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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 defining the term "program manager"; requiring that
125 the program manager work with certain licensure boards
126 and stakeholders to develop rules; authorizing the
127 program manager to provide relevant information to law
128 enforcement agencies under certain circumstances;
129 amending s. 893.0551, F.S.; providing for disclosure
130 of confidential and exempt information to applicable
131 law enforcement; providing an effective 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 clinic is owned by a publicly held corporation whose
232 shares are traded on a national exchange or on the over-the-

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233 counter market and whose total assets at the end of the
234 corporation's most recent fiscal quarter exceeded \$50 million;

235 4. The clinic is affiliated with an accredited medical
236 school at which training is provided for medical students,
237 residents, or fellows;

238 5. The clinic does not prescribe or dispense controlled
239 substances for the treatment of pain; or

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

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

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

259 (d) The department shall deny registration to any clinic
260 that is not fully owned by a physician licensed under this
261 chapter or chapter 459 or a group of physicians, each of whom is

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262 licensed under this chapter or chapter 459; or that is not a
263 health care clinic licensed under part X of chapter 400.

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

267 1. Whose Drug Enforcement Administration number has ever
268 been revoked.

269 2. Whose application for a license to prescribe, dispense,
270 or administer a controlled substance has been denied by any
271 jurisdiction.

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

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

289 (g) The department may revoke the clinic's certificate of
290 registration and prohibit all physicians associated with that

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291 pain-management clinic from practicing at that clinic location
292 based upon an annual inspection and evaluation of the factors
293 described in subsection (3).

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

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

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

313 (k) If the clinic's registration is revoked, any person
314 named in the registration documents of the pain-management
315 clinic, including persons owning or operating the pain-
316 management clinic, may not, as an individual or as a part of a
317 group, apply to operate a pain-management clinic for 5 years
318 after the date the registration is revoked.

319 (l) The period of suspension for the registration of a pain

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320 management clinic shall be prescribed by the department, but may
321 not exceed 1 year.

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

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

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

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

332 2. Effective July 1, 2012, the physician has not
333 successfully completed a pain medicine fellowship that is
334 accredited by the Accreditation Council for Graduate Medical
335 Education or a pain medicine residency that is accredited by the
336 Accreditation Council for Graduate Medical Education or, prior
337 to July 1, 2012, does not comply with rules adopted by the
338 board.

339
340 Any physician who qualifies to practice medicine in a pain-
341 management clinic pursuant to rules adopted by the Board of
342 Medicine as of July 1, 2012, may continue to practice medicine
343 in a pain-management clinic as long as the physician continues
344 to meet the qualifications set forth in the board rules. A
345 physician who violates this paragraph is subject to disciplinary
346 action by his or her appropriate medical regulatory board.

347 (b) A person may not dispense any medication, including a
348 controlled substance, on the premises of a registered pain-

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349 management clinic unless he or she is a physician licensed under
350 this chapter or chapter 459.

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

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

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

374 (3) INSPECTION.—

375 (a) The department shall inspect the pain-management clinic
376 annually, including a review of the patient records, to ensure
377 that it complies with this section and the rules of the Board of

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378 Medicine adopted pursuant to subsection (4) unless the clinic is
379 accredited by a nationally recognized accrediting agency
380 approved by the Board of Medicine.

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

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

389 (4) RULEMAKING.—

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

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

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

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407 clinic during any 24-hour period.

408 (d) The Board of Medicine shall adopt rules setting forth
409 standards of practice for physicians practicing in privately
410 owned pain-management clinics that primarily engage in the
411 treatment of pain by prescribing or dispensing controlled
412 substance medications. Such rules shall address, but need not be
413 limited to:

414 1. Facility operations;

415 2. Physical operations;

416 3. Infection control requirements;

417 4. Health and safety requirements;

418 5. Quality assurance requirements;

419 6. Patient records;

420 7. Training requirements for all facility health care
421 practitioners who are not regulated by another board;

422 8. Inspections; and

423 9. Data collection and reporting requirements.

424

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

433 (5) PENALTIES; ENFORCEMENT.—

434 (a) The department may impose an administrative fine on the
435 clinic of up to \$5,000 per violation for violating the

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436 requirements of this section; chapter 499, the Florida Drug and
437 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
438 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
439 Abuse Prevention and Control Act; chapter 893, the Florida
440 Comprehensive Drug Abuse Prevention and Control Act; or the
441 rules of the department. In determining whether a penalty is to
442 be imposed, and in fixing the amount of the fine, the department
443 shall consider the following factors:

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

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

452 3. Whether there were any previous violations at the pain-
453 management clinic.

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

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

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

464 (d) An owner or designated physician of a pain-management

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465 clinic who concurrently operates an unregistered pain-management
466 clinic is subject to an administrative fine of \$5,000 per day.

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

471 Section 5. Section 458.327, Florida Statutes, is amended to
472 read:

473 458.327 Penalty for violations.—

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

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

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

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

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

487 (e) Knowingly operating, owning, or managing a
488 nonregistered pain-management clinic that is required to be
489 registered with the Department of Health pursuant to s.
490 458.3265(1).

491 (2) Each of the following acts constitutes a misdemeanor of
492 the first degree, punishable as provided in s. 775.082 or s.
493 775.083:

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494 (a) Knowingly concealing information relating to violations
495 of this chapter.

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

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

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

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

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

522 (d) Leading the public to believe that one is licensed as a

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523 medical doctor, or is engaged in the licensed practice of
524 medicine, without holding a valid, active license.

525 (e) Practicing medicine or attempting to practice medicine
526 with an inactive or delinquent license.

527 (f) Knowingly prescribing or dispensing, or causing to be
528 prescribed or dispensed, controlled substances in a
529 nonregistered pain-management clinic that is required to be
530 registered with the Department of Health pursuant to s.
531 458.3265(1).

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

534 458.331 Grounds for disciplinary action; action by the
535 board and department.—

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

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

541 1. Registering a pain-management clinic through
542 misrepresentation or fraud;

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

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

551 4. Being convicted or found guilty of, regardless of

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552 adjudication to, a felony or any other crime involving moral
553 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
554 the courts of this state, of any other state, or of the United
555 States;

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

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

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

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

574 9. Failing to timely notify the board of the date of his or
575 her termination from a pain-management clinic as required by s.
576 458.3265(2).

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

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581 Section 7. Subsections (3), (4), and (5) of section
582 459.005, Florida Statutes, are repealed.

583 Section 8. Section 459.0137, Florida Statutes, is created
584 to read:

585 459.0137 Pain-management clinics.-

586 (1) REGISTRATION.-

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

594 1. That clinic is licensed as a facility pursuant to
595 chapter 395;

596 2. The majority of the physicians who provide services in
597 the clinic primarily provide surgical services;

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

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

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

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

609 (b) Each clinic location shall be registered separately

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610 regardless of whether the clinic is operated under the same
611 business name or management as another clinic.

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

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

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

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

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

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

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

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

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

667 (i) If a pain-management clinic registration is revoked or

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

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

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

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

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

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

696 (a) An osteopathic physician may not practice medicine in a

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697 pain-management clinic, as described in subsection (4), if:

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

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

708
709 Any physician who qualifies to practice medicine in a pain-
710 management clinic pursuant to rules adopted by the Board of
711 Osteopathic Medicine as of July 1, 2012, may continue to
712 practice medicine in a pain-management clinic as long as the
713 physician continues to meet the qualifications set forth in the
714 board rules. An osteopathic physician who violates this
715 paragraph is subject to disciplinary action by his or her
716 appropriate medical regulatory board.

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

721 (c) An osteopathic physician must perform a physical
722 examination of a patient on the same day that he or she
723 dispenses or prescribes a controlled substance to a patient at a
724 pain-management clinic. If the osteopathic physician prescribes
725 or dispenses more than a 72-hour dose of controlled substances

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726 for the treatment of chronic nonmalignant pain, the osteopathic
727 physician must document in the patient's record the reason for
728 prescribing or dispensing that quantity.

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

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

745 (3) INSPECTION.—

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

752 (b) During an onsite inspection, the department shall make
753 a reasonable attempt to discuss each violation with the owner or
754 designated physician of the pain-management clinic before

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755 issuing a formal written notification.

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

760 (4) RULEMAKING.—

761 (a) The department shall adopt rules necessary to
762 administer the registration and inspection of pain-management
763 clinics which establish the specific requirements, procedures,
764 forms, and fees.

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

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

779 (d) The Board of Osteopathic Medicine shall adopt rules
780 setting forth standards of practice for osteopathic physicians
781 practicing in privately owned pain-management clinics that
782 primarily engage in the treatment of pain by prescribing or
783 dispensing controlled substance medications. Such rules shall

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784 address, but need not be limited to:

785 1. Facility operations;

786 2. Physical operations;

787 3. Infection control requirements;

788 4. Health and safety requirements;

789 5. Quality assurance requirements;

790 6. Patient records;

791 7. Training requirements for all facility health care

792 practitioners who are not regulated by another board;

793 8. Inspections; and

794 9. Data collection and reporting requirements.

795

796 An osteopathic physician is primarily engaged in the treatment

797 of pain by prescribing or dispensing controlled substance

798 medications when the majority of the patients seen are

799 prescribed or dispensed controlled substance medications for the

800 treatment of chronic nonmalignant pain. Chronic nonmalignant

801 pain is pain unrelated to cancer which persists beyond the usual

802 course of the disease or the injury that is the cause of the

803 pain or more than 90 days after surgery.

804 (5) PENALTIES; ENFORCEMENT.—

805 (a) The department may impose an administrative fine on the

806 clinic of up to \$5,000 per violation for violating the

807 requirements of this section; chapter 499, the Florida Drug and

808 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and

809 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug

810 Abuse Prevention and Control Act; chapter 893, the Florida

811 Comprehensive Drug Abuse Prevention and Control Act; or the

812 rules of the department. In determining whether a penalty is to

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813 be imposed, and in fixing the amount of the fine, the department
814 shall consider the following factors:

815 1. The gravity of the violation, including the probability
816 that death or serious physical or emotional harm to a patient
817 has resulted, or could have resulted, from the pain-management
818 clinic's actions or the actions of the osteopathic physician,
819 the severity of the action or potential harm, and the extent to
820 which the provisions of the applicable laws or rules were
821 violated.

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

824 3. Whether there were any previous violations at the pain-
825 management clinic.

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

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

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

836 (d) An owner or designated osteopathic physician of a pain-
837 management clinic who concurrently operates an unregistered
838 pain-management clinic is subject to an administrative fine of
839 \$5,000 per day.

840 (e) If the owner of a pain-management clinic that requires
841 registration fails to apply to register the clinic upon a

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842 change-of-ownership and operates the clinic under the new
843 ownership, the owner is subject to a fine of \$5,000.

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

846 459.013 Penalty for violations.—

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

850 (a) The practice of osteopathic medicine, or an attempt to
851 practice osteopathic medicine, without an active license or
852 certificate issued pursuant to this chapter.

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

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

859 (d) Attempting to obtain or obtaining a position as an
860 osteopathic medical practitioner or osteopathic medical resident
861 in a clinic or hospital through knowing misrepresentation of
862 education, training, or experience.

863 (e) Knowingly operating, owning, or managing a
864 nonregistered pain-management clinic that is required to be
865 registered with the Department of Health pursuant to s.
866 459.0137(1).

867 (2) Each of the following acts constitutes a misdemeanor of
868 the first degree, punishable as provided in s. 775.082 or s.
869 775.083:

870 (a) Knowingly concealing information relating to violations

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871 of this chapter.

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

874 (c) The practice of medicine as a resident or intern
875 without holding a valid current registration pursuant to s.
876 459.021.

877 (d) Knowingly prescribing or dispensing, or causing to be
878 prescribed or dispensed, controlled substances in a
879 nonregistered pain-management clinic that is required to be
880 registered with the Department of Health pursuant to s.
881 459.0137(1).

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

884 459.015 Grounds for disciplinary action; action by the
885 board and department.—

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

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

891 1. Registering a pain-management clinic through
892 misrepresentation or fraud;

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

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

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900 Florida Comprehensive Drug Abuse Prevention and Control Act;

901 4. Being convicted or found guilty of, regardless of
902 adjudication to, a felony or any other crime involving moral
903 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
904 the courts of this state, of any other state, or of the United
905 States;

906 5. Being convicted of, or disciplined by a regulatory
907 agency of the Federal Government or a regulatory agency of
908 another state for any offense that would constitute a violation
909 of this chapter;

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

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

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

924 9. Failing to timely notify the board of the date of his or
925 her termination from a pain-management clinic as required by s.
926 459.0137(2).

927 (rr) Failing to timely notify the department of the theft
928 of prescription blanks from a pain-management clinic or a breach

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929 of other methods for prescribing within 24 hours as required by
930 s. 459.0137(2).

931 Section 11. Paragraph (j) is added to subsection (1),
932 paragraph (d) is added to subsection (2), and paragraph (f) is
933 added to subsection (7) of section 893.055, Florida Statutes, to
934 read:

935 893.055 Prescription drug monitoring program.—

936 (1) As used in this section, the term:

937 (j) "Program manager" means an employee of or a person
938 contracted by the Department of Health who is designated to
939 ensure the integrity of the prescription drug monitoring program
940 in accordance with the requirements established in paragraphs
941 (2) (a) and (b).

942 (2)

943 (d) The program manager shall work with professional health
944 care licensure boards and the stakeholders listed in paragraph
945 (b) to develop rules appropriate for identifying indicators of
946 controlled substance abuse.

947 (7)

948 (f) The program manager, upon determining a pattern
949 consistent with the rules established under paragraph (2) (c) and
950 having cause to believe a violation of s. 893.13(7) (a) 8.,
951 (8) (a), or (8) (b) has occurred, may provide relevant information
952 to the applicable law enforcement agency.

953 Section 12. Subsections (4), (5), and (6) of section
954 893.0551, Florida Statutes, are renumbered as subsections (5),
955 (6), and (7), respectively, and subsection (4) is added to that
956 section, to read:

957 893.0551 Public records exemption for the prescription drug

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958 monitoring program.—

959 (4) The department shall disclose such confidential and
960 exempt information to the applicable law enforcement agency in
961 accordance with s. 893.055(7)(b)2. The law enforcement agency
962 may disclose the confidential and exempt information received
963 from the department to a criminal justice agency as defined in
964 s. 119.011 as part of an active investigation that is specific
965 to a violation of s. 893.13(7)(a)8., s. 893.13(8)(a), or s.
966 893.13(8)(b).

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