

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

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1 A bill to be entitled
2 An act relating to pain management; amending s.
3 456.037, F.S.; providing that pain-management clinics
4 are business establishments subject to licensure by
5 the Department of Health; requiring a health
6 professional licensee who works at a pain-management
7 clinic that prescribes controlled substances to be
8 responsible for maintaining control and security over
9 his or her blank prescription pads and any other
10 method used to prescribe controlled substance pain
11 medication; requiring the health professional licensee
12 to notify the department within a specified time after
13 the theft or loss of blank prescription pads;
14 requiring a health professional licensee to give
15 written notice to the applicable board within a
16 specified period after the health professional
17 licensee's termination of employment at the pain-
18 management clinic; amending s. 456.057, F.S.;
19 providing that the Department of Health is not
20 required to attempt to obtain authorization from a
21 patient for the release of the patient's medical
22 records under certain circumstances; amending s.
23 456.069, F.S.; authorizing the Department of Health to
24 inspect a pain-management clinic in a lawful manner at
25 all reasonable hours for the purpose of determining if
26 any provision of ch. 456, F.S., or any rule adopted by
27 the department has been violated; authorizing the
28 department to obtain patient records without
29 authorization or subpoena if the department has

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30 probable cause to believe that a violation of s.
31 456.072, F.S., has occurred or is occurring; amending
32 s. 456.071, F.S.; providing venue for judicial
33 challenges to any subpoena or order issued by the
34 Department of Health during its investigations;
35 amending s. 456.072, F.S.; providing additional acts
36 that constitute grounds for disciplinary actions
37 against health professional licensees; amending s.
38 458.309, F.S.; requiring all privately owned pain-
39 management clinics, or offices that primarily engage
40 in the treatment of pain by prescribing or dispensing
41 controlled substance medications or that employ a
42 physician who is primarily engaged in the treatment of
43 pain by prescribing or dispensing controlled substance
44 medications, to register with the Department of Health
45 within a specified time; providing an exception;
46 authorizing the department to deny an application for
47 registering a pain-management clinic or to revoke or
48 suspend the current registration certificate of a
49 pain-management clinic for certain reasons;
50 authorizing the department to impose fines for certain
51 violations of law; requiring the department to
52 consider certain factors when calculating the amount
53 of the fine; providing that each day a violation
54 continues constitutes an separate violation; requiring
55 the pain-management clinic to document in writing all
56 efforts undertaken by the pain-management clinic to
57 correct a violation; providing that the owner or
58 designated physician of a pain-management clinic is

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59 subject to an administrative fine; providing that the
60 owner of a pain-management clinic who does not apply
61 for a change-of-ownership license and who operates the
62 clinic under a new ownership is subject to a fine;
63 requiring the department to discuss each violation
64 with the owner or designated physician of the pain-
65 management clinic before a formal written
66 notification; requiring a pain-management clinic to
67 cease operating if its registration certificate is
68 revoked or suspended; requiring certain named persons
69 to remove all signs and symbols identifying the
70 premises as a pain-management clinic; prohibiting any
71 person acting as an individual or as part of a group
72 from applying for a certificate to operate a pain-
73 management clinic for a certain period after the date
74 the person's registration certificate is revoked;
75 providing for disposition of drugs at a former pain-
76 management clinic; providing that certain clinics,
77 facilities, and offices that advertise any type of
78 pain-management services are exempt from the
79 registration provisions under certain conditions;
80 requiring the department and the Boards of Medicine
81 and Osteopathic Medicine to adopt rules; creating ss.
82 458.3265 and 459.0137, F.S.; providing for
83 requirements for the registration of pain-management
84 clinics; prohibiting a physician or an osteopathic
85 physician from practicing medicine in a pain-
86 management clinic under certain conditions; requiring
87 each location of a pain-management clinic to be

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88 registered separately regardless of whether the clinic
89 is operated under the same business name or management
90 as another clinic; prohibiting a pain-management
91 clinic from being owned by or having any contractual
92 relationship with certain specified persons; providing
93 that if the department finds that a privately owned
94 pain-management clinic is owned by a person possessing
95 disqualifying criteria, the department shall refuse to
96 register the pain-management clinic or revoke a
97 previously issued certificate of registration;
98 prohibiting a person from dispensing medication on the
99 premises of a registered pain-management clinic unless
100 he or she is a physician licensed under ch. 458 or ch.
101 459, F.S.; requiring a physician to document in the
102 patient's record why the physician is prescribing or
103 dispensing more than a specified amount of a
104 controlled substances for the treatment of chronic
105 nonmalignant pain; amending s. 458.327, F.S.;

106 providing that the commission of certain specified
107 acts while managing a pain-management clinic
108 constitutes a felony of the third degree or a
109 misdemeanor of the first degree; amending s. 459.005,
110 F.S.; requiring all privately owned pain-management
111 clinics, or offices that primarily engage in the
112 treatment of pain by prescribing or dispensing
113 controlled substance medications or that employ a
114 physician who is primarily engaged in the treatment of
115 pain by prescribing or dispensing controlled substance
116 medications, to register with the Department of Health

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117 within a specified time; providing an exception;
118 providing that certain clinics, facilities, and
119 offices that advertise any type of pain-management
120 services are exempt from the registration provisions
121 under certain conditions; authorizing the department
122 to deny an application for registering a pain-
123 management clinic or to revoke or suspend the current
124 registration certificate of a pain-management clinic
125 for certain reasons; authorizing the department to
126 impose fines for certain violations of law; requiring
127 the department to consider certain factors when
128 calculating the amount of the fine; providing that
129 each day a violation continues constitutes a separate
130 violation; requiring the pain-management clinic to
131 document in writing all efforts undertaken by the
132 pain-management clinic to correct a violation;
133 providing that the owner or designated physician of a
134 pain-management clinic is subject to an administrative
135 fine; providing that the owner of a pain-management
136 clinic who does not apply for a change-of-ownership
137 license and who operates the clinic under a new
138 ownership is subject to a fine; requiring the
139 department to discuss each violation with the owner or
140 designated physician of the pain-management clinic
141 before a formal written notification; requiring a
142 pain-management clinic to cease operating if its
143 registration certificate is revoked or suspended;
144 requiring certain named persons to remove all signs
145 and symbols identifying the premises as a pain-

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146 management clinic; prohibiting any person acting as an
147 individual or as part of a group from applying for a
148 certificate to operate a pain-management clinic for a
149 certain period after the date the person's
150 registration certificate is revoked; providing for
151 disposition of drugs at a former pain-management
152 clinic; requiring the department and the Boards of
153 Medicine and Osteopathic Medicine to adopt rules;
154 amending s. 459.013, F.S.; providing that the
155 commission of certain specified acts while managing a
156 pain-management clinic constitutes a felony of the
157 third degree or a misdemeanor of the first degree;
158 providing an effective date.

159
160 Be It Enacted by the Legislature of the State of Florida:

161
162 Section 1. Subsection (5) of section 456.037, Florida
163 Statutes, is amended, and subsection (6) is added to that
164 section, to read:

165 456.037 Business establishments; requirements for active
166 status licenses; delinquency; discipline; applicability.-

167 (5) This section applies to any business establishment
168 registered, permitted, or licensed by the department to do
169 business. Business establishments include, but are not limited
170 to, dental laboratories, electrology facilities, massage
171 establishments, ~~and~~ pharmacies, and pain-management clinics
172 required to be registered under s. 458.309 or s. 459.005.

173 (6) A licensee authorized to prescribe controlled
174 substances who practices at a pain-management clinic is

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175 responsible for maintaining the control and security of his or
176 her prescription blanks and any other method used for
177 prescribing controlled substance pain medication. The licensee
178 shall comply with the requirements for counterfeit-resistant
179 prescription blanks in s. 893.065 and the rules adopted pursuant
180 to that section. The licensee shall notify in writing:

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

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

188 Section 2. Paragraph (a) of subsection (9) of section
189 456.057, Florida Statutes, is amended to read:

190 456.057 Ownership and control of patient records; report or
191 copies of records to be furnished.—

192 (9) (a) 1. The department may obtain patient records pursuant
193 to a subpoena without written authorization from the patient if
194 the department and the probable cause panel of the appropriate
195 board, if any, find reasonable cause to believe that a health
196 care practitioner has excessively or inappropriately prescribed
197 any controlled substance specified in chapter 893 in violation
198 of this chapter or any professional practice act or that a
199 health care practitioner has practiced his or her profession
200 below that level of care, skill, and treatment required as
201 defined by this chapter or any professional practice act and
202 also find that appropriate, reasonable attempts were made to
203 obtain a patient release. Notwithstanding the foregoing, the

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204 department need not attempt to obtain a patient release when
205 investigating an offense involving the inappropriate
206 prescribing, overprescribing, or diversion of controlled
207 substances and the offense involves a pain-management clinic.

208 2. The department may obtain patient records and insurance
209 information pursuant to a subpoena without written authorization
210 from the patient if the department and the probable cause panel
211 of the appropriate board, if any, find reasonable cause to
212 believe that a health care practitioner has provided inadequate
213 medical care based on termination of insurance and also find
214 that appropriate, reasonable attempts were made to obtain a
215 patient release.

216 3. The department may obtain patient records, billing
217 records, insurance information, provider contracts, and all
218 attachments thereto pursuant to a subpoena without written
219 authorization from the patient if the department and probable
220 cause panel of the appropriate board, if any, find reasonable
221 cause to believe that a health care practitioner has submitted a
222 claim, statement, or bill using a billing code that would result
223 in payment greater in amount than would be paid using a billing
224 code that accurately describes the services performed, requested
225 payment for services that were not performed by that health care
226 practitioner, used information derived from a written report of
227 an automobile accident generated pursuant to chapter 316 to
228 solicit or obtain patients personally or through an agent
229 regardless of whether the information is derived directly from
230 the report or a summary of that report or from another person,
231 solicited patients fraudulently, received a kickback as defined
232 in s. 456.054, violated the patient brokering provisions of s.

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233 817.505, or presented or caused to be presented a false or
234 fraudulent insurance claim within the meaning of s.
235 817.234(1)(a), and also find that, within the meaning of s.
236 817.234(1)(a), patient authorization cannot be obtained because
237 the patient cannot be located or is deceased, incapacitated, or
238 suspected of being a participant in the fraud or scheme, and if
239 the subpoena is issued for specific and relevant records.

240 4. Notwithstanding subparagraphs 1.-3., when the department
241 investigates a professional liability claim or undertakes action
242 pursuant to s. 456.049 or s. 627.912, the department may obtain
243 patient records pursuant to a subpoena without written
244 authorization from the patient if the patient refuses to
245 cooperate or if the department attempts to obtain a patient
246 release and the failure to obtain the patient records would be
247 detrimental to the investigation.

248 Section 3. Section 456.069, Florida Statutes, is amended to
249 read:

250 456.069 Authority to inspect.—In addition to the authority
251 specified in s. 465.017, duly authorized agents and employees of
252 the department may ~~shall have the power to~~ inspect in a lawful
253 manner at all reasonable hours:

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

255 (2) Any establishment at which the services of a licensee
256 authorized to prescribe controlled substances specified in
257 chapter 893 are offered; or

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

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262 for the purpose of determining if any of the provisions of this
263 chapter or any practice act of a profession or any rule adopted
264 thereunder is being violated; or for the purpose of securing
265 such other evidence as may be needed for prosecution. Such
266 evidence may include, but is not limited to, patient records.
267 The department may obtain patient records without patient
268 authorization or subpoena from any pain-management clinic
269 required to be licensed if the department has probable cause to
270 believe that a violation of any provision of s. 456.072 is
271 occurring or has occurred and reasonably believes that obtaining
272 such authorization is not feasible due to the volume of the
273 dispensing and prescribing activity involving controlled
274 substances and that obtaining patient authorization or the
275 issuance of a subpoena would jeopardize the investigation.

276 Section 4. Section 456.071, Florida Statutes, is amended to
277 read:

278 456.071 Power to administer oaths, take depositions, and
279 issue subpoenas.—For the purpose of any investigation or
280 proceeding conducted by the department, the department shall
281 have the power to administer oaths, take depositions, make
282 inspections when authorized by statute, issue subpoenas which
283 shall be supported by affidavit, serve subpoenas and other
284 process, and compel the attendance of witnesses and the
285 production of books, papers, documents, and other evidence. The
286 department shall exercise this power on its own initiative or
287 whenever requested by a board or the probable cause panel of any
288 board. Challenges to, and enforcement of, the subpoenas and
289 orders shall be handled as provided in s. 120.569, except that
290 venue is in the Circuit Court for the Second Judicial Circuit,

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291 in the county where the examination, investigation, or hearing
292 is conducted, or in the county in which the person resides.

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

295 456.072 Grounds for discipline; penalties; enforcement.—

296 (1) The following acts shall constitute grounds for which
297 the disciplinary actions specified in subsection (2) may be
298 taken:

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

302 1. Registering a pain-management clinic through
303 misrepresentation or fraud;

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

307 3. Failing to comply with any requirement of chapter 499,
308 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
309 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
310 the Drug Abuse Prevention and Control Act; or chapter 893, the
311 Florida Comprehensive Drug Abuse Prevention and Control Act;

312 4. Being convicted or found guilty of, regardless of
313 adjudication to, a felony or any other crime involving moral
314 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
315 the courts of this state, of any other state, or of the United
316 States;

317 5. Being convicted of, or disciplined by a regulatory
318 agency of the Federal Government or a regulatory agency of
319 another state for, any offense that would constitute a violation

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320 of this chapter;

321 6. Being convicted of, or entering a plea of guilty or nolo
322 contendere to, regardless of adjudication, a crime in any
323 jurisdiction which relates to the practice of, or the ability to
324 practice, a licensed health care profession;

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

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

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

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

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

347 Section 6. Section 458.309, Florida Statutes, is amended to
348 read:

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349 458.309 Rulemaking authority.—

350 (1) The board has authority to adopt rules pursuant to ss.
351 120.536(1) and 120.54 to implement the provisions of this
352 chapter conferring duties upon it.

353 (2) (a) Any rules which the board adopts relating to the
354 classroom phase of medical education shall not apply to any
355 person who is enrolled in the classroom phase of medical
356 education or has graduated prior to or at the time the rule
357 becomes effective, so long as such person does not interrupt his
358 or her medical education.

359 (b)1. Any rules which the board adopts relating to the
360 clinical clerkship phase of medical education shall not apply to
361 any person who is enrolled in the clinical clerkship phase of
362 medical education prior to or at the time the rule becomes
363 effective, so long as such person does not interrupt his or her
364 medical education.

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

369 a. Had completed a clinical clerkship prior to the
370 effective date of the rule; or

371 b. Had begun a clinical clerkship but had not completed the
372 clinical clerkship prior to the effective date of the rule, so
373 long as the clinical clerkship took no longer than 3 years to
374 complete.

375 (c) Any rules which the board adopts relating to residency
376 shall not apply to any person who has begun his or her residency
377 prior to or at the time the rule becomes effective, so long as

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378 such person does not interrupt the residency.

379 (3) All physicians who perform level 2 procedures lasting
380 more than 5 minutes and all level 3 surgical procedures in an
381 office setting must register the office with the department
382 unless that office is licensed as a facility pursuant to chapter
383 395. The department shall inspect the physician's office
384 annually unless the office is accredited by a nationally
385 recognized accrediting agency or an accrediting organization
386 subsequently approved by the Board of Medicine. The actual costs
387 for registration and inspection or accreditation shall be paid
388 by the person seeking to register and operate the office setting
389 in which office surgery is performed.

390 (4) Effective January 4, 2010, all privately owned pain-
391 management clinics, facilities, or offices, hereinafter referred
392 to as "clinics," which advertise in any medium for any type of
393 pain-management services, or employ a physician who is primarily
394 engaged in the treatment of pain by prescribing or dispensing
395 controlled substance medications, must register with the
396 department ~~by January 4, 2010,~~ unless that clinic is licensed as
397 a facility pursuant to chapter 395. A physician may not practice
398 medicine in a pain-management clinic that is required to but has
399 not registered with the department. Each clinic location shall
400 be registered separately regardless of whether the clinic is
401 operated under the same business name or management as another
402 clinic. ~~If the clinic is licensed as a health care clinic under~~
403 ~~chapter 400, the medical director is responsible for registering~~
404 ~~the facility with the department.~~ If the clinic is not
405 registered pursuant to chapter 395 ~~or chapter 400,~~ the clinic
406 shall, upon registration with the department, designate a

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407 physician who is responsible for complying with all requirements
408 related to registration of the clinic. The designated physician
409 shall have a full, active, and unencumbered license ~~be licensed~~
410 under this chapter or chapter 459 and shall practice at the
411 office location for which the physician has assumed
412 responsibility. The department shall inspect the clinic
413 annually, including a review of the patient records, to ensure
414 that it complies with rules of the Board of Medicine adopted
415 pursuant to this subsection and subsection (6) ~~(5)~~ unless the
416 office is accredited by a nationally recognized accrediting
417 agency approved by the Board of Medicine. The actual costs for
418 registration and inspection or accreditation shall be paid by
419 the physician seeking to register the clinic.

420 (5) (a) The department may deny an application for
421 registering a pain-management clinic or revoke or suspend a
422 current registration. The department may impose an
423 administrative fine on the clinic of up to \$5,000 per violation
424 for violating the requirements of this section, chapter 499, the
425 Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
426 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
427 the Drug Abuse Prevention and Control Act; or chapter 893, the
428 Florida Comprehensive Drug Abuse Prevention and Control Act; or
429 the rules of the department. In determining whether a penalty is
430 to be imposed, and in fixing the amount of the fine, the
431 department shall consider the following factors:

432 1. The gravity of the violation, including the probability
433 that death or serious physical or emotional harm to a patient
434 has resulted, or could have resulted, from a licensee's actions,
435 the severity of the action or potential harm, and the extent to

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436 which the provisions of the applicable laws or rules were
437 violated.

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

440 3. Whether there were any previous violations at the pain-
441 management clinic.

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

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

447 (c) Any action taken to correct a violation shall be
448 documented in writing by the owner or designated physician of
449 the pain-management clinic and verified by followup visits by
450 departmental personnel. The department may impose a fine and, in
451 the case of an owner-operated pain-management clinic may revoke
452 or deny a clinic's registration, if the clinic's designated
453 physician knowingly and intentionally misrepresents actions
454 taken to correct a violation.

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

458 (e) If the owner of a pain-management clinic fails to apply
459 for a change-of-ownership registration and operates the clinic
460 under the new ownership, the owner is subject to a fine of
461 \$5,000.

462 (f) During an onsite inspection, the department shall make
463 a reasonable attempt to discuss each violation with the owner or
464 designated physician of the pain-management clinic before

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465 issuing a formal written notification.

466 (g)1. If the registration of a pain-management clinic is
467 revoked or suspended, the designated physician of the pain-
468 management clinic, the owner or lessor of the pain-management
469 clinic property, and the owner, manager, or proprietor shall
470 cease to operate the facility as a pain-management clinic as of
471 the effective date of the suspension or revocation.

472 2. If a pain-management clinic registration is revoked or
473 suspended, the designated physician of the pain-management
474 clinic, the owner or lessor of the clinic property, or the
475 owner, manager, or proprietor is responsible for removing all
476 signs and symbols identifying the premises as a pain-management
477 clinic.

478 3. If the clinic's registration is revoked, any person
479 named in the registration documents of the pain-management
480 clinic, including persons owning or operating the pain-
481 management clinic, may not, as an individual or as a part of a
482 group, apply to operate a pain-management clinic for 5 years
483 after the date the registration is revoked.

484 4. Upon the effective date of the suspension or revocation,
485 the pain-management clinic shall advise the department of the
486 disposition of the medicinal drugs located on the premises. The
487 disposition is subject to the supervision and approval of the
488 department. Medicinal drugs that are purchased or held by a
489 pain-management clinic that is not registered may be deemed
490 adulterated pursuant to s. 499.006.

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

493 (6) ~~(5)~~ The Board of Medicine shall adopt rules setting

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494 forth standards of practice for physicians practicing in
495 privately owned pain-management clinics that primarily engage in
496 the treatment of pain by prescribing or dispensing controlled
497 substance medications. Such rules shall address, but need not be
498 limited to, the following subjects:

- 499 (a) Facility operations;
- 500 (b) Physical operations;
- 501 (c) Infection control requirements;
- 502 (d) Health and safety requirements;
- 503 (e) Quality assurance requirements;
- 504 (f) Patient records;
- 505 (g) Training requirements for all facility health care
506 practitioners who are not regulated by another board;
- 507 (h) Inspections; and
- 508 (i) Data collection and reporting requirements.

509

510 A physician is primarily engaged in the treatment of pain by
511 prescribing or dispensing controlled substance medications when
512 the majority of the patients seen are prescribed or dispensed
513 controlled substance medications for the treatment of chronic
514 nonmalignant pain. Chronic nonmalignant pain is pain unrelated
515 to cancer which persists beyond the usual course of the disease
516 or the injury that is the cause of the pain or more than 90 days
517 after surgery.

518 (7)~~(6)~~ A privately owned clinic, facility, or office that
519 advertises in any medium for any type of pain-management
520 services or employs one or more physicians who are primarily
521 engaged in the treatment of pain by prescribing or dispensing
522 controlled substances is exempt from the registration provisions

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523 in subsection (4) if:

524 (a) The majority of the physicians who provide services in
525 the clinic, facility, or office primarily provide surgical
526 services;

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

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

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

537 (e) The clinic, facility or office is owned by a corporate
538 entity exempt from federal taxation under 26 U.S.C. s.
539 501(c) (3).

540 (8) The department shall adopt rules necessary to
541 administer the registration and inspection of pain-management
542 clinics establishing the specific requirements, procedures,
543 forms, and fees.

544 (9) The department shall adopt a rule defining what
545 constitutes practice by a designated physician at the office
546 location for which the physician has assumed responsibility, as
547 set forth in subsections (3) and (4). When adopting the rule,
548 the department shall consider the number of clinic employees,
549 the location of the pain-management clinic, its hours of
550 operation, and the amount of controlled substances being
551 prescribed, dispensed, or administered at the pain-management

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552 clinic.

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

558 Section 7. Section 458.3265, Florida Statutes, is created
559 to read:

560 458.3265 Pain-management clinics.-

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

563 1. Effective July 1, 2012, the physician has not
564 successfully completed a pain medicine fellowship that is
565 accredited by the Accreditation Council for Graduate Medical
566 Education or a pain medicine residency that is accredited by the
567 Accreditation Council for Graduate Medical Education unless
568 previously registered and qualified as a pain medicine physician
569 with the Board of Medicine; or

570 2. The pain-management clinic is not registered with the
571 department as required by s. 458.309. As provided in s.
572 458.309(4), each location of a pain-management clinic must be
573 registered separately regardless of whether the clinic is
574 operated under the same business name or management as another
575 clinic.

576
577 The department may revoke the clinic's certificate of
578 registration and prohibit all physicians associated with that
579 pain-management clinic from practicing at that office location
580 based upon an annual inspection and evaluation of the factors

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581 described in s. 458.309(5) (a). A physician who violates this
582 paragraph is subject to review by his or her appropriate medical
583 regulatory board.

584 (b) The department shall deny registration to any clinic
585 not fully owned by a physician licensed pursuant to this chapter
586 or chapter 459, a group of physicians licensed pursuant to this
587 chapter or chapter 459, or a health care clinic licensed under
588 part X of chapter 400.

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

592 1. Whose Drug Enforcement Administration number has ever
593 been revoked.

594 2. Whose application for a license to prescribe, dispense,
595 or administer a controlled substance has been denied by any
596 jurisdiction.

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

603 (d) If the department finds that a pain-management clinic
604 is owned , directly or indirectly, by a person meeting any
605 criteria listed in paragraph (b) or paragraph (c), the
606 department shall refuse to register the pain-management clinic
607 or shall revoke the certificate of registration previously
608 issued by the department. As determined by rule, the department
609 may grant an exemption if more than 10 years have elapsed since

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610 adjudication. As used in this subsection, the term "convicted"
611 includes an adjudication of guilt following a plea of guilty or
612 nolo contendere or the forfeiture of a bond when charged with a
613 crime.

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

618 (3) After a physical examination of the patient the same
619 day of dispensing a controlled substance, a physician must
620 document in the patient's record the reason for prescribing or
621 dispensing more than a 72-hour dose of a controlled substance
622 for the treatment of chronic nonmalignant pain.

623 Section 8. Section 458.327, Florida Statutes, is amended to
624 read:

625 458.327 Penalty for violations.—

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

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

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

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

635 (d) Attempting to obtain or obtaining a position as a
636 medical practitioner or medical resident in a clinic or hospital
637 through knowing misrepresentation of education, training, or
638 experience.

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639 (e) Knowingly operating, owning, or managing a
640 nonregistered pain-management clinic that is required to be
641 registered with the Department of Health pursuant to
642 s.458.309(4).

643 (2) Each of the following acts constitutes a misdemeanor of
644 the first degree, punishable as provided in s. 775.082 or s.
645 775.083:

646 (a) Knowingly concealing information relating to violations
647 of this chapter.

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

650 (c) Referring any patient, for health care goods or
651 services, to a partnership, firm, corporation, or other business
652 entity in which the physician or the physician's employer has an
653 equity interest of 10 percent or more unless, prior to such
654 referral, the physician notifies the patient of his or her
655 financial interest and of the patient's right to obtain such
656 goods or services at the location of the patient's choice. This
657 section does not apply to the following types of equity
658 interest:

659 1. The ownership of registered securities issued by a
660 publicly held corporation or the ownership of securities issued
661 by a publicly held corporation, the shares of which are traded
662 on a national exchange or the over-the-counter market;

663 2. A physician's own practice, whether he or she is a sole
664 practitioner or part of a group, when the health care good or
665 service is prescribed or provided solely for the physician's own
666 patients and is provided or performed by the physician or under
667 the physician's supervision; or

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668 3. An interest in real property resulting in a landlord-
669 tenant relationship between the physician and the entity in
670 which the equity interest is held, unless the rent is
671 determined, in whole or in part, by the business volume or
672 profitability of the tenant or is otherwise unrelated to fair
673 market value.

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

677 (e) Practicing medicine or attempting to practice medicine
678 with an inactive or delinquent license.

679 (f) Knowingly prescribing or dispensing, or causing to be
680 prescribed or dispensed, controlled substances in a
681 nonregistered pain-management clinic that is required to be
682 registered with the Department of Health pursuant to s.
683 458.309(4).

684 Section 9. Section 459.005, Florida Statutes, is amended to
685 read:

686 459.005 Rulemaking authority.—

687 (1) The board has authority to adopt rules pursuant to ss.
688 120.536(1) and 120.54 to implement the provisions of this
689 chapter conferring duties upon it.

690 (2) All physicians who perform level 2 procedures lasting
691 more than 5 minutes and all level 3 surgical procedures in an
692 office setting must register the office with the department
693 unless that office is licensed as a facility pursuant to chapter
694 395. The department shall inspect the physician's office
695 annually unless the office is accredited by a nationally
696 recognized accrediting agency or an accrediting organization

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697 subsequently approved by the Board of Osteopathic Medicine. The
698 actual costs for registration and inspection or accreditation
699 shall be paid by the person seeking to register and operate the
700 office setting in which office surgery is performed.

701 (3) Effective January 4, 2010, all privately owned pain-
702 management clinics, facilities, or offices, hereinafter referred
703 to as "clinics," which advertise in any medium for any type of
704 pain-management services, or employ a physician who is licensed
705 under this chapter and who is primarily engaged in the treatment
706 of pain by prescribing or dispensing controlled substance
707 medications, must register with the department ~~by January 4,~~
708 ~~2010,~~ unless that clinic is licensed as a facility under chapter
709 395. A physician may not practice osteopathic medicine in a
710 pain-management clinic that is required to but has not
711 registered with the department. Each clinic location shall be
712 registered separately regardless of whether the clinic is
713 operated under the same business name or management as another
714 clinic. ~~If the clinic is licensed as a health care clinic under~~
715 ~~chapter 400, the medical director is responsible for registering~~
716 ~~the facility with the department.~~ If the clinic is not
717 registered under chapter 395 ~~or chapter 400,~~ the clinic shall,
718 upon registration with the department, designate a physician who
719 is responsible for complying with all requirements related to
720 registration of the clinic. The designated physician shall have
721 a full, active, and unencumbered license ~~be licensed~~ under
722 chapter 458 or this chapter and shall practice at the office
723 location for which the physician has assumed responsibility. The
724 department shall inspect the clinic annually, including a review
725 of the patient records, to ensure that it complies with rules of

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726 the Board of Osteopathic Medicine adopted pursuant to this
727 subsection and subsection (4) unless the office is accredited by
728 a nationally recognized accrediting agency approved by the Board
729 of Osteopathic Medicine. The actual costs for registration and
730 inspection or accreditation shall be paid by the physician
731 seeking to register the clinic.

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

- 738 (a) Facility operations;
- 739 (b) Physical operations;
- 740 (c) Infection control requirements;
- 741 (d) Health and safety requirements;
- 742 (e) Quality assurance requirements;
- 743 (f) Patient records;
- 744 (g) Training requirements for all facility health care
745 practitioners who are not regulated by another board;
- 746 (h) Inspections; and
- 747 (i) Data collection and reporting requirements.

748
749 A physician is primarily engaged in the treatment of pain by
750 prescribing or dispensing controlled substance medications when
751 the majority of the patients seen are prescribed or dispensed
752 controlled substance medications for the treatment of chronic
753 nonmalignant pain. Chronic nonmalignant pain is pain unrelated
754 to cancer which persists beyond the usual course of the disease

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755 or the injury that is the cause of the pain or more than 90 days
756 after surgery.

757 (5) A privately owned clinic, facility, or office that
758 advertises in any medium for any type of pain-management
759 services or employs one or more physicians who are primarily
760 engaged in the treatment of pain by prescribing or dispensing
761 controlled substances is exempt from the registration provisions
762 in subsection (3) if:

763 (a) The majority of the physicians who provide services in
764 the clinic, facility, or office primarily provide surgical
765 services;

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

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

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

776 (e) The clinic, facility or office is owned by a corporate
777 entity exempt from federal taxation under 26 U.S.C. s.
778 501(c) (3).

779 (6) (a) The department may deny an application for
780 registering a pain-management clinic or revoke or suspend a
781 current registration. The department may impose an
782 administrative fine on the clinic of up to \$5,000 per violation
783 for violating the requirements of this section, chapter 499, the

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784 Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
785 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
786 the Drug Abuse Prevention and Control Act; or chapter 893, the
787 Florida Comprehensive Drug Abuse Prevention and Control Act; or
788 the rules of the department. In determining whether a penalty is
789 to be imposed, and in fixing the amount of the fine, the
790 department shall consider the following factors:

791 1. The gravity of the violation, including the probability
792 that death or serious physical or emotional harm to a patient
793 has resulted, or could have resulted, from a licensee's actions,
794 the severity of the action or potential harm, and the extent to
795 which the provisions of the applicable laws or rules were
796 violated.

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

799 3. Whether there were any previous violations at the pain-
800 management clinic.

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

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

806 (c) Any action taken to correct a violation shall be
807 documented in writing by the owner or designated physician of
808 the pain-management clinic and verified by followup visits by
809 departmental personnel. The department may impose a fine and, in
810 the case of an owner-operated pain-management clinic may revoke
811 or deny a clinic's registration, if the clinic's designated
812 physician knowingly and intentionally misrepresents actions

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813 taken to correct a violation.

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

817 (e) If the owner of a pain-management clinic fails to apply
818 for a change-of-ownership registration and operates the clinic
819 under the new ownership, the owner is subject to a fine of
820 \$5,000.

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

825 (g)1. If the registration of a pain-management clinic is
826 revoked or suspended, the designated physician of the pain-
827 management clinic, the owner or lessor of the pain-management
828 clinic property, and the owner, manager, or proprietor shall
829 cease to operate the facility as a pain-management clinic as of
830 the effective date of the suspension or revocation.

831 2. If a pain-management clinic's registration is revoked or
832 suspended, the designated physician of the pain-management
833 clinic, the owner or lessor of the clinic property, or the
834 owner, manager, or proprietor is responsible for removing all
835 signs and symbols identifying the premises as a pain-management
836 clinic.

837 3. If the clinic's registration is revoked, any person
838 named in the registration documents of the pain-management
839 clinic, including persons owning or operating the pain-
840 management clinic, may not, as an individual or as a part of a
841 group, apply to operate a pain-management clinic for 5 years

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842 after the date the registration is revoked.

843 4. Upon the effective date of the suspension or revocation,
844 the pain-management clinic shall advise the department of the
845 disposition of the medicinal drugs located on the premises. The
846 disposition is subject to the supervision and approval of the
847 department. Medicinal drugs that are purchased or held by a
848 pain-management clinic that is not registered may be deemed
849 adulterated pursuant to s. 499.006.

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

852 (7) The department shall adopt rules necessary to
853 administer the registration and inspection of pain-management
854 clinics establishing the specific requirements, procedures,
855 forms, and fees.

856 (8) The department shall adopt a rule defining what
857 constitutes practice by a designated physician at the office
858 location for which the physician has assumed responsibility, as
859 set forth in subsections (3) and (4). When adopting the rule,
860 the department shall consider the number of clinic employees,
861 the location of the pain-management clinic, its hours of
862 operation, and the amount of controlled substances being
863 prescribed, dispensed, or administered at the pain-management
864 clinic.

865 (9) The Boards of Medicine and Osteopathic Medicine shall
866 adopt a rule establishing the maximum number of prescriptions
867 for Schedule II or Schedule III controlled substances which may
868 can be written at any one registered pain-management clinic
869 during any 24-hour period.

870 Section 10. Section 459.0137, Florida Statutes, is created

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871 to read:

872 459.0137 Pain-management clinics.-

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

876 1. Effective July 1, 2012, the physician has not
877 successfully completed a pain medicine fellowship that is
878 accredited by the Accreditation Council for Graduate Medical
879 Education or the American Osteopathic Association or a pain
880 medicine residency that is accredited by the Accreditation
881 Council for Graduate Medical Education or the American
882 Osteopathic Association unless previously registered and
883 qualified as a pain medicine physician with the Board of
884 Osteopathic Medicine; or

885 2. The pain-management clinic is not registered with the
886 department as required by s. 459.005. As provided in s.
887 459.005(3), each location of a pain-management clinic must be
888 registered separately regardless of whether the clinic is
889 operated under the same business name or management as another
890 clinic.

891

892 The department may revoke the clinic's certificate of
893 registration and prohibit all physicians associated with that
894 pain-management clinic from practicing at that office location
895 based upon an annual inspection and evaluation of the factors
896 described in s. 459.005(6) (a). A physician who violates this
897 paragraph is subject to review by his or her appropriate medical
898 regulatory board.

899 (b) The department shall deny registration to any clinic

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900 not fully owned by a physician licensed pursuant to chapter 458
901 or this chapter, a group of physicians licensed pursuant to
902 chapter 458 or this chapter, or a health care clinic licensed
903 under part X of chapter 400.

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

907 1. Whose Drug Enforcement Administration number has ever
908 been revoked;

909 2. Whose application for a license to prescribe, dispense,
910 or administer a controlled substance has been denied by any
911 jurisdiction; or

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

918 (d) If the department finds that a pain-management clinic
919 is owned, directly or indirectly, by a person meeting any
920 criteria listed in paragraph (b) or paragraph (c), the
921 department shall refuse to register the pain-management clinic
922 or shall revoke the certificate of registration previously
923 issued by the department. As determined by rule, the department
924 may grant an exemption if more than 10 years have elapsed since
925 adjudication. As used in this subsection, the term "convicted"
926 includes an adjudication of guilt following a plea of guilty or
927 nolo contendere or the forfeiture of a bond when charged with a
928 crime.

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

933 (3) After a physical examination of the patient the same
934 day of dispensing a controlled substance, a physician must
935 document in the patient's record the reason for prescribing or
936 dispensing more than a 72-hour dose of a controlled substance
937 for the treatment of chronic nonmalignant pain.

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

940 459.013 Penalty for violations.—

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

944 (a) The practice of osteopathic medicine, or an attempt to
945 practice osteopathic medicine, without an active license or
946 certificate issued pursuant to this chapter.

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

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

953 (d) Attempting to obtain or obtaining a position as an
954 osteopathic medical practitioner or osteopathic medical resident
955 in a clinic or hospital through knowing misrepresentation of
956 education, training, or experience.

957 (e) Knowingly operating, owning, or managing a

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958 nonregistered pain-management clinic that is required to be
959 registered with the Department of Health pursuant to s.
960 459.005(3).

961 (2) Each of the following acts constitutes a misdemeanor of
962 the first degree, punishable as provided in s. 775.082 or s.
963 775.083:

964 (a) Knowingly concealing information relating to violations
965 of this chapter.

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

968 (c) The practice of medicine as a resident or intern
969 without holding a valid current registration pursuant to s.
970 459.021.

971 (d) Knowingly prescribing or dispensing, or causing to be
972 prescribed or dispensed, controlled substances in a
973 nonregistered pain-management clinic that is required to be
974 registered with the Department of Health pursuant to s.
975 459.005(3).

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