

By the Committees on Criminal Justice; Health Regulation; and Health Regulation; and Senators Fasano, Gardiner, Aronberg, Gaetz, and Gelber

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1 A bill to be entitled
2 An act relating to controlled substances; amending s.
3 456.037, F.S.; providing that pain-management clinics
4 that are required to be registered with the Department
5 of Health are business establishments; amending s.
6 456.057, F.S.; providing that the Department of Health
7 is not required to attempt to obtain authorization
8 from a patient for the release of the patient's
9 medical records under certain circumstances;
10 authorizing the department to obtain patient records
11 without authorization or subpoena if the department
12 has probable cause to believe that certain violations
13 have occurred or are occurring; repealing s.
14 458.309(4), (5), and (6), F.S., relating to pain-
15 management clinics; creating s. 458.3265, F.S.;
16 requiring all privately owned pain-management clinics,
17 or offices that primarily engage in the treatment of
18 pain by prescribing or dispensing controlled substance
19 medications or by employing a physician who is
20 primarily engaged in the treatment of pain by
21 prescribing or dispensing controlled substance
22 medications, to register with the Department of
23 Health; providing exceptions; requiring each location
24 of a pain-management clinic to register separately;
25 requiring a clinic to designate a physician who is
26 responsible for complying with requirements related to
27 registration and operation of the clinic; requiring
28 the department to deny registration or revoke the
29 registration of a pain-management clinic for certain

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30 conditions; authorizing the department to revoke a
31 clinic's certificate of registration and prohibit
32 physicians associated with the clinic from practicing
33 at the clinic's location; requiring a pain-management
34 clinic to cease operating if its registration
35 certificate is revoked or suspended; requiring certain
36 named persons to remove all signs and symbols
37 identifying the premises as a pain-management clinic;
38 requiring a pain-management clinic that has had its
39 registration revoked or suspended to advise the
40 department of the disposition of the medicinal drugs
41 located on the premises; providing that medicinal
42 drugs that are purchased or held by a pain-management
43 clinic that is not registered may be deemed
44 adulterated; prohibiting any person acting as an
45 individual or as part of a group from applying for a
46 certificate to operate a pain-management clinic for a
47 certain period after the date the person's
48 registration certificate is revoked; providing that a
49 change of ownership of a registered pain-management
50 clinic requires submission of a new registration
51 application; providing the responsibilities of a
52 physician who provides professional services at a
53 pain-management clinic; requiring the department to
54 inspect pain-management clinics and its patient
55 records; providing an exception to inspection by the
56 department; requiring a pain-management clinic to
57 document corrective action; requiring the department
58 and the Board of Medicine to adopt rules; authorizing

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59 the department to impose fines, deny a clinic's
60 registration, or revoke a clinic's registration;
61 amending s. 458.327, F.S.; providing that the
62 commission of certain specified acts involving a
63 nonregistered pain-management clinic constitutes a
64 felony of the third degree or a misdemeanor of the
65 first degree; amending s. 458.331, F.S.; providing
66 additional acts that constitute grounds for
67 disciplinary actions against health professional
68 licensees; repealing s. 459.005(3), (4), and (5),
69 F.S., relating to pain-management clinics; creating s.
70 459.0137, F.S.; requiring all privately owned pain-
71 management clinics, or offices that primarily engage
72 in the treatment of pain by prescribing or dispensing
73 controlled substance medications or by employing an
74 osteopathic physician who is primarily engaged in the
75 treatment of pain by prescribing or dispensing
76 controlled substance medications, to register with the
77 department; providing exceptions; requiring each
78 location of a pain-management clinic to register
79 separately; requiring a clinic to designate an
80 osteopathic physician who is responsible for complying
81 with requirements related to registration and
82 operation of the clinic; requiring the department to
83 deny registration or revoke the registration of a
84 pain-management clinic for certain conditions;
85 authorizing the department to revoke a clinic's
86 certificate of registration and prohibit osteopathic
87 physicians associated with the clinic from practicing

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88 at the clinic's location; requiring a pain-management
89 clinic to cease operating if its registration
90 certificate is revoked or suspended; requiring certain
91 named persons to remove all signs and symbols
92 identifying the premises as a pain-management clinic;
93 requiring a pain-management clinic that has had its
94 registration revoked or suspended to advise the
95 department of the disposition of the medicinal drugs
96 located on the premises; providing that medicinal
97 drugs that are purchased or held by a pain-management
98 clinic that is not registered may be deemed
99 adulterated; prohibiting any person acting as an
100 individual or as part of a group from applying for a
101 certificate to operate a pain-management clinic for a
102 certain period after the date the person's
103 registration certificate is revoked; providing that a
104 change of ownership of a registered pain-management
105 clinic requires submission of a new registration
106 application; providing the responsibilities of an
107 osteopathic physician who provides professional
108 services at a pain-management clinic; requiring the
109 department to inspect pain-management clinics and its
110 patient records; providing an exception to inspection
111 by the department; requiring a pain-management clinic
112 to document corrective action; requiring the
113 department and the Board of Osteopathic Medicine to
114 adopt rules; authorizing the department to impose
115 fines, deny a clinic's registration, or revoke a
116 clinic's registration; amending s. 459.013, F.S.;

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117 providing that the commission of certain specified
118 acts involving a nonregistered pain-management clinic
119 constitutes a felony of the third degree or a
120 misdemeanor of the first degree; amending s. 459.015,
121 F.S.; providing additional acts that constitute
122 grounds for disciplinary actions against health
123 professional licensees; amending s. 893.055, F.S.;
124 providing for the prescription drug monitoring
125 program's database to report certain information
126 directly to applicable law enforcement agencies for
127 investigation; requiring the department to adopt
128 rules; amending s. 893.0551, F.S.; providing for
129 disclosure of confidential and exempt information to
130 applicable law enforcement; providing an effective
131 date.

132
133 Be It Enacted by the Legislature of the State of Florida:

134
135 Section 1. Subsection (5) of section 456.037, Florida
136 Statutes, is amended to read:

137 456.037 Business establishments; requirements for active
138 status licenses; delinquency; discipline; applicability.-

139 (5) This section applies to any business establishment
140 registered, permitted, or licensed by the department to do
141 business. Business establishments include, but are not limited
142 to, dental laboratories, electrology facilities, massage
143 establishments, ~~and~~ pharmacies, and pain-management clinics
144 required to be registered under s. 458.3265 or s. 459.0137.

145 Section 2. Paragraph (a) of subsection (9) of section

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146 456.057, Florida Statutes, is amended to read:

147 456.057 Ownership and control of patient records; report or
148 copies of records to be furnished.—

149 (9) (a)1. The department may obtain patient records pursuant
150 to a subpoena without written authorization from the patient if
151 the department and the probable cause panel of the appropriate
152 board, if any, find reasonable cause to believe that a health
153 care practitioner has excessively or inappropriately prescribed
154 any controlled substance specified in chapter 893 in violation
155 of this chapter or any professional practice act or that a
156 health care practitioner has practiced his or her profession
157 below that level of care, skill, and treatment required as
158 defined by this chapter or any professional practice act and
159 also find that appropriate, reasonable attempts were made to
160 obtain a patient release. Notwithstanding the foregoing, the
161 department need not attempt to obtain a patient release when
162 investigating an offense involving the inappropriate
163 prescribing, overprescribing, or diversion of controlled
164 substances and the offense involves a pain-management clinic.
165 The department may obtain patient records without patient
166 authorization or subpoena from any pain-management clinic
167 required to be licensed if the department has probable cause to
168 believe that a violation of any provision of s. 458.3265 or s.
169 459.0137 is occurring or has occurred and reasonably believes
170 that obtaining such authorization is not feasible due to the
171 volume of the dispensing and prescribing activity involving
172 controlled substances and that obtaining patient authorization
173 or the issuance of a subpoena would jeopardize the
174 investigation.

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175 2. The department may obtain patient records and insurance
176 information pursuant to a subpoena without written authorization
177 from the patient if the department and the probable cause panel
178 of the appropriate board, if any, find reasonable cause to
179 believe that a health care practitioner has provided inadequate
180 medical care based on termination of insurance and also find
181 that appropriate, reasonable attempts were made to obtain a
182 patient release.

183 3. The department may obtain patient records, billing
184 records, insurance information, provider contracts, and all
185 attachments thereto pursuant to a subpoena without written
186 authorization from the patient if the department and probable
187 cause panel of the appropriate board, if any, find reasonable
188 cause to believe that a health care practitioner has submitted a
189 claim, statement, or bill using a billing code that would result
190 in payment greater in amount than would be paid using a billing
191 code that accurately describes the services performed, requested
192 payment for services that were not performed by that health care
193 practitioner, used information derived from a written report of
194 an automobile accident generated pursuant to chapter 316 to
195 solicit or obtain patients personally or through an agent
196 regardless of whether the information is derived directly from
197 the report or a summary of that report or from another person,
198 solicited patients fraudulently, received a kickback as defined
199 in s. 456.054, violated the patient brokering provisions of s.
200 817.505, or presented or caused to be presented a false or
201 fraudulent insurance claim within the meaning of s.
202 817.234(1)(a), and also find that, within the meaning of s.
203 817.234(1)(a), patient authorization cannot be obtained because

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204 the patient cannot be located or is deceased, incapacitated, or
205 suspected of being a participant in the fraud or scheme, and if
206 the subpoena is issued for specific and relevant records.

207 4. Notwithstanding subparagraphs 1.-3., when the department
208 investigates a professional liability claim or undertakes action
209 pursuant to s. 456.049 or s. 627.912, the department may obtain
210 patient records pursuant to a subpoena without written
211 authorization from the patient if the patient refuses to
212 cooperate or if the department attempts to obtain a patient
213 release and the failure to obtain the patient records would be
214 detrimental to the investigation.

215 Section 3. Subsections (4), (5), and (6) of section
216 458.309, Florida Statutes, are repealed.

217 Section 4. Section 458.3265, Florida Statutes, is created
218 to read:

219 458.3265 Pain-management clinics.-

220 (1) REGISTRATION.-

221 (a) All privately owned pain-management clinics,
222 facilities, or offices, hereinafter referred to as "clinics,"
223 which advertise in any medium for any type of pain-management
224 services, or employ a physician who is primarily engaged in the
225 treatment of pain by prescribing or dispensing controlled
226 substance medications, must register with the department unless:

227 1. That clinic is licensed as a facility pursuant to
228 chapter 395;

229 2. The majority of the physicians who provide services in
230 the clinic primarily provide surgical services;

231 3. The physicians who provide services in the clinic
232 primarily provide chiropractic services and do not dispense

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233 controlled substances.

234 4. The clinic is owned by a publicly held corporation whose
235 shares are traded on a national exchange or on the over-the-
236 counter market and whose total assets at the end of the
237 corporation's most recent fiscal quarter exceeded \$50 million;

238 5. The clinic is affiliated with an accredited medical
239 school at which training is provided for medical students,
240 residents, or fellows;

241 6. The clinic does not prescribe or dispense controlled
242 substances for the treatment of pain; or

243 7. The clinic is owned by a corporate entity exempt from
244 federal taxation under 26 U.S.C. s. 501(c)(3).

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

248 (c) As a part of registration, a clinic must designate a
249 physician who is responsible for complying with all requirements
250 related to registration and operation of the clinic in
251 compliance with this section. Within 10 days after termination
252 of a designated physician, the clinic must notify the department
253 of the identity of another designated physician for that clinic.
254 The designated physician shall have a full, active, and
255 unencumbered license under this chapter or chapter 459 and shall
256 practice at the clinic location for which the physician has
257 assumed responsibility. Failing to have a licensed designated
258 physician practicing at the location of the registered clinic
259 may be the basis for a summary suspension of the clinic
260 registration certificate as described in s. 456.073(8) for a
261 license or s. 120.60(6).

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262 (d) The department shall deny registration to any clinic
263 that is not fully owned by a physician licensed under this
264 chapter or chapter 459 or a group of physicians, each of whom is
265 licensed under this chapter or chapter 459; or that is not a
266 health care clinic licensed under part X of chapter 400.

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

270 1. Whose Drug Enforcement Administration number has ever
271 been revoked.

272 2. Whose application for a license to prescribe, dispense,
273 or administer a controlled substance has been denied by any
274 jurisdiction.

275 3. Who has been convicted of or plead guilty or nolo
276 contendere to, regardless of adjudication, an offense that
277 constitutes a felony for receipt of illicit and diverted drugs,
278 including a controlled substance listed in Schedule I, Schedule
279 II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in
280 this state, any other state, or the United States.

281 (f) If the department finds that a pain-management clinic
282 does not meet the requirement of paragraph (d) or is owned,
283 directly or indirectly, by a person meeting any criteria listed
284 in paragraph (e), the department shall revoke the certificate of
285 registration previously issued by the department. As determined
286 by rule, the department may grant an exemption to denying a
287 registration or revoking a previously issued registration if
288 more than 10 years have elapsed since adjudication. As used in
289 this subsection, the term "convicted" includes an adjudication
290 of guilt following a plea of guilty or nolo contendere or the

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291 forfeiture of a bond when charged with a crime.

292 (g) The department may revoke the clinic's certificate of
293 registration and prohibit all physicians associated with that
294 pain-management clinic from practicing at that clinic location
295 based upon an annual inspection and evaluation of the factors
296 described in subsection (3).

297 (h) If the registration of a pain-management clinic is
298 revoked or suspended, the designated physician of the pain-
299 management clinic, the owner or lessor of the pain-management
300 clinic property, the manager, and the proprietor shall cease to
301 operate the facility as a pain-management clinic as of the
302 effective date of the suspension or revocation.

303 (i) If a pain-management clinic registration is revoked or
304 suspended, the designated physician of the pain-management
305 clinic, the owner or lessor of the clinic property, the manager,
306 or the proprietor is responsible for removing all signs and
307 symbols identifying the premises as a pain-management clinic.

308 (j) Upon the effective date of the suspension or
309 revocation, the designated physician of the pain-management
310 clinic shall advise the department of the disposition of the
311 medicinal drugs located on the premises. The disposition is
312 subject to the supervision and approval of the department.
313 Medicinal drugs that are purchased or held by a pain-management
314 clinic that is not registered may be deemed adulterated pursuant
315 to s. 499.006.

316 (k) If the clinic's registration is revoked, any person
317 named in the registration documents of the pain-management
318 clinic, including persons owning or operating the pain-
319 management clinic, may not, as an individual or as a part of a

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320 group, apply to operate a pain-management clinic for 5 years
321 after the date the registration is revoked.

322 (1) The period of suspension for the registration of a pain
323 management clinic shall be prescribed by the department, but may
324 not exceed 1 year.

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

327 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
328 apply to any physician who provides professional services in a
329 pain-management clinic that is required to be registered in
330 subsection (1).

331 (a) A physician may not practice medicine in a pain-
332 management clinic, as described in subsection (4), if:

333 1. The pain-management clinic is not registered with the
334 department as required by this section; or

335 2. Effective July 1, 2012, the physician has not
336 successfully completed a pain medicine fellowship that is
337 accredited by the Accreditation Council for Graduate Medical
338 Education or a pain medicine residency that is accredited by the
339 Accreditation Council for Graduate Medical Education or does not
340 comply with rules adopted by the Board of Medicine.

341
342 A physician who violates this paragraph is subject to
343 disciplinary action by his or her appropriate medical regulatory
344 board.

345 (b) A person may not dispense any medication, including a
346 controlled substance, on the premises of a registered pain-
347 management clinic unless he or she is a physician licensed under
348 this chapter or chapter 459.

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349 (c) A physician must perform a physical examination of a
350 patient on the same day that he or she dispenses or prescribes a
351 controlled substance to a patient at a pain-management clinic.
352 If the physician prescribes or dispenses more than a 72-hour
353 dose of controlled substances for the treatment of chronic
354 nonmalignant pain, the physician must document in the patient's
355 record the reason for prescribing or dispensing that quantity.

356 (d) A physician authorized to prescribe controlled
357 substances who practices at a pain-management clinic is
358 responsible for maintaining the control and security of his or
359 her prescription blanks and any other method used for
360 prescribing controlled substance pain medication. The physician
361 shall comply with the requirements for counterfeit-resistant
362 prescription blanks in s. 893.065 and the rules adopted pursuant
363 to that section. The physician shall notify in writing the
364 department within 24 hours following any theft or loss of a
365 prescription blank or breach of any other method for prescribing
366 pain medication.

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

372 (3) INSPECTION.—

373 (a) The department shall inspect the pain-management clinic
374 annually, including a review of the patient records, to ensure
375 that it complies with this section and the rules of the Board of
376 Medicine adopted pursuant to subsection (4) unless the clinic is
377 accredited by a nationally recognized accrediting agency

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378 approved by the Board of Medicine.

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

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

387 (4) RULEMAKING.—

388 (a) The department shall adopt rules necessary to
389 administer the registration and inspection of pain-management
390 clinics which establish the specific requirements, procedures,
391 forms, and fees.

392 (b) The department shall adopt a rule defining what
393 constitutes practice by a designated physician at the clinic
394 location for which the physician has assumed responsibility, as
395 set forth in subsection (1). When adopting the rule, the
396 department shall consider the number of clinic employees, the
397 location of the pain-management clinic, the clinic's hours of
398 operation, and the amount of controlled substances being
399 prescribed, dispensed, or administered at the pain-management
400 clinic.

401 (c) The Board of Medicine shall adopt a rule establishing
402 the maximum number of prescriptions for Schedule II or Schedule
403 III controlled substances or the controlled substance Alprazolam
404 which may be written at any one registered pain-management
405 clinic during any 24-hour period.

406 (d) The Board of Medicine shall adopt rules setting forth

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407 standards of practice for physicians practicing in privately
408 owned pain-management clinics that primarily engage in the
409 treatment of pain by prescribing or dispensing controlled
410 substance medications. Such rules shall address, but need not be
411 limited to:

- 412 1. Facility operations;
- 413 2. Physical operations;
- 414 3. Infection control requirements;
- 415 4. Health and safety requirements;
- 416 5. Quality assurance requirements;
- 417 6. Patient records;
- 418 7. Training requirements for all facility health care
419 practitioners who are not regulated by another board;
- 420 8. Inspections; and
- 421 9. Data collection and reporting requirements.

422
423 A physician is primarily engaged in the treatment of pain by
424 prescribing or dispensing controlled substance medications when
425 the majority of the patients seen are prescribed or dispensed
426 controlled substance medications for the treatment of chronic
427 nonmalignant pain. Chronic nonmalignant pain is pain unrelated
428 to cancer which persists beyond the usual course of the disease
429 or the injury that is the cause of the pain or more than 90 days
430 after surgery.

431 (5) PENALTIES; ENFORCEMENT.—

432 (a) The department may impose an administrative fine on the
433 clinic of up to \$5,000 per violation for violating the
434 requirements of this section; chapter 499, the Florida Drug and
435 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and

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436 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
437 Abuse Prevention and Control Act; chapter 893, the Florida
438 Comprehensive Drug Abuse Prevention and Control Act; or the
439 rules of the department. In determining whether a penalty is to
440 be imposed, and in fixing the amount of the fine, the department
441 shall consider the following factors:

442 1. The gravity of the violation, including the probability
443 that death or serious physical or emotional harm to a patient
444 has resulted, or could have resulted, from the pain-management
445 clinic's actions or the actions of the physician, the severity
446 of the action or potential harm, and the extent to which the
447 provisions of the applicable laws or rules were violated.

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

450 3. Whether there were any previous violations at the pain-
451 management clinic.

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

454 (b) Each day a violation continues after the date fixed for
455 termination of the violation as ordered by the department
456 constitutes an additional, separate, and distinct violation.

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

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

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465 (e) If the owner of a pain-management clinic that requires
466 registration fails to apply to register the clinic upon a
467 change-of-ownership and operates the clinic under the new
468 ownership, the owner is subject to a fine of \$5,000.

469 Section 5. Section 458.327, Florida Statutes, is amended to
470 read:

471 458.327 Penalty for violations.—

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

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

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

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

481 (d) Attempting to obtain or obtaining a position as a
482 medical practitioner or medical resident in a clinic or hospital
483 through knowing misrepresentation of education, training, or
484 experience.

485 (e) Knowingly operating, owning, or managing a
486 nonregistered pain-management clinic that is required to be
487 registered with the Department of Health pursuant to s.
488 458.3265(1).

489 (2) Each of the following acts constitutes a misdemeanor of
490 the first degree, punishable as provided in s. 775.082 or s.
491 775.083:

492 (a) Knowingly concealing information relating to violations
493 of this chapter.

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

496 (c) Referring any patient, for health care goods or
497 services, to a partnership, firm, corporation, or other business
498 entity in which the physician or the physician's employer has an
499 equity interest of 10 percent or more unless, prior to such
500 referral, the physician notifies the patient of his or her
501 financial interest and of the patient's right to obtain such
502 goods or services at the location of the patient's choice. This
503 section does not apply to the following types of equity
504 interest:

505 1. The ownership of registered securities issued by a
506 publicly held corporation or the ownership of securities issued
507 by a publicly held corporation, the shares of which are traded
508 on a national exchange or the over-the-counter market;

509 2. A physician's own practice, whether he or she is a sole
510 practitioner or part of a group, when the health care good or
511 service is prescribed or provided solely for the physician's own
512 patients and is provided or performed by the physician or under
513 the physician's supervision; or

514 3. An interest in real property resulting in a landlord-
515 tenant relationship between the physician and the entity in
516 which the equity interest is held, unless the rent is
517 determined, in whole or in part, by the business volume or
518 profitability of the tenant or is otherwise unrelated to fair
519 market value.

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

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523 (e) Practicing medicine or attempting to practice medicine
524 with an inactive or delinquent license.

525 (f) Knowingly prescribing or dispensing, or causing to be
526 prescribed or dispensed, controlled substances in a
527 nonregistered pain-management clinic that is required to be
528 registered with the Department of Health pursuant to s.
529 458.3265(1).

530 Section 6. Paragraphs (oo) and (pp) are added to subsection
531 (1) of section 458.331, Florida Statutes, to read:

532 458.331 Grounds for disciplinary action; action by the
533 board and department.—

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

536 (oo) Applicable to a licensee who serves as the designated
537 physician of a pain-management clinic as defined in s. 458.3265
538 or s. 459.0137:

539 1. Registering a pain-management clinic through
540 misrepresentation or fraud;

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

544 3. Failing to comply with any requirement of chapter 499,
545 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
546 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
547 the Drug Abuse Prevention and Control Act; or chapter 893, the
548 Florida Comprehensive Drug Abuse Prevention and Control Act;

549 4. Being convicted or found guilty of, regardless of
550 adjudication to, a felony or any other crime involving moral
551 turpitude, fraud, dishonesty, or deceit in any jurisdiction of

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552 the courts of this state, of any other state, or of the United
553 States;

554 5. Being convicted of, or disciplined by a regulatory
555 agency of the Federal Government or a regulatory agency of
556 another state for any offense that would constitute a violation
557 of this chapter;

558 6. Being convicted of, or entering a plea of guilty or nolo
559 contendere to, regardless of adjudication, a crime in any
560 jurisdiction of the courts of this state, of any other state, or
561 of the United States which relates to the practice of, or the
562 ability to practice, a licensed health care profession;

563 7. Being convicted of, or entering a plea of guilty or nolo
564 contendere to, regardless of adjudication, a crime in any
565 jurisdiction of the courts of this state, of any other state, or
566 of the United States which relates to health care fraud;

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

572 9. Failing to timely notify the board of the date of his or
573 her termination from a pain-management clinic as required by s.
574 458.3265(2).

575 (pp) Failing to timely notify the department of the theft
576 of prescription blanks from a pain-management clinic or a breach
577 of other methods for prescribing within 24 hours as required by
578 s. 458.3265(2).

579 Section 7. Subsections (3), (4), and (5) of section
580 459.005, Florida Statutes, are repealed.

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581 Section 8. Section 459.0137, Florida Statutes, is created
582 to read:

583 459.0137 Pain-management clinics.-

584 (1) REGISTRATION.-

585 (a) All privately owned pain-management clinics,
586 facilities, or offices, hereinafter referred to as "clinics,"
587 which advertise in any medium for any type of pain-management
588 services, or employ an osteopathic physician who is primarily
589 engaged in the treatment of pain by prescribing or dispensing
590 controlled substance medications, must register with the
591 department unless:

592 1. That clinic is licensed as a facility pursuant to
593 chapter 395;

594 2. The majority of the physicians who provide services in
595 the clinic primarily provide surgical services;

596 3. The physicians who provide services in the clinic
597 primarily provide chiropractic services and do not dispense
598 controlled substances.

599 4. The clinic is owned by a publicly held corporation whose
600 shares are traded on a national exchange or on the over-the-
601 counter market and whose total assets at the end of
602 corporation's most recent fiscal quarter exceeded \$50 million;

603 5. The clinic is affiliated with an accredited medical
604 school at which training is provided for medical students,
605 residents, or fellows;

606 6. The clinic does not prescribe or dispense controlled
607 substances for the treatment of pain; or

608 7. The clinic is owned by a corporate entity exempt from
609 federal taxation under 26 U.S.C. s. 501(c)(3).

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

613 (c) As a part of registration, a clinic must designate an
614 osteopathic physician who is responsible for complying with all
615 requirements related to registration and operation of the clinic
616 in compliance with this section. Within 10 days after
617 termination of a designated osteopathic physician, the clinic
618 must notify the department of the identity of another designated
619 physician for that clinic. The designated physician shall have a
620 full, active, and unencumbered license under chapter 458 or this
621 chapter and shall practice at the clinic location for which the
622 physician has assumed responsibility. Failing to have a licensed
623 designated osteopathic physician practicing at the location of
624 the registered clinic may be the basis for a summary suspension
625 of the clinic registration certificate as described in s.
626 456.073(8) for a license or s. 120.60(6).

627 (d) The department shall deny registration to any clinic
628 that is not fully owned by a physician licensed under chapter
629 458 or this chapter or a group of physicians, each of whom is
630 licensed under chapter 458 or this chapter; or that is not a
631 health care clinic licensed under part X of chapter 400.

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

635 1. Whose Drug Enforcement Administration number has ever
636 been revoked.

637 2. Whose application for a license to prescribe, dispense,
638 or administer a controlled substance has been denied by any

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639 jurisdiction.

640 3. Who has been convicted of or plead guilty or nolo
641 contendere to, regardless of adjudication, an offense that
642 constitutes a felony for receipt of illicit and diverted drugs,
643 including a controlled substance listed in Schedule I, Schedule
644 II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in
645 this state, any other state, or the United States.

646 (f) If the department finds that a pain-management clinic
647 does not meet the requirement of paragraph (d) or is owned,
648 directly or indirectly, by a person meeting any criteria listed
649 in paragraph (e), the department shall revoke the certificate of
650 registration previously issued by the department. As determined
651 by rule, the department may grant an exemption to denying a
652 registration or revoking a previously issued registration if
653 more than 10 years have elapsed since adjudication. As used in
654 this subsection, the term "convicted" includes an adjudication
655 of guilt following a plea of guilty or nolo contendere or the
656 forfeiture of a bond when charged with a crime.

657 (g) The department may revoke the clinic's certificate of
658 registration and prohibit all physicians associated with that
659 pain-management clinic from practicing at that clinic location
660 based upon an annual inspection and evaluation of the factors
661 described in subsection (3).

662 (h) If the registration of a pain-management clinic is
663 revoked or suspended, the designated physician of the pain-
664 management clinic, the owner or lessor of the pain-management
665 clinic property, the manager, and the proprietor shall cease to
666 operate the facility as a pain-management clinic as of the
667 effective date of the suspension or revocation.

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668 (i) If a pain-management clinic registration is revoked or
669 suspended, the designated physician of the pain-management
670 clinic, the owner or lessor of the clinic property, the manager,
671 or the proprietor is responsible for removing all signs and
672 symbols identifying the premises as a pain-management clinic.

673 (j) Upon the effective date of the suspension or
674 revocation, the designated physician of the pain-management
675 clinic shall advise the department of the disposition of the
676 medicinal drugs located on the premises. The disposition is
677 subject to the supervision and approval of the department.
678 Medicinal drugs that are purchased or held by a pain-management
679 clinic that is not registered may be deemed adulterated pursuant
680 to s. 499.006.

681 (k) If the clinic's registration is revoked, any person
682 named in the registration documents of the pain-management
683 clinic, including persons owning or operating the pain-
684 management clinic, may not as an individual or as a part of a
685 group, make application for a permit to operate a pain-
686 management clinic for 5 years after the date the registration is
687 revoked.

688 (l) The period of suspension for the registration of a pain
689 management clinic shall be prescribed by the department, but may
690 not exceed 1 year.

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

693 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
694 apply to any osteopathic physician who provides professional
695 services in a pain-management clinic that is required to be
696 registered in subsection (1).

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697 (a) An osteopathic physician may not practice medicine in a
698 pain-management clinic, as described in subsection (4), if:

699 1. The pain-management clinic is not registered with the
700 department as required by this section; or

701 2. Effective July 1, 2012, the physician has not
702 successfully completed a pain medicine fellowship that is
703 accredited by the Accreditation Council for Graduate Medical
704 Education or the American Osteopathic Association or a pain
705 medicine residency that is accredited by the Accreditation
706 Council for Graduate Medical Education or the American
707 Osteopathic Association or does not comply with rules adopted by
708 the Board of Osteopathic Medicine.

709
710 An osteopathic physician who violates this paragraph is subject
711 to disciplinary action by his or her appropriate medical
712 regulatory board.

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

717 (c) An osteopathic physician must perform a physical
718 examination of a patient on the same day that he or she
719 dispenses or prescribes a controlled substance to a patient at a
720 pain-management clinic. If the osteopathic physician prescribes
721 or dispenses more than a 72-hour dose of controlled substances
722 for the treatment of chronic nonmalignant pain, the osteopathic
723 physician must document in the patient's record the reason for
724 prescribing or dispensing that quantity.

725 (d) An osteopathic physician authorized to prescribe

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726 controlled substances who practices at a pain-management clinic
727 is responsible for maintaining the control and security of his
728 or her prescription blanks and any other method used for
729 prescribing controlled substance pain medication. The
730 osteopathic physician shall comply with the requirements for
731 counterfeit-resistant prescription blanks in s. 893.065 and the
732 rules adopted pursuant to that section. The osteopathic
733 physician shall notify in writing the department within 24 hours
734 following any theft or loss of a prescription blank or breach of
735 any other method for prescribing pain medication.

736 (e) The designated osteopathic physician of a pain-
737 management clinic shall notify the applicable board in writing
738 of the date of termination of employment within 10 days after
739 terminating his or her employment with a pain-management clinic
740 that is required to be registered under subsection (1).

741 (3) INSPECTION.—

742 (a) The department shall inspect the pain-management clinic
743 annually, including a review of the patient records, to ensure
744 that it complies with this section and the rules of the Board of
745 Osteopathic Medicine adopted pursuant to subsection (4) unless
746 the clinic is accredited by a nationally recognized accrediting
747 agency approved by the Board of Osteopathic Medicine.

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

752 (c) Any action taken to correct a violation shall be
753 documented in writing by the owner or designated physician of
754 the pain-management clinic and verified by followup visits by

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755 departmental personnel.

756 (4) RULEMAKING.—

757 (a) The department shall adopt rules necessary to
758 administer the registration and inspection of pain-management
759 clinics which establish the specific requirements, procedures,
760 forms, and fees.

761 (b) The department shall adopt a rule defining what
762 constitutes practice by a designated osteopathic physician at
763 the clinic location for which the physician has assumed
764 responsibility, as set forth in subsection (1). When adopting
765 the rule, the department shall consider the number of clinic
766 employees, the location of the pain-management clinic, the
767 clinic's hours of operation, and the amount of controlled
768 substances being prescribed, dispensed, or administered at the
769 pain-management clinic.

770 (c) The Board of Osteopathic Medicine shall adopt a rule
771 establishing the maximum number of prescriptions for Schedule II
772 or Schedule III controlled substances or the controlled
773 substance Alprazolam which may be written at any one registered
774 pain-management clinic during any 24-hour period.

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

- 781 1. Facility operations;
782 2. Physical operations;
783 3. Infection control requirements;

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- 784 4. Health and safety requirements;
785 5. Quality assurance requirements;
786 6. Patient records;
787 7. Training requirements for all facility health care
788 practitioners who are not regulated by another board;
789 8. Inspections; and
790 9. Data collection and reporting requirements.

791

792 An osteopathic physician is primarily engaged in the treatment
793 of pain by prescribing or dispensing controlled substance
794 medications when the majority of the patients seen are
795 prescribed or dispensed controlled substance medications for the
796 treatment of chronic nonmalignant pain. Chronic nonmalignant
797 pain is pain unrelated to cancer which persists beyond the usual
798 course of the disease or the injury that is the cause of the
799 pain or more than 90 days after surgery.

800 (5) PENALTIES; ENFORCEMENT.—

801 (a) The department may impose an administrative fine on the
802 clinic of up to \$5,000 per violation for violating the
803 requirements of this section; chapter 499, the Florida Drug and
804 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
805 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
806 Abuse Prevention and Control Act; chapter 893, the Florida
807 Comprehensive Drug Abuse Prevention and Control Act; or the
808 rules of the department. In determining whether a penalty is to
809 be imposed, and in fixing the amount of the fine, the department
810 shall consider the following factors:

- 811 1. The gravity of the violation, including the probability
812 that death or serious physical or emotional harm to a patient

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813 has resulted, or could have resulted, from the pain-management
814 clinic's actions or the actions of the osteopathic physician,
815 the severity of the action or potential harm, and the extent to
816 which the provisions of the applicable laws or rules were
817 violated.

818 2. What actions, if any, the owner or designated
819 osteopathic physician took to correct the violations.

820 3. Whether there were any previous violations at the pain-
821 management clinic.

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

824 (b) Each day a violation continues after the date fixed for
825 termination of the violation as ordered by the department
826 constitutes an additional, separate, and distinct violation.

827 (c) The department may impose a fine and, in the case of an
828 owner-operated pain-management clinic, revoke or deny a pain-
829 management clinic's registration, if the clinic's designated
830 osteopathic physician knowingly and intentionally misrepresents
831 actions taken to correct a violation.

832 (d) An owner or designated osteopathic physician of a pain-
833 management clinic who concurrently operates an unregistered
834 pain-management clinic is subject to an administrative fine of
835 \$5,000 per day.

836 (e) If the owner of a pain-management clinic that requires
837 registration fails to apply to register the clinic upon a
838 change-of-ownership and operates the clinic under the new
839 ownership, the owner is subject to a fine of \$5,000.

840 Section 9. Subsections (1) and (2) of section 459.013,
841 Florida Statutes, are amended to read:

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842 459.013 Penalty for violations.—

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

846 (a) The practice of osteopathic medicine, or an attempt to
847 practice osteopathic medicine, without an active license or
848 certificate issued pursuant to this chapter.

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

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

855 (d) Attempting to obtain or obtaining a position as an
856 osteopathic medical practitioner or osteopathic medical resident
857 in a clinic or hospital through knowing misrepresentation of
858 education, training, or experience.

859 (e) Knowingly operating, owning, or managing a
860 nonregistered pain-management clinic that is required to be
861 registered with the Department of Health pursuant to s.
862 459.0137(1).

863 (2) Each of the following acts constitutes a misdemeanor of
864 the first degree, punishable as provided in s. 775.082 or s.
865 775.083:

866 (a) Knowingly concealing information relating to violations
867 of this chapter.

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

870 (c) The practice of medicine as a resident or intern

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871 without holding a valid current registration pursuant to s.
872 459.021.

873 (d) Knowingly prescribing or dispensing, or causing to be
874 prescribed or dispensed, controlled substances in a
875 nonregistered pain-management clinic that is required to be
876 registered with the Department of Health pursuant to s.
877 459.0137(1).

878 Section 10. Paragraphs (qq) and (rr) are added to
879 subsection (1) of section 459.015, Florida Statutes, to read:

880 459.015 Grounds for disciplinary action; action by the
881 board and department.—

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

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

887 1. Registering a pain-management clinic through
888 misrepresentation or fraud;

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

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

897 4. Being convicted or found guilty of, regardless of
898 adjudication to, a felony or any other crime involving moral
899 turpitude, fraud, dishonesty, or deceit in any jurisdiction of

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900 the courts of this state, of any other state, or of the United
901 States;

902 5. Being convicted of, or disciplined by a regulatory
903 agency of the Federal Government or a regulatory agency of
904 another state for any offense that would constitute a violation
905 of this chapter;

906 6. Being convicted of, or entering a plea of guilty or nolo
907 contendere to, regardless of adjudication, a crime in any
908 jurisdiction of the courts of this state, of any other state, or
909 of the United States which relates to the practice of, or the
910 ability to practice, a licensed health care profession;

911 7. Being convicted of, or entering a plea of guilty or nolo
912 contendere to, regardless of adjudication, a crime in any
913 jurisdiction of the courts of this state, of any other state, or
914 of the United States which relates to health care fraud;

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

920 9. Failing to timely notify the board of the date of his or
921 her termination from a pain-management clinic as required by s.
922 459.0137(2).

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

927 Section 11. Paragraph (b) of subsection (7) of section
928 893.055, Florida Statutes, is amended to read:

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929 893.055 Prescription drug monitoring program.—

930 (7)

931 (b)1. A pharmacy, prescriber, or dispenser shall have
932 access to information in the prescription drug monitoring
933 program's database which relates to a patient of that pharmacy,
934 prescriber, or dispenser in a manner established by the
935 department as needed for the purpose of reviewing the patient's
936 controlled substance prescription history.

937 2. The prescription drug monitoring program's database
938 shall report information directly to applicable law enforcement
939 agencies to investigate whether any violation of s.
940 893.13(7)(a)8., s. 893.13(8)(a), or s. 893.13(8)(b), has
941 occurred regarding controlled substances in Schedule II,
942 Schedule III, or Schedule IV. The department shall adopt rules
943 to identify the factors that might be indicative of a violation
944 of s. 893.13(7)(a)8., s. 893.13(8)(a), or s. 893.13(8)(b), based
945 on input from the Department of Law Enforcement and
946 representatives of local law enforcement, the Florida Medical
947 Association, the Florida Osteopathic Medical Association, the
948 Florida Pharmacy Association, and other relevant stakeholders.

949 3. Other access to the program's database shall be limited
950 to the program's manager and to the designated program and
951 support staff, who may act only at the direction of the program
952 manager or, in the absence of the program manager, as
953 authorized. Access by the program manager or such designated
954 staff is for prescription drug program management only or for
955 management of the program's database and its system in support
956 of the requirements of this section and in furtherance of the
957 prescription drug monitoring program. Confidential and exempt

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958 information in the database shall be released only as provided
959 in paragraph (c) and s. 893.0551.

960 Section 12. Subsections (4), (5), and (6) of section
961 893.0551, Florida Statutes, are renumbered as subsections (5),
962 (6), and (7), respectively, and subsection (4) is added to that
963 section, to read:

964 893.0551 Public records exemption for the prescription drug
965 monitoring program.—

966 (4) The department shall disclose such confidential and
967 exempt information to the applicable law enforcement agency in
968 accordance with s. 893.055(7)(b)2. The law enforcement agency
969 may disclose the confidential and exempt information received
970 from the department to a criminal justice agency as defined in
971 s. 119.011 as part of an active investigation that is specific
972 to a violation of s. 893.13(7)(a)8., s. 893.13(8)(a), or s.
973 893.13(8)(b).

974 Section 13. This act shall take effect October 1, 2010.