with requirements related to registration of the  
911 clinic; requiring the department to deny registration





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912 or revoke the registration of a pain-management clinic  
913 for certain conditions; authorizing the department to  
914 revoke a clinic's certificate of registration and  
915 prohibit osteopathic physicians associated with the  
916 clinic from practicing at the clinic's office  
917 location; requiring a pain-management clinic to cease  
918 operating if its registration certificate is revoked  
919 or suspended; requiring certain named persons to  
920 remove all signs and symbols identifying the premises  
921 as a pain-management clinic; requiring a pain-  
922 management clinic that has had its registration  
923 revoked or suspended to advise the department of the  
924 disposition of the medicinal drugs located on the  
925 premises; providing that medicinal drugs that are  
926 purchased or held by a pain-management clinic that is  
927 not registered may be deemed adulterated; prohibiting  
928 any person acting as an individual or as part of a  
929 group from applying for a certificate to operate a  
930 pain-management clinic for a certain period after the  
931 date the person's registration certificate is revoked;  
932 providing that a change of ownership of a registered  
933 pain-management clinic requires submission of a new  
934 registration application; providing the  
935 responsibilities of an osteopathic physician that  
936 provides professional services at a pain-management  
937 clinic; prohibiting certain practitioners from  
938 dispensing a specified dosage of certain controlled  
939 substances to patients who pay by cash, check, or  
940 credit card; providing an exception; providing a



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941 criminal penalty; providing for nonapplication;  
942 requiring the department to inspect pain-management  
943 clinics and its patient records; requiring the  
944 department and the Board of Osteopathic Medicine to  
945 adopt rules; authorizing the department to impose  
946 fines, deny a clinic's registration, or revoke a  
947 clinic's registration; amending s. 459.013, F.S.;  
948 providing that committing certain specified acts  
949 involving a nonregistered pain-management clinic  
950 constitutes a felony of the third degree or a  
951 misdemeanor of the first degree; amending s. 459.015,  
952 F.S.; providing additional acts that constitute  
953 grounds for disciplinary actions against health  
954 professional licensees; providing an effective date.