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

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

47 |
 48 | Be It Enacted by the Legislature of the State of Florida:

49 |
 50 | Section 1. (1) DEFINITIONS.—As used in this section, the
 51 | term:

52 | (a) "Controlled substance" means a substance named or
 53 | described in Schedule I, Schedule II, Schedule III, Schedule IV,
 54 | or Schedule V of s. 893.03, Florida Statutes.

55 | (b) "Controlled substance agreement" means an agreement
 56 | between the treating physician and the patient which establishes

57 guidelines for proper use of a controlled substance.
 58 (c) "Adverse incident" means an incident set forth in s.
 59 458.351(4)(a)-(e), Florida Statutes.
 60 (d) "Board-certified pain-management physician" means a
 61 physician who possesses board certification:
 62 1. By a specialty board recognized by the American Board
 63 of Medical Specialties and holds a subspecialty certification in
 64 pain medicine; or
 65 2. In pain medicine by the American Board of Pain
 66 Medicine.
 67 (e) "Addiction medicine specialist" means:
 68 1. A board-certified psychiatrist who has a subspecialty
 69 certification in addiction medicine;
 70 2. A board-certified psychiatrist who is eligible for such
 71 subspecialty certification in addiction medicine; or
 72 3. A physician who specializes in addiction medicine and
 73 who is certified or eligible for certification by the American
 74 Society of Addiction Medicine.
 75 (f) "Mental health addiction facility" means a facility
 76 licensed under chapter 394 or chapter 397, Florida Statutes.
 77 (2) STANDARDS OF PRACTICE IN PAIN-MANAGEMENT CLINICS.—
 78 (a) Evaluation of a patient's medical diagnosis.—Before a
 79 physician starts a patient on any treatment, the physician shall
 80 conduct a complete medical history and a physical examination
 81 and document the results of the medical history and physical
 82 examination in the patient's medical record. The exact
 83 components of the physical examination shall be left to the
 84 judgment of the physician. The physician shall document in the

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

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

105 (c) *Informed consent and agreement for treatment.*—The
106 physician shall discuss the risks and benefits of the use of
107 controlled substances, including the risks of abuse and
108 addiction as well as physical dependence and its consequences,
109 with the patient, persons designated by the patient, or the
110 patient's surrogate or guardian if the patient is incompetent.
111 The physician shall employ the use of a written controlled
112 substance agreement with the patient which outlines the

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113 patient's responsibilities, including, but not limited to:

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

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

122 3. Patient compliance and reasons for which drug therapy
123 may be discontinued.

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

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

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141 month intervals.

142 (e) Consultation.—The physician shall refer the patient as
143 necessary for additional evaluation and treatment in order to
144 achieve treatment objectives. The physician shall give special
145 attention to those pain patients who are at risk for misusing
146 their medications and those whose living arrangements pose a
147 risk for medication misuse or diversion. The management of pain
148 in patients having a history of substance abuse or having a
149 comorbid psychiatric disorder requires extra care, monitoring,
150 and documentation, and requires consultation with or referral to
151 an addictionologist or psychiatrist.

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

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

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

168 3. The specimen shall be collected and tested in the

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

175
176 The treating physician shall review the results of the testing
177 before the initial issuance or dispensing of a controlled
178 substance prescription, and thereafter on a random basis at
179 least twice a year and when requested by the treating physician.
180 This paragraph does not preclude a pain-management clinic from
181 employing additional measures to ensure the integrity of the
182 urine specimens provided by patients. As used in this paragraph,
183 the term "Clinical Laboratory Improvement Amendments" or "CLIA"
184 means the amendments that were passed by Congress in 1988, 42
185 C.F.R. part 493, which established a program in which the
186 Centers for Medicare and Medicaid Services regulate all
187 laboratory testing, except research, which is performed on
188 humans in the United States by creating quality standards for
189 all laboratory testing and issuing certificates for clinical
190 laboratory testing.

191 (g) Patient medical records.—

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

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

196 b. Diagnostic, therapeutic, and laboratory results.

- 197 | c. Evaluations and consultations.
- 198 | d. Treatment objectives.
- 199 | e. Discussion of risks and benefits.
- 200 | f. Treatments.
- 201 | g. Medications, including date, type, dosage, and quantity
- 202 | prescribed.
- 203 | h. Instructions and agreements.
- 204 | i. Periodic reviews.
- 205 | j. Drug testing results.
- 206 | k. A photocopy of the patient's government-issued photo
- 207 | identification.
- 208 | 2. If the treating physician gives a written prescription
- 209 | to the patient for a controlled substance, a duplicate of the
- 210 | prescription must be maintained in the patient's medical record.
- 211 | 3. Each patient's medical record at a pain-management
- 212 | clinic must contain the physician's full name presented in a
- 213 | legible manner. In addition, each clinic must maintain a log on
- 214 | the premises which must contain the full name, presented in a
- 215 | legible manner, along with a corresponding sample signature and
- 216 | initials of each physician, anesthesiologist assistant, and
- 217 | physician assistant working in the clinic.
- 218 | 4. Each physician at a pain-management clinic shall
- 219 | regularly update information in each patient's medical record,
- 220 | maintain the medical record in an accessible manner, and have
- 221 | the medical record readily available for review. The physician
- 222 | shall also ensure that the patient's medical record fully
- 223 | complies with rule 64B8-9.003, Florida Administrative Code, and
- 224 | s. 458.331(1) (m), Florida Statutes.

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

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

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253 2. For a patient currently in treatment by the physician
254 or any other physician in the same pain-management clinic, the
255 physician shall immediately refer the patient who has signs or
256 symptoms of substance abuse to a board-certified pain-management
257 physician, an addiction medicine specialist, or a mental health
258 addiction facility as it pertains to drug abuse or addiction
259 unless the physician is board-certified or board-eligible in
260 pain management. Throughout the period before receiving the
261 consultant's report, a prescribing physician shall clearly and
262 completely document medical justification for continued
263 treatment with controlled substances and those steps taken to
264 ensure the medically appropriate use of controlled substances by
265 the patient. Upon receipt of the consultant's written report,
266 the prescribing physician shall incorporate the consultant's
267 recommendations for continuing, modifying, or discontinuing
268 controlled-substance therapy. The physician shall document the
269 resulting changes in treatment in the patient's medical record.

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

277 (i) Facility and physical operations.—

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

280 a. A sign that can be viewed by the public which contains

281 the clinic name, hours of operations, and a street address.

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

285 c. An emergency lighting and communications system.

286 d. A reception and waiting area.

287 e. A restroom.

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

290 g. A private examination room for patients.

291 h. A treatment room if treatment is being provided to the
 292 patient.

293 i. A printed sign located in a conspicuous place in the
 294 waiting room which is viewable by the public and discloses the
 295 name and contact information of the clinic's designated
 296 physician and the names of each physician practicing in the
 297 clinic.

298 2. A pain-management clinic that stores and dispenses
 299 prescription drugs must comply with ss. 499.0121 and 893.07,
 300 Florida Statutes, and rule 64F-12.012, Florida Administrative
 301 Code.

302 3. This paragraph does not excuse a physician from
 303 providing any treatment or performing any medical duty without
 304 the proper equipment and materials as required by the standard
 305 of care.

306 (j) Infection control.—The designated physician at a pain-
 307 management clinic shall:

308 1. Maintain equipment and supplies to support infection

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- 309 prevention and control activities.
- 310 2. Identify infection risks based on:
- 311 a. The geographic location, community, and population
- 312 served;
- 313 b. The care, treatment, and services it provides; and
- 314 c. An analysis of its infection surveillance and control
- 315 data.
- 316 3. Maintain written infection-prevention policies and
- 317 procedures that address:
- 318 a. The prioritized risks;
- 319 b. A limitation on unprotected exposure to pathogens;
- 320 c. A limitation on the transmission of infections
- 321 associated with procedures performed in the clinic; and
- 322 d. A limitation on the transmission of infections
- 323 associated with the use of medical equipment, devices, and
- 324 supplies at the pain-management clinic.
- 325 (k) Health and safety.—
- 326 1. The pain-management clinic, including its grounds,
- 327 buildings, furniture, appliances, and equipment, must be
- 328 structurally sound, in good repair, clean, and free from health
- 329 and safety hazards.
- 330 2. The pain-management clinic must have evacuation
- 331 procedures if an emergency occurs which include provisions for
- 332 the evacuation of disabled patients and employees.
- 333 3. The pain-management clinic must have a written
- 334 facility-specific disaster plan that sets forth actions that are
- 335 taken if the clinic closes due to unforeseen disasters. This
- 336 plan must include provisions for the protection of medical

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337 records and any controlled substances.

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

342 (1) Quality assurance.—Each pain-management clinic must
343 have an ongoing quality assurance program that objectively and
344 systematically monitors and evaluates the quality and
345 appropriateness of patient care, evaluates methods to improve
346 patient care, identifies and corrects deficiencies within the
347 facility, alerts the designated physician to identify and
348 resolve recurring problems, and provides for opportunities to
349 improve the facility's performance and to enhance and improve
350 the quality of care provided to the public. The designated
351 physician shall establish a quality assurance program that
352 includes the following components:

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

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

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

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

362

363 A state-licensed risk manager shall review the quality assurance
364 program once every 3 years, provide the Department of Health

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365 with documentation of the review and any corrective action plan
366 within 30 days after the review, and maintain the review for
367 inspection purposes.

368 (m) Data collection and reporting.—

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

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

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

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

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

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421 s. 456.065(3); and

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

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

427 (3) INSPECTION.—

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

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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,
457 the 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
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
476 department with documentation of correction of all deficiencies

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477 within 30 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
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~~
 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
 549 an osteopathic physician who is responsible for complying with
 550 all requirements related to registration and operation of the
 551 clinic in compliance with this section. It is the designated
 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

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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
577 section 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.

581 (3) INSPECTION.—

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

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589 held to the same board-determined practice standards for
590 registering a 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
610 6 months.

611 (e) If the clinic is determined to be in noncompliance,
612 the inspector shall notify the designated osteopathic physician
613 and give the designated osteopathic physician a written
614 statement at the time of inspection. Such written notice shall
615 specify the deficiencies. Unless the deficiencies constitute an
616 immediate and imminent danger to the public, the designated

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617 osteopathic physician shall be given 30 days after the date of
618 inspection to correct any documented deficiencies and notify the
619 department of corrective action plan. Upon written notification
620 from the designated osteopathic physician that all deficiencies
621 have been corrected, the department may reinspect for
622 compliance. If the designated osteopathic physician fails to
623 submit a corrective action plan within 30 days after the
624 inspection, the department may reinspect the office to ensure
625 that the deficiencies have 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
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
 668 substances being prescribed, dispensed, or administered at the
 669 pain-management clinic.

670 (b)~~(e)~~ The Board of Osteopathic Medicine shall adopt a
 671 rule establishing the maximum number of prescriptions for
 672 Schedule II or Schedule III controlled substances or the

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673 controlled substance Alprazolam which may be written at any one
674 registered 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~~
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.