

By Senator Fasano

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1                   A bill to be entitled  
2           An act relating to pain management; amending s.  
3           456.013, F.S.; requiring the Department of Health and  
4           applicable boards within the Department of Health to  
5           approve a mandatory continuing education course for  
6           any practitioner who prescribes, administers, or  
7           dispenses controlled substances that are listed in  
8           Schedule II, Schedule III, or Schedule IV of ch. 893,  
9           F.S.; requiring the training course to include certain  
10          specified topics; providing that completion of the  
11          course satisfies in part, the practitioner's  
12          continuing education requirements; authorizing the  
13          department to exempt practitioners who have obtained  
14          specialty training in or related to pain management;  
15          providing dates of applicability for licensees and  
16          initial applicants for licenses; requiring the  
17          department to adopt rules to administer the training  
18          requirements; amending s. 456.037, F.S.; providing  
19          that pain-management clinics are business  
20          establishments subject to licensure by the Department  
21          of Health; requiring a health professional licensee  
22          who works at a pain-management clinic that prescribes  
23          controlled substances to be responsible for  
24          maintaining control and security over his or her blank  
25          prescription pads and any other method used to  
26          prescribe controlled substance pain medication;  
27          requiring the health professional licensee to notify  
28          the department within a specified time of the theft or  
29          loss of the blank prescription pads; requiring a

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30 health professional licensee to give written notice to  
31 the applicable board within a specified period after  
32 the health professional licensee's termination of  
33 employment at the pain-management clinic; amending s.  
34 456.057, F.S.; providing that the Department of Health  
35 is not required to attempt to obtain authorization  
36 from a patient for the release of the patient's  
37 medical records under certain circumstances; amending  
38 s. 456.069, F.S.; authorizing the Department of Health  
39 to inspect a pain-management clinic in a lawful manner  
40 at all reasonable hours for the purpose of determining  
41 if any provision of ch. 456, F.S., or any rule adopted  
42 by the department has been violated; amending s.  
43 456.071, F.S.; providing venue for judicial challenges  
44 to any subpoena or order issued by the Department of  
45 Health during its investigations; amending s. 456.072,  
46 F.S.; providing additional acts that constitute  
47 grounds for disciplinary actions against health  
48 professional licensees; amending s. 456.309, F.S.;  
49 requiring all privately owned pain-management clinics,  
50 or offices that primarily engage in the treatment of  
51 pain by prescribing or dispensing controlled substance  
52 medications or employ a physician who is primarily  
53 engaged in the treatment of pain by prescribing or  
54 dispensing controlled substance medications, to  
55 register with the Department of Health within a  
56 specified time; providing an exception; authorizing  
57 the department to deny an application for registering  
58 a pain-management clinic or to revoke or suspend the

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59 current registration certificate of a pain-management  
60 clinic for certain reasons; authorizing the department  
61 to impose fines for certain violations of law;  
62 requiring the department to consider certain factors  
63 when calculating the amount of the fine; providing  
64 that each day constitutes an additional fine;  
65 requiring the pain-management clinic to document in  
66 writing all efforts undertaken by the pain-management  
67 clinic to correct a violation; requiring a pain-  
68 management clinic to cease operating if its  
69 registration certificate is revoked or suspended;  
70 requiring certain named persons to remove all signs  
71 and symbols identifying the premises as a pain-  
72 management clinic; prohibiting any person acting as an  
73 individual or as part of a group from applying for a  
74 certificate to operate a pain-management clinic for a  
75 period of 5 years after the date the person's  
76 registration certificate was revoked; providing for  
77 disposition of drugs at the former pain-management  
78 clinic; requiring the department to adopt rules;  
79 creating ss. 458.3265 and 459.0137, F.S.; providing  
80 for requirements for the registration of pain-  
81 management clinics; prohibiting a physician or an  
82 osteopathic physician from practicing medicine in a  
83 pain-management clinic if the pain-management clinic  
84 is not registered with the Department of Health;  
85 requiring each location of a pain-management clinic to  
86 be registered separately regardless of whether the  
87 clinic is operated under the same business name or

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88 management as another clinic; prohibiting a pain-  
89 management clinic from being owned by or having any  
90 contractual relationship with certain specified  
91 persons; providing that if the department finds that a  
92 privately owned pain-management clinic is owned by a  
93 person possessing disqualifying criteria, the  
94 department shall refuse to register the pain-  
95 management clinic or revoke a previously issued  
96 certificate of registration; requiring the owner,  
97 operator, or designated physician to be responsible  
98 for the onsite management of a pain-management clinic;  
99 providing that an owner or operator who fails to  
100 comply with certain stated conditions commits a  
101 misdemeanor of the first degree; providing criminal  
102 penalties; providing that only certain designated  
103 persons may dispense medication; requiring a physician  
104 to document in the patient's record why the physician  
105 is prescribing or dispensing more than a specified  
106 amount of a controlled substances for the treatment of  
107 chronic nonmalignant pain; defining terms; requiring,  
108 on or after a specified date, any person submitting an  
109 application for an initial or renewal registration  
110 certificate to operate a pain-management clinic to  
111 include certain specified information on the  
112 application form to the department; requiring the  
113 department to send to the Department of Law  
114 Enforcement fingerprints as a part of an applicant's  
115 criminal history background check of registered  
116 persons for a statewide criminal record check, and to

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117 the Federal Bureau of Investigation for a national  
118 criminal history record check; requiring each person  
119 who applies for an initial or renewal registration to  
120 pay the department a fee for the cost of preparing and  
121 retaining the fingerprints and performing the ongoing  
122 searches of arrest records; requiring the State  
123 Surgeon General to order a pain-management clinic to  
124 cease operations if the owner or operator of the pain-  
125 management clinic fails to pass a criminal history  
126 background check; providing an exemption; requiring  
127 the department and the Department of Law Enforcement  
128 to adopt rules; amending ss. 458.327 and 459.013,  
129 F.S.; providing that committing certain specified acts  
130 while managing a pain-management clinic constitutes a  
131 felony of the third degree or a misdemeanor of the  
132 first degree; amending s. 459.005, F.S.; authorizing  
133 the department to deny an application for registering  
134 a pain-management clinic, or to revoke or suspend the  
135 current registration for certain reasons; permitting  
136 the department to impose fines for certain violations  
137 of law; requiring the department to consider certain  
138 factors when calculating the amount of the fine;  
139 providing that each day constitutes an additional  
140 fine; requiring a pain-management clinic to cease  
141 operating as a pain-management clinic if its  
142 registration is revoked or suspended; requiring  
143 certain named persons to remove all signs and symbols  
144 identifying the premises as a pain-management clinic;  
145 prohibiting any person acting as an individual or as

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146 part of a group, make application for a permit to  
147 operate a pain-management clinic for a period of 5  
148 years after the date the registration was revoked;  
149 providing for disposition of drugs at the former pain-  
150 management clinic; requiring the department to adopt  
151 certain rules; providing an effective date.

152  
153 Be It Enacted by the Legislature of the State of Florida:

154  
155 Section 1. Subsection (7) of section 456.013, Florida  
156 Statutes, is amended to read:

157 456.013 Department; general licensing provisions.—

158 (7) (a) The boards, or the department when there is no  
159 board, shall require the completion of a 2-hour course relating  
160 to prevention of medical errors as part of the licensure and  
161 renewal process. The 2-hour course shall count towards the total  
162 number of continuing education hours required for the  
163 profession. The course shall be approved by the board or  
164 department, as appropriate, and shall include a study of root-  
165 cause analysis, error reduction and prevention, and patient  
166 safety. In addition, the course approved by the Board of  
167 Medicine and the Board of Osteopathic Medicine shall include  
168 information relating to the five most misdiagnosed conditions  
169 during the previous biennium, as determined by the board. If the  
170 course is being offered by a facility licensed pursuant to  
171 chapter 395 for its employees, the board may approve up to 1  
172 hour of the 2-hour course to be specifically related to error  
173 reduction and prevention methods used in that facility.

174 (b) The boards, or the department if there is no board,

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175 shall require the completion of a 3-hour continuing education  
176 course relating to prescribing, administering, or dispensing  
177 controlled substances listed in Schedule II, Schedule III, or  
178 Schedule IV, as set forth in s. 893.03, as a condition for  
179 receiving an initial license or a license renewal. The course is  
180 required for any practitioner licensed pursuant to chapter 458,  
181 chapter 459, chapter 461, chapter 466, or chapter 457 who  
182 prescribes, administers, or dispenses controlled substances. The  
183 course must include, but need not be limited to:

184 1. The goals of administering controlled substances to  
185 patients who require short-term and ongoing pain management;

186 2. The guidelines and rules for prescribing controlled  
187 substances, including the use of a controlled substance  
188 agreement;

189 3. The application of drug screening or drug testing to  
190 patients, including instruction on the usefulness and  
191 limitations of drug screening and drug testing;

192 4. The role of controlled substances in treating short-term  
193 and ongoing pain syndromes, including instruction on the  
194 usefulness and limitations of controlled substance in treating  
195 pain;

196 5. The use of evidenced-based, noncontrolled-substance  
197 pharmacological pain treatments on patients;

198 6. The use of evidenced-based, nonpharmacological pain  
199 treatments on patients;

200 7. The importance of properly obtaining a full medical  
201 history and completing a comprehensive physical examination of  
202 patients;

203 8. The importance of keeping appropriate progress notes

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204 during the care of patients;

205 9. The relationship of the co-occurring morbidities that  
206 occur with pain disorders, such as psychiatric and addictive  
207 disorders;

208 10. The identification and prevention of drug abuse and  
209 drug diversion; and

210 11. The laws and rules of this state which govern the  
211 prescription, administration, and distribution of controlled  
212 substances.

213

214 The course hours must be included in the total number of hours  
215 of continuing education required by the profession and must be  
216 approved by the board, or by the department if there is no  
217 board. A course offered under the auspices of a facility  
218 licensed pursuant to chapter 395 for its employees must be  
219 approved by the board, or by the department if there is no  
220 board, if the course is at least 3 hours in duration and covers  
221 the topic of prescribing, administering, and dispensing  
222 controlled substances.

223 (c) The boards may exempt a licensee from the training  
224 requirements set forth in paragraph (b) if the licensee has  
225 obtained specialty or subspecialty certification in or related  
226 to pain management from a specialty board recognized by the  
227 respective board.

228 (d) The course requirements set forth in paragraph (b)  
229 apply to each licensee when renewing his or her license  
230 beginning on or after July 1, 2011, and to all applicants who  
231 are approved for licensure on or after January 1, 2012.

232 (e) The boards, or the department if there is no board,



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233 shall adopt rules to administer this subsection by July 1, 2011.

234 Section 2. Section 456.037, Florida Statutes, is amended to  
235 read:

236 456.037 Business establishments; requirements for active  
237 status licenses; delinquency; discipline; applicability.-

238 (1) A business establishment regulated by the Division of  
239 Medical Quality Assurance pursuant to this chapter may provide  
240 regulated services only if the business establishment has an  
241 active status license. A business establishment that provides  
242 regulated services without an active status license is in  
243 violation of this section and s. 456.072, and the board, or the  
244 department if there is no board, may impose discipline on the  
245 business establishment.

246 (2) A business establishment must apply with a complete  
247 application, as defined by rule of the board, or the department  
248 if there is no board, to renew an active status license before  
249 the license expires. If a business establishment fails to renew  
250 before the license expires, the license becomes delinquent,  
251 except as otherwise provided in statute, in the license cycle  
252 following expiration.

253 (3) A delinquent business establishment must apply with a  
254 complete application, as defined by rule of the board, or the  
255 department if there is no board, for active status within 6  
256 months after becoming delinquent. Failure of a delinquent  
257 business establishment to renew the license within the 6 months  
258 after the expiration date of the license renders the license  
259 null without any further action by the board or the department.  
260 Any subsequent licensure shall be as a result of applying for  
261 and meeting all requirements imposed on a business establishment

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262 for new licensure.

263 (4) The status or a change in status of a business  
264 establishment license does not alter in any way the right of the  
265 board, or of the department if there is no board, to impose  
266 discipline or to enforce discipline previously imposed on a  
267 business establishment for acts or omissions committed by the  
268 business establishment while holding a license, whether active  
269 or null.

270 (5) This section applies to any business establishment  
271 registered, permitted, or licensed by the department to do  
272 business. Business establishments include, but are not limited  
273 to, dental laboratories, electrology facilities, massage  
274 establishments, ~~and~~ pharmacies, and pain-management clinics  
275 required to be registered under s. 458.309 or s. 459.005.

276 (6) A licensee authorized to prescribe controlled  
277 substances who practices at a pain-management clinic is  
278 responsible for maintaining the control and security of his or  
279 her prescription blanks and any other method used for  
280 prescribing controlled substance pain medication. The licensee  
281 shall comply with the requirements for counterfeit-resistant  
282 prescription blanks in s. 893.065 and the rules adopted pursuant  
283 to that section. The licensee shall notify in writing:

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

287 (b) The applicable board of the date of termination of  
288 employment within 10 days after terminating his or her  
289 employment with a pain-management clinic.

290 Section 3. Paragraph (a) of subsection (9) of section

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291 456.057, Florida Statutes, is amended to read:

292 456.057 Ownership and control of patient records; report or  
293 copies of records to be furnished.—

294 (9) (a)1. The department may obtain patient records pursuant  
295 to a subpoena without written authorization from the patient if  
296 the department and the probable cause panel of the appropriate  
297 board, if any, find reasonable cause to believe that a health  
298 care practitioner has excessively or inappropriately prescribed  
299 any controlled substance specified in chapter 893 in violation  
300 of this chapter or any professional practice act or that a  
301 health care practitioner has practiced his or her profession  
302 below that level of care, skill, and treatment required as  
303 defined by this chapter or any professional practice act and  
304 also find that appropriate, reasonable attempts were made to  
305 obtain a patient release. Notwithstanding the foregoing, the  
306 department need not attempt to obtain a patient release when  
307 investigating an offense involving the inappropriate  
308 prescribing, overprescribing, or diversion of controlled  
309 substances and the offense involves a pain-management clinic.

310 2. The department may obtain patient records and insurance  
311 information pursuant to a subpoena without written authorization  
312 from the patient if the department and the probable cause panel  
313 of the appropriate board, if any, find reasonable cause to  
314 believe that a health care practitioner has provided inadequate  
315 medical care based on termination of insurance and also find  
316 that appropriate, reasonable attempts were made to obtain a  
317 patient release.

318 3. The department may obtain patient records, billing  
319 records, insurance information, provider contracts, and all

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320 attachments thereto pursuant to a subpoena without written  
321 authorization from the patient if the department and probable  
322 cause panel of the appropriate board, if any, find reasonable  
323 cause to believe that a health care practitioner has submitted a  
324 claim, statement, or bill using a billing code that would result  
325 in payment greater in amount than would be paid using a billing  
326 code that accurately describes the services performed, requested  
327 payment for services that were not performed by that health care  
328 practitioner, used information derived from a written report of  
329 an automobile accident generated pursuant to chapter 316 to  
330 solicit or obtain patients personally or through an agent  
331 regardless of whether the information is derived directly from  
332 the report or a summary of that report or from another person,  
333 solicited patients fraudulently, received a kickback as defined  
334 in s. 456.054, violated the patient brokering provisions of s.  
335 817.505, or presented or caused to be presented a false or  
336 fraudulent insurance claim within the meaning of s.  
337 817.234(1)(a), and also find that, within the meaning of s.  
338 817.234(1)(a), patient authorization cannot be obtained because  
339 the patient cannot be located or is deceased, incapacitated, or  
340 suspected of being a participant in the fraud or scheme, and if  
341 the subpoena is issued for specific and relevant records.

342 4. Notwithstanding subparagraphs 1.-3., when the department  
343 investigates a professional liability claim or undertakes action  
344 pursuant to s. 456.049 or s. 627.912, the department may obtain  
345 patient records pursuant to a subpoena without written  
346 authorization from the patient if the patient refuses to  
347 cooperate or if the department attempts to obtain a patient  
348 release and the failure to obtain the patient records would be

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349 detrimental to the investigation.

350 Section 4. Section 456.069, Florida Statutes, is amended to  
351 read:

352 456.069 Authority to inspect.—In addition to the authority  
353 specified in s. 465.017, duly authorized agents and employees of  
354 the department may ~~shall have the power to~~ inspect in a lawful  
355 manner at all reasonable hours:

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

357 (2) Any establishment at which the services of a licensee  
358 authorized to prescribe controlled substances specified in  
359 chapter 893 are offered; ~~or~~

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

363  
364 for the purpose of determining if any of the provisions of this  
365 chapter or any practice act of a profession or any rule adopted  
366 thereunder is being violated; or for the purpose of securing  
367 such other evidence as may be needed for prosecution. Such  
368 evidence may include, but is not limited to, patient records.

369 The department may obtain patient records without patient  
370 authorization or subpoena from any pain-management clinic  
371 required to be licensed if the department reasonably believes  
372 that obtaining such authorization is not feasible due to the  
373 volume of the dispensing and prescribing activity involving  
374 controlled substances or that obtaining patient authorization or  
375 the issuance of a subpoena would jeopardize the investigation.

376 Section 5. Section 456.071, Florida Statutes, is amended to  
377 read:

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378 456.071 Power to administer oaths, take depositions, and  
379 issue subpoenas.—For the purpose of any investigation or  
380 proceeding conducted by the department, the department shall  
381 have the power to administer oaths, take depositions, make  
382 inspections when authorized by statute, issue subpoenas which  
383 shall be supported by affidavit, serve subpoenas and other  
384 process, and compel the attendance of witnesses and the  
385 production of books, papers, documents, and other evidence. The  
386 department shall exercise this power on its own initiative or  
387 whenever requested by a board or the probable cause panel of any  
388 board. Challenges to, and enforcement of, the subpoenas and  
389 orders shall be handled as provided in s. 120.569, except that  
390 venue is in the Circuit Court for the Second Judicial Circuit,  
391 in the county where the examination, investigation, or hearing  
392 is conducted, or in the county in which the person resides.

393 Section 6. Paragraphs (mm), (nn), and (oo) are added to  
394 subsection (1) of section 456.072, Florida Statutes, to read:

395 456.072 Grounds for discipline; penalties; enforcement.—

396 (1) The following acts shall constitute grounds for which  
397 the disciplinary actions specified in subsection (2) may be  
398 taken:

399 (mm) Applicable to a licensee who serves as the medical  
400 director or the designated physician of a pain-management clinic  
401 as defined in s. 458.305 or s. 459.005:

402 1. Registering a pain-management clinic through  
403 misrepresentation or fraud or through an error of the department  
404 or board;

405 2. Procuring, or attempting to procure, the registration of  
406 a pain-management clinic for any other person by making or

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407 causing to be made, any false representation;

408 3. Failing to comply with any requirement of chapter 499,  
409 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the  
410 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,  
411 the Comprehensive Drug Abuse Prevention and Control Act; or  
412 chapter 893;

413 4. Being convicted or found guilty of, regardless of  
414 adjudication to, a felony or any other crime involving moral  
415 turpitude fraud, dishonesty, or deceit in any jurisdiction of  
416 the courts of this state, of any other state, or of the United  
417 States;

418 5. Being convicted of, or disciplined by a regulatory  
419 agency of the Federal Government or a regulatory agency of  
420 another state for, any offense that would constitute a violation  
421 of this chapter;

422 6. Being convicted of, or entering a plea of guilty or nolo  
423 contendere to, regardless of adjudication, a crime in any  
424 jurisdiction which relates to the practice of, or the ability to  
425 practice, a licensed health care profession;

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

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

434 9. Failing to have a licensed medical director employed or  
435 under contract with the clinic as required by chapter 400 or

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436 failing to have the licensed designated physician practicing at  
437 the location of the registered clinic.

438

439 A violation of this paragraph may be the basis for a summary  
440 suspension as described in s. 456.073(8) or s. 120.60(6).

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

445 (oo) Failing to timely notify the applicable board  
446 governing his or her prescribing privileges of the date of his  
447 or her termination from a pain-management clinic as required by  
448 s. 456.037(6).

449 Section 7. Section 458.309, Florida Statutes, is amended to  
450 read:

451 458.309 Rulemaking authority.—

452 (1) The board has authority to adopt rules pursuant to ss.  
453 120.536(1) and 120.54 to implement the provisions of this  
454 chapter conferring duties upon it.

455 (2) (a) Any rules which the board adopts relating to the  
456 classroom phase of medical education shall not apply to any  
457 person who is enrolled in the classroom phase of medical  
458 education or has graduated prior to or at the time the rule  
459 becomes effective, so long as such person does not interrupt his  
460 or her medical education.

461 (b) 1. Any rules which the board adopts relating to the  
462 clinical clerkship phase of medical education shall not apply to  
463 any person who is enrolled in the clinical clerkship phase of  
464 medical education prior to or at the time the rule becomes



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465 effective, so long as such person does not interrupt his or her  
466 medical education.

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

471 a. Had completed a clinical clerkship prior to the  
472 effective date of the rule; or

473 b. Had begun a clinical clerkship but had not completed the  
474 clinical clerkship prior to the effective date of the rule, so  
475 long as the clinical clerkship took no longer than 3 years to  
476 complete.

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

481 (3) All physicians who perform level 2 procedures lasting  
482 more than 5 minutes and all level 3 surgical procedures in an  
483 office setting must register the office with the department  
484 unless that office is licensed as a facility pursuant to chapter  
485 395. The department shall inspect the physician's office  
486 annually unless the office is accredited by a nationally  
487 recognized accrediting agency or an accrediting organization  
488 subsequently approved by the Board of Medicine. The actual costs  
489 for registration and inspection or accreditation shall be paid  
490 by the person seeking to register and operate the office setting  
491 in which office surgery is performed.

492 (4) Effective January 4, 2010, all privately owned pain-  
493 management clinics, facilities, or offices primarily engaged in

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494 the treatment of pain by prescribing or dispensing controlled  
495 substance medications, hereinafter referred to as "clinics,"  
496 which advertise in any medium for any type of pain-management  
497 services, or employ a physician who is primarily engaged in the  
498 treatment of pain by prescribing or dispensing controlled  
499 substance medications, must register with the department ~~by~~  
500 ~~January 4, 2010~~, unless that clinic is licensed as a facility  
501 pursuant to chapter 395. A physician may not practice medicine  
502 in a pain-management clinic that is required to but has not  
503 registered with the department. Each clinic location shall be  
504 registered separately regardless of whether the clinic is  
505 operated under the same business name or management as another  
506 clinic. ~~If the clinic is licensed as a health care clinic under~~  
507 ~~chapter 400, the medical director is responsible for registering~~  
508 ~~the facility with the department.~~ If the clinic is not  
509 registered pursuant to chapter 395 or chapter 400, the clinic  
510 shall, upon registration with the department, designate a  
511 physician who is responsible for complying with all requirements  
512 related to registration of the clinic. The designated physician  
513 shall have a full, active, and unencumbered license ~~be licensed~~  
514 under this chapter or chapter 459 and shall practice at the  
515 office location for which the physician has assumed  
516 responsibility. The department shall inspect the clinic  
517 annually, including a review of patient records, to ensure that  
518 it complies with rules of the Board of Medicine adopted pursuant  
519 to this subsection and subsection (8) ~~(5)~~ unless the office is  
520 accredited by a nationally recognized accrediting agency  
521 approved by the Board of Medicine. The actual costs for  
522 registration and inspection or accreditation shall be paid by

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523 the physician seeking to register the clinic.

524 (5) (a) The department may deny an application for  
525 registering a pain-management clinic or revoke or suspend a  
526 current registration. The department may impose an  
527 administrative fine on the clinic of up to \$5,000 per violation  
528 for violating the requirements of this section, chapter 499, the  
529 Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the  
530 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,  
531 the Comprehensive Drug Abuse Prevention and Control Act; chapter  
532 893; or the rules of the department. In determining whether a  
533 penalty is to be imposed, and in fixing the amount of the fine,  
534 the department shall consider the following factors:

535 1. The gravity of the violation, including the probability  
536 that death or serious physical or emotional harm to a patient  
537 has resulted, or could have resulted, from a licensee's actions,  
538 the severity of the action or potential harm, and the extent to  
539 which the provisions of the applicable laws or rules were  
540 violated.

541 2. What actions, if any, the owner, medical director, or  
542 designated physician took to correct the violations.

543 3. Whether there were any previous violations at the pain-  
544 management clinic.

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

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

550 (c) Any action taken to correct a violation shall be  
551 documented in writing by the owner, medical director, or

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552 designated physician of the pain-management clinic and verified  
553 by followup visits by departmental personnel. The department may  
554 impose a fine and, in the case of an owner-operated pain-  
555 management clinic, revoke or deny a clinic's license if the  
556 medical director of the pain-management clinic, or the clinic's  
557 designated physician, knowingly and intentionally misrepresents  
558 actions taken to correct a violation.

559 (d) An owner, medical director, or designated physician of  
560 a pain-management clinic who concurrently operates an unlicensed  
561 pain-management clinic is subject to an administrative fine of  
562 \$5,000 per day.

563 (e) Any pain-management clinic whose owner fails to apply  
564 for a change-of-ownership license and operates the clinic under  
565 the new ownership is subject to a fine of \$5,000.

566 (f) During an onsite inspection, the department shall make  
567 a reasonable attempt to discuss each violation with the owner,  
568 medical director, or designated physician of the pain-management  
569 clinic before issuing a formal written notification.

570 (g)1. If the registration of a pain-management clinic is  
571 revoked or suspended, the designated physician or medical  
572 director of the pain-management clinic, the owner or lessor of  
573 the pain-management clinic property, and the owner, manager, or  
574 proprietor shall cease to operate the facility as a pain-  
575 management clinic as of the effective date of the suspension or  
576 revocation.

577 2. If a pain-management clinic registration is revoked or  
578 suspended, the designated physician or medical director of the  
579 pain-management clinic, the owner or lessor of the clinic  
580 property, or the owner, manager, or proprietor is responsible

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581 for removing all signs and symbols identifying the premises as a  
582 pain-management clinic.

583 3. If the clinic's registration is revoked, any person  
584 named in the registration documents of the pain-management  
585 clinic, including persons owning or operating the pain-  
586 management clinic, may not as an individual or as a part of a  
587 group, make application for a permit to operate a pain-  
588 management clinic for 5 years after the date the registration is  
589 revoked.

590 4. Upon the effective date of the suspension or revocation,  
591 the pain-management clinic shall advise the department of the  
592 disposition of the medicinal drugs located on the premises. The  
593 disposition is subject to the supervision and approval of the  
594 department. Failure by a pain-management clinic to be registered  
595 as required by law is cause for all medicinal drugs purchased or  
596 held by the pain-management clinic to be adulterated pursuant to  
597 s. 499.006.

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

600 (6) The department shall adopt rules necessary to  
601 administer the registration and inspection of pain-management  
602 clinics establishing the specific requirements, procedures,  
603 forms, and fees.

604 (7) The department shall adopt a rule defining what  
605 constitutes practice by a designated physician at the office  
606 location for which the physician has assumed responsibility, as  
607 set forth in subsections (3) and (4). When adopting the rule,  
608 the department shall consider the number of clinic employees,  
609 the location of the pain-management clinic, its hours of

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610 operation, and the amount of controlled substances being  
611 prescribed, dispensed, or administered at the pain-management  
612 clinic.

613 (8)~~(5)~~ The Board of Medicine shall adopt rules setting  
614 forth standards of practice for physicians practicing in  
615 privately owned pain-management clinics that primarily engage in  
616 the treatment of pain by prescribing or dispensing controlled  
617 substance medications. Such rules shall address, but need not be  
618 limited to, the following subjects:

- 619 (a) Facility operations;  
620 (b) Physical operations;  
621 (c) Infection control requirements;  
622 (d) Health and safety requirements;  
623 (e) Quality assurance requirements;  
624 (f) Patient records;  
625 (g) Training requirements for all facility health care  
626 practitioners who are not regulated by another board;  
627 (h) Inspections; and  
628 (i) Data collection and reporting requirements.

629

630 A physician is primarily engaged in the treatment of pain by  
631 prescribing or dispensing controlled substance medications when  
632 the majority of the patients seen are prescribed or dispensed  
633 controlled substance medications for the treatment of chronic  
634 nonmalignant pain. Chronic nonmalignant pain is pain unrelated  
635 to cancer which persists beyond the usual course of the disease  
636 or the injury that is the cause of the pain or more than 90 days  
637 after surgery.

638 (9)~~(6)~~ A privately owned clinic, facility, or office that

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639 advertises in any medium for any type of pain-management  
640 services or employs one or more physicians who are primarily  
641 engaged in the treatment of pain by prescribing or dispensing  
642 controlled substances is exempt from the registration provisions  
643 in subsection (4) if the majority of the physicians who provide  
644 services in the clinic, facility, or office primarily provide  
645 surgical services.

646 Section 8. Section 458.3265, Florida Statutes, is created  
647 to read:

648 458.3265 Pain-management clinics.—

649 (1) (a) A physician may not practice medicine in a pain-  
650 management clinic, as described in s. 458.309(4), if the pain-  
651 management clinic is not registered with the department as  
652 required by that section. As provided in s. 458.309(4), each  
653 location of a pain-management clinic must be registered  
654 separately regardless of whether the clinic is operated under  
655 the same business name or management as another clinic. If a  
656 pain-management clinic fails an annual inspection, the  
657 department may revoke the clinic's certificate of registration  
658 and prohibit all physicians associated with that pain-management  
659 clinic from practicing at that office location. A physician who  
660 violates this paragraph is subject to review by his or her  
661 appropriate medical regulatory board.

662 (b) A pain-management clinic may not be owned, in whole or  
663 in part, by or have any contractual relationship, whether  
664 through employment or by independent contract, with:

665 1. A physician who during the course of his or her practice  
666 has been denied the privilege of prescribing, dispensing,  
667 administering, supplying, or selling any controlled substance or

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668 who has, during the course of his or her practice, had the board  
669 take disciplinary action in this state or any other state or by  
670 the United States, against his or her medical license as a  
671 result of violating laws or rules relating to prescribing or  
672 dispensing controlled substances or for his or her dependency on  
673 drugs or alcohol.

674 2. A person whose application for a license to prescribe,  
675 dispense, or administer a controlled substance has been denied  
676 by any jurisdiction.

677 3. The holder of a license issued by any jurisdiction which  
678 allowed the owner, employee, or person to prescribe, dispense,  
679 or administer a controlled substance and which has been  
680 restricted or revoked by the issuing jurisdiction.

681 4. A person who is the subject of a disciplinary proceeding  
682 by any licensing entity for conduct resulting from  
683 inappropriately prescribing, dispensing, or administering a  
684 controlled substance.

685 5. A person who has been convicted of or pled guilty or  
686 nolo contendere to, regardless of adjudication, an offense that  
687 constitutes a felony or a misdemeanor for receipt of illicit and  
688 diverted drugs, including a controlled substance listed in  
689 Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule  
690 V of s. 893.03, in this state, any other state, or the United  
691 States.

692 (c) If the department finds that a privately owned pain-  
693 management clinic is owned, directly or indirectly, by a person  
694 meeting any criteria listed in paragraph (b), the department  
695 shall refuse to register the pain-management clinic or shall  
696 revoke the certificate of registration previously issued by the



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697 department. As determined by rule, the department may grant an  
698 exemption if more than 10 years have elapsed since adjudication.  
699 As used in this subsection, the term "convicted" includes an  
700 adjudication of guilt following a plea of guilty or nolo  
701 contendere or the forfeiture of a bond when charged with a  
702 crime.

703 (d) The owner, operator, or designated physician of a pain-  
704 management clinic shall:

705 1. Be onsite at the pain-management clinic for at least 33  
706 percent of the operating hours of the pain-management clinic,  
707 with exemptions provided by department rule. If this requirement  
708 is not met by a designated physician, the owner or operator  
709 shall be physically present at the pain-management clinic at  
710 least once a week to inspect the facility in accordance with  
711 department rule. Exemptions may be provided by department rule  
712 if the designated physician, owner, or operator is present  
713 weekly and conducts inspections; and

714 2. Review on a weekly basis at least 33 percent of the  
715 total number of patient files of the clinic, including the  
716 patient files in the possession of a clinic employee or  
717 contractor to whom authority for patient care has been delegated  
718 by the pain-management clinic, with exemptions provided by  
719 department rule.

720 (e) A violation of this subsection is grounds for  
721 disciplinary action against the clinic, its owner, its operator,  
722 or designated physician under s. 458.309. An owner or operator  
723 who fails to comply with this subsection commits a misdemeanor  
724 of the first degree, punishable as provided in s. 775.082 or s.  
725 775.083.

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726       (2) A person may not dispense any medication, including a  
727 controlled substance, on the premises of a pain-management  
728 clinic unless he or she is a physician licensed under this  
729 chapter or chapter 459; however, a pharmacist licensed under  
730 chapter 465 may dispense any medication, including a controlled  
731 substance, on the premises of a pain-management clinic.

732       (3) After a physical examination of the patient the same  
733 day of dispensing a controlled substance, a physician must  
734 document in the patient's record the reason for prescribing or  
735 dispensing more than a 72-hour dose of a controlled substance  
736 for the treatment of chronic nonmalignant pain. A physician  
737 shall follow the department's rules for treating pain when  
738 prescribing the use of controlled substances and dispensing  
739 controlled substances. The failure to follow the department's  
740 rules is grounds for disciplinary action by the Board of  
741 Medicine and the possible revocation of the clinic's certificate  
742 of registration by the department.

743       (4) As used in subsections (4) through (8), the term:

744       (a) "Controlled substance" means a controlled substance  
745 listed in Schedule II, Schedule III, or Schedule IV of s.  
746 893.03.

747       (b) "Parties affiliated with a pain-management clinic"  
748 means:

749       1. A director, officer, trustee, partner, or committee  
750 member of a pain-management clinic or applicant, or a subsidiary  
751 or service corporation of the pain-management clinic or  
752 applicant; or

753       2. A person who, directly or indirectly, manages, controls,  
754 or oversees the operation of a pain-management clinic or

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755 applicant, regardless of whether the person is a partner,  
756 shareholder, manager, member, officer, director, independent  
757 contractor, or employee of the pain-management clinic or  
758 applicant.

759 (5) On or after January 3, 2011, an application for an  
760 initial or renewal registration of a pain-management clinic must  
761 include:

762 (a) The name, full business address, and telephone number  
763 of the applicant.

764 (b) All trade or business names used by the applicant.

765 (c) The address, telephone numbers, and names of contact  
766 persons for each facility used by the applicant for the  
767 prescribing or dispensing of controlled substance medications in  
768 the treatment of pain.

769 (d) The type of ownership or operation, such as a  
770 partnership, corporation, or sole proprietorship.

771 (e) The names of each owner and each operator of the pain-  
772 management clinic, including:

773 1. If an individual, the name of the individual.

774 2. If a partnership, the name of each partner and the name  
775 of the partnership.

776 3. If a corporation:

777 a. The name, address, and title of each corporate officer  
778 and director.

779 b. The name and address of the corporation and the resident  
780 agent of the corporation, the resident agent's address, and the  
781 corporation's state of incorporation.

782 c. The name and address of each shareholder of the  
783 corporation owning 5 percent or more of the outstanding stock of

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784 the corporation.

785 4. If a sole proprietorship, the full name of the sole  
786 proprietor and the name of the business entity.

787 5. If a limited liability company:

788 a. The name and address of each member.

789 b. The name and address of each manager.

790 c. The name and address of the limited liability company,  
791 the resident agent of the limited liability company, and the  
792 name of the state in which the limited liability company was  
793 organized.

794 (f) The tax year of the applicant.

795 (g) A copy of the deed for the property on which the  
796 applicant's pain-management clinic is located, if the clinic is  
797 owned by the applicant, or a copy of the applicant's lease for  
798 the property on which the applicant's pain-management clinic is  
799 located, which must have an original term of not less than 1  
800 calendar year, if the pain-management clinic is not owned by the  
801 applicant.

802 (h) A list of all licenses and permits issued to the  
803 applicant by any other state which authorize the applicant to  
804 purchase or possess prescription drugs.

805 (i) The name of the manager of the pain-management clinic  
806 that is applying for the initial or renewal registration, the  
807 next four highest ranking employees responsible for operations  
808 of the pain-management clinic, the name of all parties  
809 affiliated with the pain-management clinic, and the personal  
810 information statement and set of fingerprints required under  
811 subsection (6) for each person.

812 (6) (a) Each person required by subsection (5) to provide a

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813 personal information statement and fingerprints shall provide  
814 the following information to the department on forms prescribed  
815 by the department:

816 1. The person's places of residence for the past 7 years.

817 2. The person's date and place of birth.

818 3. The person's occupations, positions of employment, and  
819 offices held during the past 7 years.

820 4. The principal business and address of any business,  
821 corporation, or other organization in which the person:

822 a. Held an office during the past 7 years; or

823 b. Had an occupation or position of employment during the  
824 past 7 years.

825 5. Whether the person has been, during the past 7 years,  
826 the subject of any proceeding for the revocation of any license  
827 and, if so, the nature of the proceeding and the disposition of  
828 the proceeding.

829 6. Whether, during the past 7 years, the person has been  
830 enjoined, temporarily or permanently, by a court of competent  
831 jurisdiction from violating any federal or state law regulating  
832 the possession, control, or distribution of controlled  
833 substances, together with details concerning any such event.

834 7. A description of any involvement by the person during  
835 the past 7 years, including any investments, other than the  
836 ownership of stock in a publicly traded company or mutual fund,  
837 with any business that manufactured, administered, prescribed,  
838 distributed, or stored pharmaceutical products and any lawsuits  
839 in which the businesses were named as a party.

840 8. A description of any felony criminal offense of which  
841 the person, as an adult, was found guilty, regardless of whether

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842 adjudication of guilt was withheld or whether the person pled  
843 guilty or nolo contendere. A criminal offense committed in  
844 another jurisdiction which would have been a felony in this  
845 state must be reported. If the person indicates that a criminal  
846 conviction is under appeal and submits a copy of the notice of  
847 appeal of that criminal offense, the applicant shall, within 15  
848 days after the disposition of the appeal, submit to the  
849 department a copy of the final written order of disposition.

850 9. A photograph of the person taken in the previous 30  
851 days.

852 10. A set of fingerprints from the person on a form and  
853 under procedures specified by the department and payment of a  
854 fee equal to the cost incurred by the department for the  
855 criminal history record check of the person.

856 11. The name, address, occupation, and date and place of  
857 birth for each member of the person's immediate family who is 18  
858 years of age or older. As used in this subparagraph, the term  
859 "member of the person's immediate family" includes the person's  
860 spouse, children, parents, siblings, the spouses of the person's  
861 children, and the spouses of the person's siblings.

862 12. Any other relevant information that the department  
863 requires.

864 (b) The information required under paragraph (a) shall be  
865 provided under oath.

866 (c)1. The department shall submit the fingerprints provided  
867 with an application for initial registration on or after January  
868 4, 2010, to the Department of Law Enforcement for a statewide  
869 criminal record check and for forwarding to the Federal Bureau  
870 of Investigation for a national criminal record check.

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871       2. For the renewal of a registration on or after January 3,  
872 2011, the department shall submit the fingerprints provided as a  
873 part of a renewal application and background check of registered  
874 persons to the Department of Law Enforcement for a statewide  
875 criminal record check, and for forwarding to the Federal Bureau  
876 of Investigation for a national criminal record check. For any  
877 subsequent renewal of a registration, the department shall  
878 submit the required information for a statewide and national  
879 criminal record check.

880       3. Any person who submits to the department a set of  
881 fingerprints for a criminal record check is not required to  
882 provide a subsequent set of fingerprints for a criminal record  
883 check if the person has undergone a criminal record check with  
884 submission of fingerprints for background screening as a  
885 condition of the issuance of an initial registration or the  
886 initial renewal of a registration on or after January 4, 2010.

887       4. The department shall submit fingerprints for those  
888 undergoing a background screening and they must be submitted  
889 electronically. The department shall screen background results  
890 to determine if an applicant meets registration requirements.

891       5. The cost for the processing fingerprints for an initial  
892 or renewal registration must be borne by the person subject to  
893 the background check. The Department of Law Enforcement shall  
894 receive payment for processing the fingerprints submitted to it  
895 each month by invoice to the Department of Health or by credit  
896 card from the applicant or a vendor acting on behalf of the  
897 applicant.

898       6. All fingerprints submitted to the Department of Law  
899 Enforcement shall be retained by the Department of Law

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900 Enforcement in a manner provided by rule and entered into the  
901 statewide automated fingerprint identification system authorized  
902 by s. 943.05(2)(b). The fingerprints shall thereafter be  
903 available for all purposes and uses authorized for arrest  
904 fingerprint cards entered in the statewide automated fingerprint  
905 identification system pursuant to s. 943.051.

906 7. Fingerprints for arrests submitted or received under s.  
907 943.051 shall be searched against the fingerprints retained in  
908 the statewide automated fingerprint identification system. Any  
909 arrest record that is identified with the retained fingerprints  
910 of a person subject to the background screening under this  
911 section shall be reported to the department.

912 8. Each person shall pay to the department a fee for the  
913 cost of retaining the fingerprints and performing the ongoing  
914 searches of arrest records. The Department of Law Enforcement  
915 shall receive payment for processing and retaining the  
916 fingerprints submitted to it each month by invoice to the  
917 Department of Health or by credit card from the applicant or a  
918 vendor acting on behalf of the applicant.

919 9. The Department of Law Enforcement shall adopt rules  
920 establishing the amount of the fee and procedures for retaining  
921 the fingerprints, performing the searches, and disseminating the  
922 search results. The department shall notify the Department of  
923 Law Enforcement of any change in a person's status as a person  
924 listed s. 458.3265 if, as a result of the change, the person's  
925 fingerprints are no longer required to be retained under  
926 paragraph (a).

927 (7) The State Surgeon General shall order a clinic closed  
928 for operations if closure is warranted following failure of the



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929 owner or operator of the pain-management clinic to pass a  
930 background check of his or her criminal history. As determined  
931 by rule, the department may grant an exemption if more than 10  
932 years have elapsed since adjudication.

933 (8) By January 3, 2011, the department and the Department  
934 of Law Enforcement shall adopt rules pursuant to ss. 120.536(1)  
935 and 120.54 to administer the provisions of this section, which  
936 shall include, as necessary, the reporting, management,  
937 development, and implementation of the fingerprint requirements  
938 in this section.

939 Section 9. Paragraph (e) is added to subsection (1) of  
940 section 458.327, Florida Statutes, and paragraph (f) is added to  
941 subsection (2) of that section, to read:

942 458.327 Penalty for violations.—

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

946 (e) Knowingly operating, owning, or managing a  
947 nonregistered pain-management clinic that is required to be  
948 registered with the Department of Health pursuant to s.  
949 458.309(4).

950 (2) Each of the following acts constitutes a misdemeanor of  
951 the first degree, punishable as provided in s. 775.082 or s.  
952 775.083:

953 (f) Knowingly prescribing or dispensing, or causing to be  
954 prescribed or dispensed, controlled substances in a  
955 nonregistered pain-management clinic that is required to be  
956 registered with the Department of Health pursuant to s.  
957 458.309(4).

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958 Section 10. Section 459.005, Florida Statutes, is amended  
959 to read:

960 459.005 Rulemaking authority.—

961 (1) The department and the board ~~may has authority to~~ adopt  
962 rules pursuant to ss. 120.536(1) and 120.54 to implement the  
963 provisions of this chapter conferring duties upon it.

964 (2) All physicians who perform level 2 procedures lasting  
965 more than 5 minutes and all level 3 surgical procedures in an  
966 office setting must register the office with the department  
967 unless that office is licensed as a facility pursuant to chapter  
968 395. The department shall inspect the physician's office  
969 annually unless the office is accredited by a nationally  
970 recognized accrediting agency or an accrediting organization  
971 subsequently approved by the Board of Osteopathic Medicine. The  
972 actual costs for registration and inspection or accreditation  
973 shall be paid by the person seeking to register and operate the  
974 office setting in which office surgery is performed.

975 (3) Effective January 4, 2010, all privately owned pain-  
976 management clinics, facilities, or offices, primarily engaged in  
977 the treatment of pain by prescribing or dispensing controlled  
978 substance medications, hereinafter referred to as "clinics,"  
979 which advertise in any medium for any type of pain-management  
980 services, or employ a physician who is licensed under this  
981 chapter and who is primarily engaged in the treatment of pain by  
982 prescribing or dispensing controlled substance medications, must  
983 register with the department ~~by January 4, 2010,~~ unless that  
984 clinic is licensed as a facility under chapter 395. A physician  
985 may not practice osteopathic medicine in a pain-management  
986 clinic that is required to but has not registered with the

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987 department. Each clinic location shall be registered separately  
988 regardless of whether the clinic is operated under the same  
989 business name or management as another clinic. If the clinic is  
990 licensed as a health care clinic under chapter 400, the medical  
991 director is responsible for registering the facility with the  
992 department. If the clinic is not registered under chapter 395 or  
993 chapter 400, the clinic shall, upon registration with the  
994 department, designate a physician who is responsible for  
995 complying with all requirements related to registration of the  
996 clinic. The designated physician shall have a full, active, and  
997 unencumbered license ~~be licensed~~ under chapter 458 or this  
998 chapter and shall practice at the office location for which the  
999 physician has assumed responsibility. The department shall  
1000 inspect the clinic annually to ensure that it complies with  
1001 rules of the Board of Osteopathic Medicine adopted pursuant to  
1002 this subsection and subsection ~~(7)~~~~(4)~~ unless the office is  
1003 accredited by a nationally recognized accrediting agency  
1004 approved by the Board of Osteopathic Medicine. The actual costs  
1005 for registration and inspection or accreditation shall be paid  
1006 by the physician seeking to register the clinic.

1007 (4) (a) The department may deny an application for  
1008 registering a pain-management clinic or revoke or suspend a  
1009 current registration. The department may impose an  
1010 administrative fine on the clinic of up to \$5,000 per violation  
1011 for violating the requirements of this section, chapter 499, the  
1012 Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the  
1013 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,  
1014 the Comprehensive Drug Abuse Prevention and Control Act; chapter  
1015 893; or the rules of the department. In determining whether a

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1016 penalty is to be imposed, and in fixing the amount of the fine,  
1017 the department shall consider the following factors:

1018 1. The gravity of the violation, including the probability  
1019 that death or serious physical or emotional harm to a patient  
1020 has resulted, or could have resulted, from a licensee's actions,  
1021 the severity of the action or potential harm, and the extent to  
1022 which the provisions of the applicable laws or rules were  
1023 violated.

1024 2. What actions, if any, the owner, medical director, or  
1025 designated physician took to correct the violations.

1026 3. Whether there were any previous violations at the pain-  
1027 management clinic.

1028 4. The financial benefits that the pain-management clinic  
1029 derived from committing or continuing to commit the violation.

1030 (b) Each day a violation continues after the date fixed for  
1031 termination as ordered by the department, constitutes an  
1032 additional, separate, and distinct violation.

1033 (c) Any action taken to correct a violation shall be  
1034 documented in writing by the owner, medical director, or  
1035 designated physician of the pain-management clinic and verified  
1036 by followup visits by department personnel. The department may  
1037 impose a fine and, in the case of an owner-operated pain-  
1038 management clinic, revoke or deny a clinic's license if the  
1039 medical director of the pain-management clinic, or the clinic's  
1040 designated physician, knowingly and intentionally misrepresents  
1041 actions taken to correct a violation.

1042 (d) An owner, medical director, or designated physician of  
1043 a pain-management clinic who concurrently operates an unlicensed  
1044 pain-management clinic is subject to an administrative fine of

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1045 \$5,000 per day.

1046 (e) Any pain-management clinic whose owner fails to apply  
1047 for a change-of-ownership license and operates the clinic under  
1048 the new ownership is subject to a fine of \$5,000.

1049 (f) During an onsite inspection, the department shall make  
1050 a reasonable attempt to discuss each violation with the owner,  
1051 medical director, or designated physician of the pain-management  
1052 clinic before issuing a formal written notification.

1053 (g)1. If the registration of a pain-management clinic is  
1054 revoked or suspended, the designated physician or medical  
1055 director of the pain-management clinic, the owner or lessor of  
1056 the pain-management clinic property, and the owner, manager, or  
1057 proprietor shall cease to operate the facility as a pain-  
1058 management clinic as of the effective date of the suspension or  
1059 revocation.

1060 2. If a pain-management clinic registration is revoked or  
1061 suspended, the designated physician or medical director of the  
1062 pain-management clinic, the owner or lessor of the clinic  
1063 property, and the owner, manager, or proprietor are responsible  
1064 for removing all signs and symbols identifying the premises as a  
1065 pain-management clinic.

1066 3. If the clinic's registration is revoked, any person  
1067 named in the registration documents of the pain-management  
1068 clinic, including persons owning or operating the pain-  
1069 management clinic, may not as an individual or as a part of a  
1070 group, make application for a permit to operate a pain-  
1071 management clinic for 5 years after the date the registration is  
1072 revoked.

1073 4. Upon the effective date of the suspension or revocation,

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1074 the pain-management clinic shall advise the department of the  
1075 disposition of the medicinal drugs located on the premises. The  
1076 disposition is subject to the supervision and approval of the  
1077 department. Failure by a pain-management clinic to be registered  
1078 as required by law is cause for all medicinal drugs purchased or  
1079 held by the pain-management clinic to be adulterated pursuant to  
1080 s. 499.006.

1081 5. The period of the suspension shall be prescribed by the  
1082 department, but may not exceed 1 year.

1083 (5) The department shall adopt rules necessary to  
1084 administer the registration and inspection of pain-management  
1085 clinics establishing the specific requirements, procedures,  
1086 forms, and fees.

1087 (6) The department shall adopt a rule defining what  
1088 constitutes practice by a designated physician at the office  
1089 location for which the physician has assumed responsibility as  
1090 set forth in subsection (4). When adopting the rule, the  
1091 department shall consider the number of clinic employees, the  
1092 location of the pain-management clinic, its hours of operation,  
1093 and the amount of controlled substances being prescribed,  
1094 dispensed, or administered at the pain-management clinic.

1095 (7)~~(4)~~ The Board of Osteopathic Medicine shall adopt rules  
1096 setting forth standards of practice for physicians who practice  
1097 in privately owned pain-management clinics that primarily engage  
1098 in the treatment of pain by prescribing or dispensing controlled  
1099 substance medications. The ~~Such~~ rules shall address, but need  
1100 not be limited to, the following subjects:

1101 (a) Facility operations;

1102 (b) Physical operations;

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- 1103 (c) Infection control requirements;  
1104 (d) Health and safety requirements;  
1105 (e) Quality assurance requirements;  
1106 (f) Patient records;  
1107 (g) Training requirements for all facility health care  
1108 practitioners who are not regulated by another board;  
1109 (h) Inspections; and  
1110 (i) Data collection and reporting requirements.

1111  
1112 A physician is primarily engaged in the treatment of pain by  
1113 prescribing or dispensing controlled substance medications when  
1114 the majority of the patients seen are prescribed or dispensed  
1115 controlled substance medications for the treatment of chronic  
1116 nonmalignant pain. Chronic nonmalignant pain is pain unrelated  
1117 to cancer which persists beyond the usual course of the disease  
1118 or the injury that is the cause of the pain or more than 90 days  
1119 after surgery.

1120 (8)~~(5)~~ A privately owned clinic, facility, or office that  
1121 advertises in any medium for any type of pain-management  
1122 services or employs one or more physicians who are primarily  
1123 engaged in the treatment of pain by prescribing or dispensing  
1124 controlled substances is exempt from the registration provisions  
1125 in subsection (3) if the majority of the physicians who provide  
1126 services in the clinic, facility, or office primarily provide  
1127 surgical services.

1128 Section 11. Paragraph (e) is added to subsection (1) of  
1129 section 459.013, Florida Statutes, and paragraph (d) is added to  
1130 subsection (2) of that section, to read:

1131 459.013 Penalty for violations.—

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1132 (1) Each of the following acts constitutes a felony of the  
1133 third degree, punishable as provided in s. 775.082, s. 775.083,  
1134 or s. 775.084:

1135 (e) Knowingly operating, owning, or managing a  
1136 nonregistered pain-management clinic that is required to be  
1137 registered with the Department of Health pursuant to s.  
1138 459.005(3).

1139 (2) Each of the following acts constitutes a misdemeanor of  
1140 the first degree, punishable as provided in s. 775.082 or s.  
1141 775.083:

1142 (d) Knowingly prescribing, dispensing, or causing to be  
1143 prescribed or dispensed controlled substances in a nonregistered  
1144 pain-management clinic that is required to be registered with  
1145 the Department of Health pursuant to s. 459.005(3).

1146 Section 12. Section 459.0137, Florida Statutes, is created  
1147 to read:

1148 459.0137 Pain-management clinics.-

1149 (1) (a) An osteopathic physician may not practice  
1150 osteopathic medicine in a pain-management clinic that is not  
1151 registered with the department as required by s. 459.005(3) Each  
1152 location of a pain-management clinic must be registered  
1153 separately regardless of whether the clinic is operated under  
1154 the same business name or management as another clinic. If a  
1155 pain-management clinic fails an annual inspection pursuant to s.  
1156 459.005(3), the department may revoke the clinic's certificate  
1157 of registration and prohibit all physicians associated with that  
1158 pain-management clinic from practicing at that office location.  
1159 A physician who violates this paragraph is subject to review by  
1160 his or her appropriate medical regulatory board.



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1161 (b) A pain-management clinic may not be owned, in whole or  
1162 in part, by or have any contractual relationship, whether  
1163 through employment or by independent contract, with:

1164 1. An osteopathic physician who during the course of his or  
1165 her practice has been denied the privilege of prescribing,  
1166 dispensing, administering, supplying, or selling any controlled  
1167 substance and who has, during the course of his or her practice,  
1168 or had the board take disciplinary action in this state or any  
1169 other state or by the United States against his or her medical  
1170 license as a result of violating laws or rules relating to  
1171 prescribing or dispensing controlled substances or for his or  
1172 her dependency on drugs or alcohol.

1173 2. A person whose application for a license to prescribe,  
1174 dispense, or administer a controlled substance has been denied  
1175 by any jurisdiction.

1176 3. The holder of a license issued by any jurisdiction which  
1177 allowed the owner, employee, or person to prescribe, dispense,  
1178 or administer a controlled substance and which has been  
1179 restricted or revoked by the issuing jurisdiction.

1180 4. A person who is the subject of a disciplinary proceeding  
1181 by any licensing entity for conduct resulting from  
1182 inappropriately prescribing, dispensing, or administering a  
1183 controlled substance.

1184 5. A person who has been convicted of or pled guilty or  
1185 nolo contendere to, regardless of adjudication, an offense that  
1186 constitutes a felony or a misdemeanor for receiving illicit and  
1187 diverted drugs, including a controlled substance listed in  
1188 Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule  
1189 V of s. 893.03, in this state, any other state, or the United

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1190 States.

1191 (c) If the department finds that a privately owned pain-  
1192 management clinic is owned, directly or indirectly, by a person  
1193 meeting any criteria listed in paragraph (b), the department  
1194 shall refuse to register the pain-management clinic or shall  
1195 revoke the certificate of registration previously issued by the  
1196 department. As determined by rule, the department may grant an  
1197 exemption if more than 10 years have elapsed since adjudication.  
1198 As used in this subsection, the term "convicted" includes an  
1199 adjudication of guilt following a plea of guilty or nolo  
1200 contendere or the forfeiture of a bond when charged with a  
1201 crime.

1202 (d) The owner, operator, or designated osteopathic  
1203 physician of a pain-management clinic shall:

1204 1. Be onsite at the pain-management clinic for at least 33  
1205 percent of the operating hours of the pain-management clinic  
1206 with exemptions provided by department rule. If this requirement  
1207 is not met by a designated physician, the owner or operator  
1208 shall be physically present at the pain-management clinic at  
1209 least once a week to inspect the facility in accordance with  
1210 department rule. Exemptions may be provided by department rule  
1211 if the designated osteopathic physician is present weekly and  
1212 conducts inspections; and

1213 2. Review on a weekly basis at least 33 percent of the  
1214 total number of patient files of the pain-management clinic,  
1215 including the patient files in the possession of a pain-  
1216 management clinic employee or contractor to whom authority for  
1217 patient care has been delegated by the pain-management clinic,  
1218 with exemptions provided by department rule.

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1219 (e) A violation of this subsection is grounds for  
1220 disciplinary action against the pain-management clinic, its  
1221 owner, its operator or designated osteopathic physician under s.  
1222 459.005. An owner or operator who fails to comply with this  
1223 subsection commits a misdemeanor of the first degree, punishable  
1224 as provided in s. 775.082 or s. 775.083.

1225 (2) A person may not dispense any medication, including a  
1226 controlled substance, on the premises of a pain-management  
1227 clinic unless he or she is a physician licensed under this  
1228 chapter or chapter 458; however, a pharmacist licensed under  
1229 chapter 465 may dispense any medication, including a controlled  
1230 substance, on the premises of a pain-management clinic.

1231 (3) After a physical examination of the patient the same  
1232 day that a controlled substance is dispensed, a physician must  
1233 document in the patient's record the reason for prescribing or  
1234 dispensing more than a 72-hour dose of a controlled substance  
1235 for the treatment of chronic nonmalignant pain. A physician  
1236 shall follow the department's rules for treating pain when  
1237 prescribing the use of controlled substances and dispensing  
1238 controlled substances. The failure to follow the department's  
1239 rules is grounds for disciplinary action by the Board of  
1240 Osteopathic Medicine and the possible revocation of the clinic's  
1241 certificate of registration by the department.

1242 (4) As used in this section, the term:

1243 (a) "Controlled substance" means a controlled substance  
1244 listed in Schedule II, Schedule III, or Schedule IV of s.  
1245 893.03.

1246 (b) "Parties affiliated with a pain-management clinic"  
1247 means:

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1248 1. A director, officer, trustee, partner, or committee  
1249 member of a pain-management clinic or applicant, or a subsidiary  
1250 or service corporation of the pain-management clinic or  
1251 applicant; or

1252 2. A person who, directly or indirectly, manages, controls,  
1253 or oversees the operation of a pain-management clinic or  
1254 applicant, regardless of whether the person is a partner,  
1255 shareholder, manager, member, officer, director, independent  
1256 contractor, or employee of the pain-management clinic or  
1257 applicant.

1258 (5) On or after January 3, 2011, an application for an  
1259 initial or renewal registration of a pain-management clinic must  
1260 include:

1261 (a) The name, full business address, and telephone number  
1262 of the applicant.

1263 (b) All trade or business names used by the applicant.

1264 (c) The address, telephone numbers, and names of contact  
1265 persons for each facility used by the applicant for the  
1266 prescribing or dispensing of controlled substance medications in  
1267 the treatment of pain.

1268 (d) The type of ownership or operation, such as a  
1269 partnership, corporation, or sole proprietorship.

1270 (e) The names of each owner and each operator of the pain-  
1271 management clinic, including:

1272 1. If an individual, the name of the individual.

1273 2. If a partnership, the name of each partner and the name  
1274 of the partnership.

1275 3. If a corporation:

1276 a. The name, address, and title of each corporate officer

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1277 and director.

1278 b. The name and address of the corporation and the resident  
1279 agent of the corporation, the resident agent's address, and the  
1280 corporation's state of incorporation.

1281 c. The name and address of each shareholder of the  
1282 corporation that owns 5 percent or more of the outstanding stock  
1283 of the corporation.

1284 4. If a sole proprietorship, the full name of the sole  
1285 proprietor and the name of the business entity.

1286 5. If a limited liability company:

1287 a. The name and address of each member.

1288 b. The name and address of each manager.

1289 c. The name and address of the limited liability company,  
1290 the resident agent of the limited liability company, and the  
1291 name of the state in which the limited liability company was  
1292 organized.

1293 (f) The tax year of the applicant.

1294 (g) A copy of the deed for the property on which the  
1295 applicant's pain-management clinic is located, if the clinic is  
1296 owned by the applicant, or a copy of the applicant's lease for  
1297 the property on which the applicant's pain-management clinic is  
1298 located, which must have an original term of not less than 1  
1299 calendar year, if the pain-management clinic is not owned by the  
1300 applicant.

1301 (h) A list of all licenses and permits issued to the  
1302 applicant by any other state which authorize the applicant to  
1303 purchase or possess prescription drugs.

1304 (i) The name of the manager of the pain-management clinic  
1305 that is applying for the initial or renewal registration, the

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1306 next four highest ranking employees responsible for operations  
1307 of the pain-management clinic, the name of all parties  
1308 affiliated with the pain-management clinic, and the personal  
1309 information statement and fingerprints required under subsection  
1310 (6) for each person.

1311 (6) (a) Each person required by subsection (5) to provide a  
1312 personal information statement and fingerprints shall provide  
1313 the following information to the department on forms prescribed  
1314 by the department:

1315 1. The person's places of residence for the past 7 years.

1316 2. The person's date and place of birth.

1317 3. The person's occupations, positions of employment, and  
1318 offices held during the past 7 years.

1319 4. The principal business and address of any business,  
1320 corporation, or other organization in which the person:

1321 a. Held an office during the past 7 years; or

1322 b. Had an occupation or position of employment during the  
1323 past 7 years.

1324 5. Whether the person has been, during the past 7 years,  
1325 the subject of any proceeding for the revocation of any license  
1326 and, if so, the nature of the proceeding and the disposition of  
1327 the proceeding.

1328 6. Whether, during the past 7 years, the person has been  
1329 enjoined, temporarily or permanently, by a court of competent  
1330 jurisdiction from violating any federal or state law regulating  
1331 the possession, control, or distribution of controlled  
1332 substances, together with details concerning any such event.

1333 7. A description of any involvement by the person during  
1334 the past 7 years, including any investments, other than the

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1335 ownership of stock in a publicly traded company or mutual fund,  
1336 with any business that manufactured, administered, prescribed,  
1337 distributed, or stored pharmaceutical products and any lawsuits  
1338 in which the businesses were named as a party.

1339 8. A description of any felony criminal offense of which  
1340 the person, as an adult, was found guilty, regardless of whether  
1341 adjudication of guilt was withheld or whether the person pled  
1342 guilty or nolo contendere. A criminal offense committed in  
1343 another jurisdiction which would have been a felony in this  
1344 state must be reported. If the person indicates that a criminal  
1345 conviction is under appeal and submits a copy of the notice of  
1346 appeal of that criminal offense, the applicant shall, within 15  
1347 days after the disposition of the appeal, submit to the  
1348 department a copy of the final written order of disposition.

1349 9. A photograph of the person taken in the previous 30  
1350 days.

1351 10. A set of fingerprints from the person on a form and  
1352 under procedures specified by the department and payment of a  
1353 fee equal to the cost incurred by the department for the  
1354 criminal history record check of the person.

1355 11. The name, address, occupation, and date and place of  
1356 birth for each member of the person's immediate family who is 18  
1357 years of age or older. As used in this subparagraph, the term  
1358 "member of the person's immediate family" includes the person's  
1359 spouse, children, parents, siblings, the spouses of the person's  
1360 children, and the spouses of the person's siblings.

1361 12. Any other relevant information that the department  
1362 requires.

1363 (b) The information required under paragraph (a) shall be

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1364 provided under oath.

1365 (c)1. The department shall submit the fingerprints provided  
1366 with an application for initial registration to the Department  
1367 of Law Enforcement for a statewide criminal record check and for  
1368 forwarding to the Federal Bureau of Investigation for a national  
1369 criminal record check.

1370 2. For the renewal of a registration on or after January 3,  
1371 2011, the department shall submit the fingerprints provided as a  
1372 part of a renewal application and background check of registered  
1373 persons to the Department of Law Enforcement for a statewide  
1374 criminal record check, and for forwarding to the Federal Bureau  
1375 of Investigation for a national criminal record check. For any  
1376 subsequent renewal of a registration, the department shall  
1377 submit the required information for a statewide and national  
1378 criminal record check.

1379 3. Any person who submits to the department a set of  
1380 fingerprints for a criminal record check is not required to  
1381 provide a subsequent set of fingerprints for a criminal record  
1382 check if the person has undergone a criminal record check with  
1383 submission of fingerprints for background screening as a  
1384 condition of the issuance of an initial registration or the  
1385 renewal of a registration on or after January 4, 2011.

1386 4. The department shall submit fingerprints for those  
1387 undergoing a background screening and they must be submitted  
1388 electronically. The department shall screen background results  
1389 to determine if an applicant meets registration requirements.

1390 5. The cost for the processing fingerprints for an initial  
1391 or renewal registration must be borne by the person subject to  
1392 the background check. The Department of Law Enforcement shall



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1393 receive payment for processing the fingerprints submitted to it  
1394 each month by invoice to the Department of Health or by credit  
1395 card from the applicant or a vendor acting on behalf of the  
1396 applicant.

1397 6. All fingerprints submitted to the Department of Law  
1398 Enforcement shall be retained by the Department of Law  
1399 Enforcement in a manner provided by rule and entered into the  
1400 statewide automated fingerprint identification system authorized  
1401 by s. 943.05(2)(b). The fingerprints shall thereafter be  
1402 available for all purposes and uses authorized for arrest  
1403 fingerprint cards entered in the statewide automated fingerprint  
1404 identification system pursuant to s. 943.051.

1405 7. Fingerprints for arrests submitted or received under s.  
1406 943.051 shall be searched against the fingerprints retained in  
1407 the statewide automated fingerprint identification system. Any  
1408 arrest record that is identified with the retained fingerprints  
1409 of a person subject to the background screening under this  
1410 section shall be reported to the department.

1411 8. Each person shall pay to the department a fee for the  
1412 cost of retaining the fingerprints and performing the ongoing  
1413 searches of arrest records. The Department of Law Enforcement  
1414 shall receive payment for processing and retaining the  
1415 fingerprints submitted to it each month by invoice to the  
1416 Department of Health or by credit card from the applicant or a  
1417 vendor acting on behalf of the applicant.

1418 9. The Department of Law Enforcement shall adopt rules  
1419 establishing the amount of the fee and procedures for retaining  
1420 the fingerprints, performing the searches, and disseminating the  
1421 search results. The department shall notify the Department of

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1422 Law Enforcement of any change in a person's status as a person  
1423 listed in s. 458.3265 if, as a result of the change, the  
1424 person's fingerprints are no longer required to be retained  
1425 under paragraph (a).

1426 (7) The State Surgeon General shall order a clinic closed  
1427 for operations if closure is warranted following failure of the  
1428 owner or operator of the clinic to pass a background check of  
1429 his or her criminal history. As determined by rule, the  
1430 department may grant an exemption if more than 10 years have  
1431 elapsed since adjudication.

1432 (8) By January 3, 2011, the department and the Department  
1433 of Law Enforcement shall adopt rules pursuant to ss. 120.536(1)  
1434 and 120.54 to administer the provisions of this section, which  
1435 shall include, as necessary, the reporting, management,  
1436 development, and implementation of the fingerprint requirements  
1437 in this section.

1438 Section 13. This act shall take effect July 1, 2010.