

By Senator Fasano

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1 A bill to be entitled
2 An act relating to pain-management clinics; providing
3 definitions; providing specific standards of practice
4 in pain-management clinics with regard to evaluations
5 of a patient's medical diagnosis, treatment plans,
6 informed consent, agreements for treatment, a
7 physician's periodic review of a patient,
8 consultation, patient drug testing, patient medical
9 records, denial or termination of controlled-substance
10 therapy, facility and physical operations, infection
11 control, health and safety, quality assurance, and
12 data collection and reporting; amending ss. 458.3265
13 and 459.0137, F.S.; providing that the designated
14 physician at a pain-management clinic is responsible
15 for ensuring that the clinic is registered with the
16 Department of Health; requiring a pain-management
17 clinic to notify the department of the identity of a
18 newly designated physician when the former designated
19 physician is terminated or when there are any changes
20 to the registration information; providing
21 requirements for the registration of a pain-management
22 clinic; holding nationally recognized accrediting
23 agencies to the same board-determined practice
24 standards for registering pain-management clinics;
25 requiring the department to conduct unannounced annual
26 inspections of clinics; requiring the designated
27 physician to cooperate with the department's inspector
28 and make medical records available to the inspector;
29 requiring the department's inspector to determine

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30 compliance with specific standards of practice in
31 pain-management clinics; providing a procedure for
32 when a pain-management clinic is noncompliant with
33 specific standards of practice; requiring the
34 inspector to forward the written results of the
35 inspection, deficiency notice, and any subsequent
36 documentation to the department; requiring the
37 department to review the results and determine whether
38 action against the clinic is merited; providing that
39 the department's authority is not limited with regard
40 to investigating a complaint without prior notice;
41 requiring the designated physician to submit written
42 notification of the current accreditation survey of
43 the pain-management clinic under certain
44 circumstances; requiring the designated physician to
45 notify the Board of Medicine or Board of Osteopathic
46 Medicine of a plan of correction if the pain-
47 management clinic receives a provisional or
48 conditional accreditation; conforming provisions to
49 changes made by the act; providing an effective date.

50
51 Be It Enacted by the Legislature of the State of Florida:

52
53 Section 1. (1) DEFINITIONS.—As used in this section, the
54 term:

55 (a) "Controlled substance" means a substance named or
56 described in Schedule I, Schedule II, Schedule III, Schedule IV,
57 or Schedule V of s. 893.03, Florida Statutes.

58 (b) "Controlled substance agreement" means an agreement

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59 between the treating physician and the patient which establishes
60 guidelines for proper use of a controlled substance.

61 (c) "Adverse incident" means an incident set forth in s.
62 458.351(4)(a)-(e), Florida Statutes.

63 (d) "Board-certified pain-management physician" means a
64 physician who possesses board certification:

65 1. By a specialty board recognized by the American Board of
66 Medical Specialties and holds a subspecialty certification in
67 pain medicine; or

68 2. In pain medicine by the American Board of Pain Medicine.

69 (e) "Addiction medicine specialist" means:

70 1. A board-certified psychiatrist who has a subspecialty
71 certification in addiction medicine;

72 2. A board-certified psychiatrist who is eligible for such
73 subspecialty certification in addiction medicine; or

74 3. A physician who specializes in addiction medicine and
75 who is certified or eligible for certification by the American
76 Society of Addiction Medicine.

77 (f) "Mental health addiction facility" means a facility
78 licensed under chapter 394 or chapter 397, Florida Statutes.

79 (2) STANDARDS OF PRACTICE IN PAIN-MANAGEMENT CLINICS.-

80 (a) Evaluation of a patient's medical diagnosis.-Before a
81 physician starts a patient on any treatment, the physician shall
82 conduct a complete medical history and a physical examination
83 and document the results of the medical history and physical
84 examination in the patient's medical record. The exact
85 components of the physical examination shall be left to the
86 judgment of the physician. The physician shall document in the
87 medical record, at a minimum, the nature and intensity of the

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88 pain, current and past treatments for pain, underlying or
89 coexisting diseases or conditions, the effect of the pain on
90 physical and psychological function, a review of prior medical
91 records, previous diagnostic studies, and history of alcohol and
92 substance abuse. The physician shall also document in the
93 medical record the presence of one or more recognized medical
94 indications for the use of a controlled substance.

95 (b) Treatment plan.—The written individualized treatment
96 plan must include objectives that will be used to determine
97 treatment success, such as pain relief and improved physical and
98 psychosocial function, and indicate if any further diagnostic
99 evaluations or other treatments are planned. After treatment
100 begins, the physician shall adjust drug therapy to the
101 individual medical needs of each patient. Other treatment
102 modalities, including a rehabilitation program, shall be
103 considered depending on the etiology of the pain and the extent
104 to which the pain is associated with physical and psychosocial
105 impairment. The physician shall document the interdisciplinary
106 nature of the treatment plan.

107 (c) Informed consent and agreement for treatment.—The
108 physician shall discuss the risks and benefits of the use of
109 controlled substances, including the risks of abuse and
110 addiction as well as physical dependence and its consequences,
111 with the patient, persons designated by the patient, or the
112 patient's surrogate or guardian if the patient is incompetent.
113 The physician shall employ the use of a written controlled
114 substance agreement with the patient which outlines the
115 patient's responsibilities, including, but not limited to:

116 1. Drug testing of the patient and the results reviewed

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117 before the initial issuance or dispensing of a controlled
118 substance prescription, and thereafter, on a random basis at
119 least twice a year and when requested by the treating physician
120 for the purpose of medical necessity and safety of any
121 controlled substances that the physician may consider
122 prescribing as part of the patient's treatment plan.

123 2. The number and frequency of all prescription refills.

124 3. Patient compliance and reasons for which drug therapy
125 may be discontinued.

126 4. An agreement that controlled substances for the
127 treatment of chronic nonmalignant pain shall be prescribed by a
128 single treating physician unless otherwise authorized by the
129 treating physician and documented in the medical record.

130 (d) Periodic review.—The physician shall see the patient at
131 regular intervals, not to exceed 3 months, to assess the
132 efficacy of treatment, ensure that controlled-substance therapy
133 continues as indicated, evaluate the patient's progress toward
134 treatment objectives, consider adverse drug effects, and review
135 the etiology of the pain. Continuation or modification of
136 therapy shall depend on the physician's evaluation of the
137 patient's progress. If treatment goals are not being achieved,
138 despite medication adjustments, the physician shall reevaluate
139 the appropriateness of continued treatment. The physician shall
140 monitor the patient's compliance in medication usage, related
141 treatment plans, controlled substance agreements, and
142 indications of substance abuse or diversion at a minimum of 3-
143 month intervals.

144 (e) Consultation.—The physician shall refer the patient as
145 necessary for additional evaluation and treatment in order to

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146 achieve treatment objectives. The physician shall give special
147 attention to those pain patients who are at risk for misusing
148 their medications and those whose living arrangements pose a
149 risk for medication misuse or diversion. The management of pain
150 in patients having a history of substance abuse or having a
151 comorbid psychiatric disorder requires extra care, monitoring,
152 and documentation, and requires consultation with or referral to
153 an addictionologist or psychiatrist.

154 (f) Patient drug testing.—To ensure the medical necessity
155 and safety of any controlled substances that the physician may
156 consider prescribing as part of the patient's treatment plan,
157 the physician shall perform patient drug testing in accordance
158 with one of the following collection methods:

159 1. A physician shall send the patient to a laboratory that
160 is certified by the Clinical Laboratory Improvement Amendments
161 (CLIA) or a collection site owned or operated by a CLIA-
162 certified laboratory.

163 2. A physician shall collect in the office the patient
164 specimen to be used for drug testing in a device that measures
165 pH, specific gravity, and temperature and the specimen shall be
166 sent to a CLIA-certified laboratory. The physician shall follow
167 the collection procedures required by the agreement the pain-
168 management clinic has entered into with the CLIA-certified
169 laboratory it uses.

170 3. The specimen shall be collected and tested in the
171 physician's office. A physician shall collect and test the
172 specimen to be used for drug testing using a CLIA-waived point-
173 of-care test or a CLIA-approved test that uses a device that
174 measures the pH, specific gravity, and temperature. Results of

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175 the drug test shall be read according to the manufacturer's
176 instructions.

177
178 The treating physician shall review the results of the testing
179 before the initial issuance or dispensing of a controlled
180 substance prescription, and thereafter on a random basis at
181 least twice a year and when requested by the treating physician.
182 This paragraph does not preclude a pain-management clinic from
183 employing additional measures to ensure the integrity of the
184 urine specimens provided by patients. As used in this paragraph,
185 the term "Clinical Laboratory Improvement Amendments" or "CLIA"
186 means the amendments that were passed by Congress in 1988, 42
187 C.F.R. part 493, which established a program in which the
188 Centers for Medicare and Medicaid Services regulate all
189 laboratory testing, except research, which is performed on
190 humans in the United States by creating quality standards for
191 all laboratory testing and issuing certificates for clinical
192 laboratory testing.

193 (g) Patient medical records.-

194 1. The physician shall keep accurate and complete records,
195 including, but not be limited to:

196 a. The complete medical history and a physical examination,
197 including history of drug abuse or dependence.

198 b. Diagnostic, therapeutic, and laboratory results.

199 c. Evaluations and consultations.

200 d. Treatment objectives.

201 e. Discussion of risks and benefits.

202 f. Treatments.

203 g. Medications, including date, type, dosage, and quantity

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204 prescribed.

205 h. Instructions and agreements.

206 i. Periodic reviews.

207 j. Drug testing results.

208 k. A photocopy of the patient's government-issued photo
209 identification.

210 2. If the treating physician gives a written prescription
211 to the patient for a controlled substance, a duplicate of the
212 prescription must be maintained in the patient's medical record.

213 3. Each patient's medical record at a pain-management
214 clinic must contain the physician's full name presented in a
215 legible manner. In addition, each clinic must maintain a log on
216 the premises which must contain the full name, presented in a
217 legible manner, along with a corresponding sample signature and
218 initials of each physician, anesthesiologist assistant, and
219 physician assistant working in the clinic.

220 4. Each physician at a pain-management clinic shall
221 regularly update information in each patient's medical record,
222 maintain the medical record in an accessible manner, and have
223 the medical record readily available for review. The physician
224 shall also ensure that the patient's medical record fully
225 complies with rule 64B8-9.003, Florida Administrative Code, and
226 s. 458.331(1)(m), Florida Statutes.

227 (h) Denial or termination of controlled-substance therapy.—

228 1. If a patient's initial drug testing reflects the
229 adulteration of the specimen or the presence of illegal or
230 controlled substances, other than medications for which there
231 are approved prescriptions, or if the testing result is
232 questioned by the patient or the physician, the treating

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233 physician shall send to a CLIA-certified laboratory the specimen
234 for confirmation by gas or liquid chromatography or mass
235 spectrometry. If the result of the testing of the liquid
236 chromatography or mass spectrometry is positive, the physician
237 shall refer the patient for further consultation with a board-
238 certified pain-management physician, an addiction medicine
239 specialist, or to a mental health addiction facility as it
240 pertains to drug abuse or addiction. After consultation is
241 obtained, the physician shall document in the medical record the
242 results of the consultation. The treating physician may not
243 prescribe or dispense any controlled substances until there is a
244 written concurrence of medical necessity of continued
245 controlled-substance therapy provided by a board-certified pain-
246 management physician, an addiction medicine specialist, or from
247 a mental health addiction facility. If the treating physician is
248 a board-certified pain-management physician or an addiction
249 specialist, the physician need not refer the patient for further
250 consultation. If the physician suspects diversion, the physician
251 shall discharge the patient and document all of the results of
252 testing and actions taken by the physician in the patient's
253 medical record.

254 2. For a patient currently in treatment by the physician or
255 any other physician in the same pain-management clinic, the
256 physician shall immediately refer the patient who has signs or
257 symptoms of substance abuse to a board-certified pain-management
258 physician, an addiction medicine specialist, or a mental health
259 addiction facility as it pertains to drug abuse or addiction
260 unless the physician is board-certified or board-eligible in
261 pain management. Throughout the period before receiving the

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262 consultant's report, a prescribing physician shall clearly and
263 completely document medical justification for continued
264 treatment with controlled substances and those steps taken to
265 ensure the medically appropriate use of controlled substances by
266 the patient. Upon receipt of the consultant's written report,
267 the prescribing physician shall incorporate the consultant's
268 recommendations for continuing, modifying, or discontinuing
269 controlled-substance therapy. The physician shall document the
270 resulting changes in treatment in the patient's medical record.

271 3. For patients who are currently in treatment by the
272 physician or any other physician in the same pain-management
273 clinic, the physician shall discontinue the controlled-substance
274 therapy if the patient demonstrates evidence or behavioral
275 indications of diversion. The physician shall document all
276 results of testing and actions taken by the physician in the
277 patient's medical record.

278 (i) Facility and physical operations.-

279 1. A pain-management clinic must be located and operated at
280 a publicly accessible fixed location and contain:

281 a. A sign that can be viewed by the public which contains
282 the clinic name, hours of operations, and a street address.

283 b. A publicly listed telephone number and a dedicated
284 telephone number to send and receive facsimiles, with a
285 facsimile machine that operates 24 hours per day.

286 c. An emergency lighting and communications system.

287 d. A reception and waiting area.

288 e. A restroom.

289 f. An administrative area, including a room for storage of
290 medical records, supplies, and equipment.

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- 291 g. A private examination room for patients.
- 292 h. A treatment room if treatment is being provided to the
293 patient.
- 294 i. A printed sign located in a conspicuous place in the
295 waiting room which is viewable by the public and discloses the
296 name and contact information of the clinic's designated
297 physician and the names of each physician practicing in the
298 clinic.
- 299 2. A pain-management clinic that stores and dispenses
300 prescription drugs must comply with ss. 499.0121 and 893.07,
301 Florida Statutes, and rule 64F-12.012, Florida Administrative
302 Code.
- 303 3. This paragraph does not excuse a physician from
304 providing any treatment or performing any medical duty without
305 the proper equipment and materials as required by the standard
306 of care.
- 307 (j) Infection control.—The designated physician at a pain-
308 management clinic shall:
- 309 1. Maintain equipment and supplies to support infection
310 prevention and control activities.
- 311 2. Identify infection risks based on:
- 312 a. The geographic location, community, and population
313 served;
- 314 b. The care, treatment, and services it provides; and
- 315 c. An analysis of its infection surveillance and control
316 data.
- 317 3. Maintain written infection-prevention policies and
318 procedures that address:
- 319 a. The prioritized risks;

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320 b. A limitation on unprotected exposure to pathogens;

321 c. A limitation on the transmission of infections
322 associated with procedures performed in the clinic; and

323 d. A limitation on the transmission of infections
324 associated with the use of medical equipment, devices, and
325 supplies at the pain-management clinic.

326 (k) Health and safety.—

327 1. The pain-management clinic, including its grounds,
328 buildings, furniture, appliances, and equipment, must be
329 structurally sound, in good repair, clean, and free from health
330 and safety hazards.

331 2. The pain-management clinic must have evacuation
332 procedures if an emergency occurs which include provisions for
333 the evacuation of disabled patients and employees.

334 3. The pain-management clinic must have a written facility-
335 specific disaster plan that sets forth actions that are taken if
336 the clinic closes due to unforeseen disasters. This plan must
337 include provisions for the protection of medical records and any
338 controlled substances.

339 4. At least one employee who is certified in basic life
340 support and trained in reacting to accidents and medical
341 emergencies must be on the premises of a pain-management clinic
342 during patient-care hours.

343 (l) Quality assurance.—Each pain-management clinic must
344 have an ongoing quality assurance program that objectively and
345 systematically monitors and evaluates the quality and
346 appropriateness of patient care, evaluates methods to improve
347 patient care, identifies and corrects deficiencies within the
348 facility, alerts the designated physician to identify and

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349 resolve recurring problems, and provides for opportunities to
350 improve the facility's performance and to enhance and improve
351 the quality of care provided to the public. The designated
352 physician shall establish a quality assurance program that
353 includes the following components:

354 1. The identification, investigation, and analysis of the
355 frequency and causes of adverse incidents to patients.

356 2. The identification of trends or patterns of incidents.

357 3. The development of measures to correct, reduce,
358 minimize, or eliminate the risk of adverse incidents to
359 patients.

360 4. The documentation and periodic review of these functions
361 in subparagraphs 1., 2., and 3. at least quarterly by the
362 designated physician.

363
364 A state-licensed risk manager shall review the quality assurance
365 program once every 3 years, provide the Department of Health
366 with documentation of the review and any corrective action plan
367 within 30 days after the review, and maintain the review for
368 inspection purposes.

369 (m) Data collection and reporting.—

370 1. The designated physician for each pain-management clinic
371 shall report all adverse incidents to the Department of Health
372 as set forth in s. 458.351, Florida Statutes.

373 2. The designated physician shall also report to the Board
374 of Medicine each quarter, in writing, the following data:

375 a. The number of new and repeat patients seen and treated
376 at the pain-management clinic who were prescribed or dispensed
377 controlled substances for the treatment of chronic, nonmalignant

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378 pain.

379 b. The number of patients discharged due to drug abuse.

380 c. The number of patients discharged due to drug diversion.

381 d. The number of patients treated at the pain-management
382 clinic whose domicile is located somewhere other than in this
383 state. A patient's domicile is the patient's fixed or permanent
384 home to which the patient intends to return even though he or
385 she may temporarily reside elsewhere.

386 3. A physician that practices in a pain-management clinic
387 shall advise the Board of Medicine, in writing, within 10
388 calendar days after beginning or ending his or her practice at a
389 pain-management clinic.

390 Section 2. Paragraph (c) of subsection (1) and subsections
391 (3) and (4) of section 458.3265, Florida Statutes, are amended
392 to read:

393 458.3265 Pain-management clinics.—

394 (1) REGISTRATION.—

395 (c)1. As a part of registration, a clinic must designate a
396 physician who is responsible for complying with all requirements
397 related to registration and operation of the clinic in
398 compliance with this section. It is the designated physician's
399 responsibility to ensure that the clinic is registered,
400 regardless of whether other physicians are practicing in the
401 same office or whether the office is not owned by a physician.
402 Within 10 days after termination of a designated physician, the
403 clinic must notify the department of the identity of another
404 designated physician for that clinic or of any changes to the
405 registration information. The designated physician shall have a
406 full, active, and unencumbered license under this chapter or

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407 chapter 459 and shall practice at the clinic location for which
408 the physician has assumed responsibility. Failing to have a
409 licensed designated physician practicing at the location of the
410 registered clinic may be the basis for a summary suspension of
411 the clinic registration certificate as described in s.
412 456.073(8) for a license or s. 120.60(6).

413 2. In order to register a pain-management clinic, the
414 designated physician shall:

415 a. Pay an inspection fee of \$1,500 for each location
416 required to be inspected;

417 b. Pay a registration fee of \$145. The fee must also be
418 paid if the physical location of the clinic changes or the
419 ownership changes. An additional fee of \$5 shall be added to the
420 cost of registration to cover unlicensed activity as required by
421 s. 456.065(3); and

422 c. Provide documentation to support compliance with section
423 1 of this act.

424 3. The designated physician shall post the documentation of
425 registration in a conspicuous place in the waiting room which is
426 viewable by the public.

427 (3) INSPECTION.—

428 (a) The department shall inspect the pain-management clinic
429 annually, including a review of the patient records, to ensure
430 that it complies with this section and the rules of the Board of
431 Medicine adopted pursuant to subsection (4) unless the clinic is
432 accredited by a nationally recognized accrediting agency
433 approved by the Board of Medicine. Each nationally recognized
434 accrediting agency shall be held to the same board-determined
435 practice standards for registering pain-management clinic in

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436 this state.

437 (b) The department shall conduct unannounced annual
438 inspections of clinics pursuant to this subsection. ~~During an~~
439 ~~onsite inspection, the department shall make a reasonable~~
440 ~~attempt to discuss each violation with the owner or designated~~
441 ~~physician of the pain-management clinic before issuing a formal~~
442 ~~written notification.~~

443 (c) The designated physician shall cooperate with the
444 inspector, make medical records available to the inspector, and
445 be responsive to all reasonable requests. ~~Any action taken to~~
446 ~~correct a violation shall be documented in writing by the owner~~
447 ~~or designated physician of the pain-management clinic and~~
448 ~~verified by followup visits by departmental personnel.~~

449 (d) The inspector shall determine compliance with the
450 requirements of section 1 of this act. These requirements
451 include a review of a random selection of patient records for
452 patients who are treated for pain. The inspector shall select
453 such patient records from each physician practicing in the
454 clinic or who has practiced in the clinic during the past 6
455 months.

456 (e) If the clinic is determined to be in noncompliance, the
457 inspector shall notify the designated physician and give the
458 designated physician a written statement at the time of
459 inspection. Such written notice shall specify the deficiencies
460 in the inspection. Unless the deficiencies constitute an
461 immediate and imminent danger to the public, the designated
462 physician shall be given 30 days after the date of inspection to
463 correct any documented deficiencies and notify the department of
464 a corrective action plan. Upon written notification from the

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465 designated physician that all deficiencies have been corrected,
466 the department may reinspect for compliance. If the designated
467 physician fails to submit a corrective action plan within 30
468 days after the inspection, the department may reinspect the
469 clinic to ensure that the deficiencies have been corrected.

470 (f) The inspector shall forward to the department the
471 written results of the inspection, deficiency notice, and any
472 subsequent documentation, including, but not limited to:

473 1. Whether the deficiencies constituted an immediate and
474 serious danger to the public;

475 2. Whether the designated physician provided the department
476 with documentation of correction of all deficiencies within 30
477 days after the date of inspection; and

478 3. The results of any reinspection.

479 (g) The department shall review the results of the
480 inspection and determine whether action against the clinic's
481 registration is merited.

482 (h) The department's authority is not limited with regard
483 to investigating a complaint without prior notice.

484 (i) If the clinic is accredited by a nationally recognized
485 accrediting agency that is approved by the board, the designated
486 physician shall submit written notification of the current
487 accreditation survey of his or her clinic in lieu of undergoing
488 an inspection by the department.

489 (j) The designated physician shall submit, within 30 days
490 after accreditation, a copy of the current accreditation survey
491 of the clinic and shall immediately notify the board of any
492 accreditation changes that occur. For purposes of initial
493 registration, the designated physician shall submit a copy of

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494 the most recent accreditation survey of the clinic in lieu of
495 undergoing an inspection by the department.

496 (k) If a provisional or conditional accreditation is
497 received, the designated physician shall notify the board in
498 writing and include a plan of correction.

499 (4) RULEMAKING.—

500 ~~(a) The department shall adopt rules necessary to~~
501 ~~administer the registration and inspection of pain-management~~
502 ~~clinics which establish the specific requirements, procedures,~~
503 ~~forms, and fees.~~

504 (a) ~~(b)~~ The department shall adopt a rule defining what
505 constitutes practice by a designated physician at the clinic
506 location for which the physician has assumed responsibility, as
507 set forth in subsection (1). When adopting the rule, the
508 department shall consider the number of clinic employees, the
509 location of the pain-management clinic, the clinic's hours of
510 operation, and the amount of controlled substances being
511 prescribed, dispensed, or administered at the pain-management
512 clinic.

513 (b) ~~(e)~~ The Board of Medicine shall adopt a rule
514 establishing the maximum number of prescriptions for Schedule II
515 or Schedule III controlled substances or the controlled
516 substance Alprazolam which may be written at any one registered
517 pain-management clinic during any 24-hour period.

518 ~~(d) The Board of Medicine shall adopt rules setting forth~~
519 ~~standards of practice for physicians practicing in privately~~
520 ~~owned pain-management clinics that primarily engage in the~~
521 ~~treatment of pain by prescribing or dispensing controlled~~
522 ~~substance medications. Such rules shall address, but need not be~~

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523 ~~limited to:~~

- 524 ~~1. Facility operations;~~
- 525 ~~2. Physical operations;~~
- 526 ~~3. Infection control requirements;~~
- 527 ~~4. Health and safety requirements;~~
- 528 ~~5. Quality assurance requirements;~~
- 529 ~~6. Patient records;~~
- 530 ~~7. Training requirements for all facility health care~~
- 531 ~~practitioners who are not regulated by another board;~~
- 532 ~~8. Inspections; and~~
- 533 ~~9. Data collection and reporting requirements.~~

534

535 ~~A physician is primarily engaged in the treatment of pain by~~

536 ~~prescribing or dispensing controlled substance medications when~~

537 ~~the majority of the patients seen are prescribed or dispensed~~

538 ~~controlled substance medications for the treatment of chronic~~

539 ~~nonmalignant pain. Chronic nonmalignant pain is pain unrelated~~

540 ~~to cancer which persists beyond the usual course of the disease~~

541 ~~or the injury that is the cause of the pain or more than 90 days~~

542 ~~after surgery.~~

543 Section 3. Paragraph (c) of subsection (1) and subsections

544 (3) and (4) of section 459.0137, Florida Statutes, are amended

545 to read:

546 459.0137 Pain-management clinics.—

547 (1) REGISTRATION.—

548 (c)1. As a part of registration, a clinic must designate an

549 osteopathic physician who is responsible for complying with all

550 requirements related to registration and operation of the clinic

551 in compliance with this section. It is the designated

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552 osteopathic physician's responsibility to ensure that the clinic
553 is registered, regardless of whether other physicians are
554 practicing in the same office or whether the office is not owned
555 by a physician. Within 10 days after termination of a designated
556 osteopathic physician, the clinic must notify the department of
557 the identity of another designated physician for that clinic of
558 any changes to the registration information. The designated
559 physician shall have a full, active, and unencumbered license
560 under chapter 458 or this chapter and shall practice at the
561 clinic location for which the physician has assumed
562 responsibility. Failing to have a licensed designated
563 osteopathic physician practicing at the location of the
564 registered clinic may be the basis for a summary suspension of
565 the clinic registration certificate as described in s.
566 456.073(8) for a license or s. 120.60(6).

567 2. In order to register a clinic, the designated
568 osteopathic physician shall:

569 a. Pay an inspection fee of \$1,500 for each location
570 required to be inspected;

571 b. Pay a registration fee of \$145. The fee must also be
572 paid if the physical location of the clinic changes or the
573 ownership changes. An additional fee of \$5 shall be added to the
574 cost of registration to cover unlicensed activity as required by
575 s. 456.065(3); and

576 c. Provide documentation to support compliance with section
577 1 of this act.

578 3. The designated osteopathic physician shall post the
579 documentation of registration in a conspicuous place in the
580 waiting room which is viewable by the public.

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581 (3) INSPECTION.—

582 (a) The department shall inspect the pain-management clinic
583 annually, including a review of the patient records, to ensure
584 that it complies with this section and the rules of the Board of
585 Osteopathic Medicine adopted pursuant to subsection (4) unless
586 the clinic is accredited by a nationally recognized accrediting
587 agency approved by the Board of Osteopathic Medicine. Each
588 nationally recognized accrediting agency shall be held to the
589 same board-determined practice standards for registering a
590 clinic in this state.

591 (b) The department shall conduct unannounced annual
592 inspections of clinics pursuant to this subsection. ~~During an~~
593 ~~onsite inspection, the department shall make a reasonable~~
594 ~~attempt to discuss each violation with the owner or designated~~
595 ~~physician of the pain-management clinic before issuing a formal~~
596 ~~written notification.~~

597 (c) The designated osteopathic physician shall cooperate
598 with the inspector, make medical records available to the
599 inspector, and be responsive to all reasonable requests. ~~Any~~
600 ~~action taken to correct a violation shall be documented in~~
601 ~~writing by the owner or designated physician of the pain-~~
602 ~~management clinic and verified by followup visits by~~
603 ~~departmental personnel.~~

604 (d) The inspector shall determine compliance with the
605 requirements of section 1 of this act. These requirements
606 include a review of a random selection of patient records for
607 patients who are treated for pain. The inspector shall select
608 such patient records from each osteopathic physician practicing
609 in the clinic or who has practiced in the clinic during the past

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610 6 months.

611 (e) If the clinic is determined to be in noncompliance, the
612 inspector shall notify the designated osteopathic physician and
613 give the designated osteopathic physician a written statement at
614 the time of inspection. Such written notice shall specify the
615 deficiencies. Unless the deficiencies constitute an immediate
616 and imminent danger to the public, the designated osteopathic
617 physician shall be given 30 days after the date of inspection to
618 correct any documented deficiencies and notify the department of
619 corrective action plan. Upon written notification from the
620 designated osteopathic physician that all deficiencies have been
621 corrected, the department may reinspect for compliance. If the
622 designated osteopathic physician fails to submit a corrective
623 action plan within 30 days after the inspection, the department
624 may reinspect the office to ensure that the deficiencies have
625 been corrected.

626 (f) The inspector shall forward to the department the
627 written results of the inspection, deficiency notice and any
628 subsequent documentation, including, but not limited to:

629 1. Whether the deficiencies constituted an immediate and
630 serious danger to the public;

631 2. Whether the designated osteopathic physician provided
632 the department with documentation of correction of all
633 deficiencies within 30 days after the date of inspection; and

634 3. The results of any reinspection.

635 (g) The department shall review the results of the
636 inspection and determine whether action against the clinic's
637 registration is merited.

638 (h) The department's authority is not limited with regard

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639 to investigating a complaint without prior notice.

640 (i) If the clinic is accredited by a nationally recognized
641 accrediting agency approved by the board, the designated
642 osteopathic physician shall submit written notification of the
643 current accreditation survey of his or her clinic in lieu of
644 undergoing an inspection by the department.

645 (j) The designated osteopathic physician shall submit,
646 within 30 days after accreditation, a copy of the current
647 accreditation survey of the clinic and shall immediately notify
648 the board of any accreditation changes that occur. For purposes
649 of initial registration, the designated osteopathic physician
650 shall submit a copy of the most recent accreditation survey of
651 the clinic in lieu of undergoing an inspection by the
652 department.

653 (k) If a provisional or conditional accreditation is
654 received, the designated osteopathic physician shall notify the
655 board in writing and shall include a plan of correction.

656 (4) RULEMAKING.—

657 ~~(a) The department shall adopt rules necessary to~~
658 ~~administer the registration and inspection of pain-management~~
659 ~~clinics which establish the specific requirements, procedures,~~
660 ~~forms, and fees.~~

661 (a) ~~(b)~~ The department shall adopt a rule defining what
662 constitutes practice by a designated osteopathic physician at
663 the clinic location for which the physician has assumed
664 responsibility, as set forth in subsection (1). When adopting
665 the rule, the department shall consider the number of clinic
666 employees, the location of the pain-management clinic, the
667 clinic's hours of operation, and the amount of controlled

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668 substances being prescribed, dispensed, or administered at the
669 pain-management clinic.

670 (b)~~(e)~~ The Board of Osteopathic Medicine shall adopt a rule
671 establishing the maximum number of prescriptions for Schedule II
672 or Schedule III controlled substances or the controlled
673 substance Alprazolam which may be written at any one registered
674 pain-management clinic during any 24-hour period.

675 ~~(d) The Board of Osteopathic Medicine shall adopt rules~~
676 ~~setting forth standards of practice for osteopathic physicians~~
677 ~~practicing in privately owned pain-management clinics that~~
678 ~~primarily engage in the treatment of pain by prescribing or~~
679 ~~dispensing controlled substance medications. Such rules shall~~
680 ~~address, but need not be limited to:~~

- 681 ~~1. Facility operations;~~
- 682 ~~2. Physical operations;~~
- 683 ~~3. Infection control requirements;~~
- 684 ~~4. Health and safety requirements;~~
- 685 ~~5. Quality assurance requirements;~~
- 686 ~~6. Patient records;~~
- 687 ~~7. Training requirements for all facility health care~~
688 ~~practitioners who are not regulated by another board;~~
- 689 ~~8. Inspections; and~~
- 690 ~~9. Data collection and reporting requirements.~~

691
692 ~~An osteopathic physician is primarily engaged in the treatment~~
693 ~~of pain by prescribing or dispensing controlled substance~~
694 ~~medications when the majority of the patients seen are~~
695 ~~prescribed or dispensed controlled substance medications for the~~
696 ~~treatment of chronic nonmalignant pain. Chronic nonmalignant~~

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697 ~~pain is pain unrelated to cancer which persists beyond the usual~~
698 ~~course of the disease or the injury that is the cause of the~~
699 ~~pain or more than 90 days after surgery.~~

700 Section 4. This act shall take effect July 1, 2011.