20102272e2

A bill to be entitled

An act relating to controlled substances; amending s. 456.037, F.S.; providing that pain-management clinics that are required to be registered with the Department of Health are business establishments; amending s. 456.057, F.S.; providing that the Department of Health is not required to attempt to obtain authorization from a patient for the release of the patient's medical records under certain circumstances; authorizing the department to obtain patient records without authorization or subpoena if the department has probable cause to believe that certain violations have occurred or are occurring; repealing s. 458.309(4), (5), and (6), F.S., relating to pain-management clinics; creating s. 458.3265, F.S.; requiring all privately owned pain-management clinics, or offices that primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications or by employing a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, to register with the Department of Health; providing exceptions; requiring each location of a pain-management clinic to register separately; requiring a clinic to designate a physician who is responsible for complying with requirements related to registration and operation of the clinic; requiring the department to deny registration or revoke the registration of a pain-management clinic for certain

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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.;

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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. 465.0276, F.S.;
124 prohibiting registered dispensing practitioners from
125 dispensing more than a specified amount of certain
126 controlled substances; providing penalties; providing
127 exceptions; amending s. 893.055, F.S.; defining the
128 term “program manager”; requiring that the program
129 manager work with certain licensure boards and
130 stakeholders to develop rules; authorizing the program
131 manager to provide relevant information to law
132 enforcement agencies under certain circumstances;
133 amending s. 893.0551, F.S.; providing for disclosure
134 of confidential and exempt information to applicable
135 law enforcement; providing an effective date.
136
137 Be It Enacted by the Legislature of the State of Florida:
138
139 Section 1. Subsection (5) of section 456.037, Florida
140 Statutes, is amended to read:
141 456.037 Business establishments; requirements for active
142 status licenses; delinquency; discipline; applicability.—
143 (5) This section applies to any business establishment
144 registered, permitted, or licensed by the department to do
145 business. Business establishments include, but are not limited

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

146 to, dental laboratories, electrology facilities, massage
147 establishments, ~~and~~ pharmacies, and pain-management clinics
148 required to be registered under s. 458.3265 or s. 459.0137.
149 Section 2. Paragraph (a) of subsection (9) of section
150 456.057, Florida Statutes, is amended to read:
151 456.057 Ownership and control of patient records; report or
152 copies of records to be furnished.—
153 (9)(a)1. The department may obtain patient records pursuant
154 to a subpoena without written authorization from the patient if
155 the department and the probable cause panel of the appropriate
156 board, if any, find reasonable cause to believe that a health
157 care practitioner has excessively or inappropriately prescribed
158 any controlled substance specified in chapter 893 in violation
159 of this chapter or any professional practice act or that a
160 health care practitioner has practiced his or her profession
161 below that level of care, skill, and treatment required as
162 defined by this chapter or any professional practice act and
163 also find that appropriate, reasonable attempts were made to
164 obtain a patient release. Notwithstanding the foregoing, the
165 department need not attempt to obtain a patient release when
166 investigating an offense involving the inappropriate
167 prescribing, overprescribing, or diversion of controlled
168 substances and the offense involves a pain-management clinic.
169 The department may obtain patient records without patient
170 authorization or subpoena from any pain-management clinic
171 required to be licensed if the department has probable cause to
172 believe that a violation of any provision of s. 458.3265 or s.
173 459.0137 is occurring or has occurred and reasonably believes
174 that obtaining such authorization is not feasible due to the

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

175 volume of the dispensing and prescribing activity involving
176 controlled substances and that obtaining patient authorization
177 or the issuance of a subpoena would jeopardize the
178 investigation.
179 2. The department may obtain patient records and insurance
180 information pursuant to a subpoena without written authorization
181 from the patient if the department and the probable cause panel
182 of the appropriate board, if any, find reasonable cause to
183 believe that a health care practitioner has provided inadequate
184 medical care based on termination of insurance and also find
185 that appropriate, reasonable attempts were made to obtain a
186 patient release.
187 3. The department may obtain patient records, billing
188 records, insurance information, provider contracts, and all
189 attachments thereto pursuant to a subpoena without written
190 authorization from the patient if the department and probable
191 cause panel of the appropriate board, if any, find reasonable
192 cause to believe that a health care practitioner has submitted a
193 claim, statement, or bill using a billing code that would result
194 in payment greater in amount than would be paid using a billing
195 code that accurately describes the services performed, requested
196 payment for services that were not performed by that health care
197 practitioner, used information derived from a written report of
198 an automobile accident generated pursuant to chapter 316 to
199 solicit or obtain patients personally or through an agent
200 regardless of whether the information is derived directly from
201 the report or a summary of that report or from another person,
202 solicited patients fraudulently, received a kickback as defined
203 in s. 456.054, violated the patient brokering provisions of s.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

204 817.505, or presented or caused to be presented a false or
205 fraudulent insurance claim within the meaning of s.
206 817.234(1)(a), and also find that, within the meaning of s.
207 817.234(1)(a), patient authorization cannot be obtained because
208 the patient cannot be located or is deceased, incapacitated, or
209 suspected of being a participant in the fraud or scheme, and if
210 the subpoena is issued for specific and relevant records.
211 4. Notwithstanding subparagraphs 1.-3., when the department
212 investigates a professional liability claim or undertakes action
213 pursuant to s. 456.049 or s. 627.912, the department may obtain
214 patient records pursuant to a subpoena without written
215 authorization from the patient if the patient refuses to
216 cooperate or if the department attempts to obtain a patient
217 release and the failure to obtain the patient records would be
218 detrimental to the investigation.
219 Section 3. Subsections (4), (5), and (6) of section
220 458.309, Florida Statutes, are repealed.
221 Section 4. Section 458.3265, Florida Statutes, is created
222 to read:
223 458.3265 Pain-management clinics.—
224 (1) REGISTRATION.—
225 (a) All privately owned pain-management clinics,
226 facilities, or offices, hereinafter referred to as “clinics,”
227 which advertise in any medium for any type of pain-management
228 services, or employ a physician who is primarily engaged in the
229 treatment of pain by prescribing or dispensing controlled
230 substance medications, must register with the department unless:
231 1. That clinic is licensed as a facility pursuant to
232 chapter 395;

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

233 2. The majority of the physicians who provide services in
234 the clinic primarily provide surgical services;
235 3. The clinic is owned by a publicly held corporation whose
236 shares are traded on a national exchange or on the over-the-
237 counter market and whose total assets at the end of the
238 corporation's most recent fiscal quarter exceeded $50 million;
239 4. The clinic is affiliated with an accredited medical
240 school at which training is provided for medical students,
241 residents, or fellows;
242 5. The clinic does not prescribe or dispense controlled
243 substances for the treatment of pain; or
244 6. The clinic is owned by a corporate entity exempt from
245 federal taxation under 26 U.S.C. s. 501(c)(3).
246 (b) Each clinic location shall be registered separately
247 regardless of whether the clinic is operated under the same
248 business name or management as another clinic.
249 (c) As a part of registration, a clinic must designate a
250 physician who is responsible for complying with all requirements
251 related to registration and operation of the clinic in
252 compliance with this section. Within 10 days after termination
253 of a designated physician, the clinic must notify the department
254 of the identity of another designated physician for that clinic.
255 The designated physician shall have a full, active, and
256 unencumbered license under this chapter or chapter 459 and shall
257 practice at the clinic location for which the physician has
258 assumed responsibility. Failing to have a licensed designated
259 physician practicing at the location of the registered clinic
260 may be the basis for a summary suspension of the clinic
261 registration certificate as described in s. 456.073(8) for a

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

262 license or s. 120.60(6).
263 (d) The department shall deny registration to any clinic
264 that is not fully owned by a physician licensed under this
265 chapter or chapter 459 or a group of physicians, each of whom is
266 licensed under this chapter or chapter 459; or that is not a
267 health care clinic licensed under part X of chapter 400.
268 (e) The department shall deny registration to any pain-
269 management clinic owned by or with any contractual or employment
270 relationship with a physician:
271 1. Whose Drug Enforcement Administration number has ever
272 been revoked.
273 2. Whose application for a license to prescribe, dispense,
274 or administer a controlled substance has been denied by any
275 jurisdiction.
276 3. Who has been convicted of or plead guilty or nolo
277 contendere to, regardless of adjudication, an offense that
278 constitutes a felony for receipt of illicit and diverted drugs,
279 including a controlled substance listed in Schedule I, Schedule
280 II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in
281 this state, any other state, or the United States.
282 (f) If the department finds that a pain-management clinic
283 does not meet the requirement of paragraph (d) or is owned,
284 directly or indirectly, by a person meeting any criteria listed
285 in paragraph (e), the department shall revoke the certificate of
286 registration previously issued by the department. As determined
287 by rule, the department may grant an exemption to denying a
288 registration or revoking a previously issued registration if
289 more than 10 years have elapsed since adjudication. As used in
290 this subsection, the term “convicted” includes an adjudication

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

291 of guilt following a plea of guilty or nolo contendere or the
292 forfeiture of a bond when charged with a crime.
293 (g) The department may revoke the clinic's certificate of
294 registration and prohibit all physicians associated with that
295 pain-management clinic from practicing at that clinic location
296 based upon an annual inspection and evaluation of the factors
297 described in subsection (3).
298 (h) If the registration of a pain-management clinic is
299 revoked or suspended, the designated physician of the pain-
300 management clinic, the owner or lessor of the pain-management
301 clinic property, the manager, and the proprietor shall cease to
302 operate the facility as a pain-management clinic as of the
303 effective date of the suspension or revocation.
304 (i) If a pain-management clinic registration is revoked or
305 suspended, the designated physician of the pain-management
306 clinic, the owner or lessor of the clinic property, the manager,
307 or the proprietor is responsible for removing all signs and
308 symbols identifying the premises as a pain-management clinic.
309 (j) Upon the effective date of the suspension or
310 revocation, the designated physician of the pain-management
311 clinic shall advise the department of the disposition of the
312 medicinal drugs located on the premises. The disposition is
313 subject to the supervision and approval of the department.
314 Medicinal drugs that are purchased or held by a pain-management
315 clinic that is not registered may be deemed adulterated pursuant
316 to s. 499.006.
317 (k) If the clinic's registration is revoked, any person
318 named in the registration documents of the pain-management
319 clinic, including persons owning or operating the pain-

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

320 management clinic, may not, as an individual or as a part of a
321 group, apply to operate a pain-management clinic for 5 years
322 after the date the registration is revoked.
323 (l) The period of suspension for the registration of a pain
324 management clinic shall be prescribed by the department, but may
325 not exceed 1 year.
326 (m) A change of ownership of a registered pain-management
327 clinic requires submission of a new registration application.
328 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
329 apply to any physician who provides professional services in a
330 pain-management clinic that is required to be registered in
331 subsection (1).
332 (a) A physician may not practice medicine in a pain-
333 management clinic, as described in subsection (4), if:
334 1. The pain-management clinic is not registered with the
335 department as required by this section; or
336 2. Effective July 1, 2012, the physician has not
337 successfully completed a pain medicine fellowship that is
338 accredited by the Accreditation Council for Graduate Medical
339 Education or a pain medicine residency that is accredited by the
340 Accreditation Council for Graduate Medical Education or, prior
341 to July 1, 2012, does not comply with rules adopted by the
342 board.
343
344 Any physician who qualifies to practice medicine in a pain-
345 management clinic pursuant to rules adopted by the Board of
346 Medicine as of July 1, 2012, may continue to practice medicine
347 in a pain-management clinic as long as the physician continues
348 to meet the qualifications set forth in the board rules. A

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

349 physician who violates this paragraph is subject to disciplinary
350 action by his or her appropriate medical regulatory board.
351 (b) A person may not dispense any medication, including a
352 controlled substance, on the premises of a registered pain-
353 management clinic unless he or she is a physician licensed under
354 this chapter or chapter 459.
355 (c) A physician must perform a physical examination of a
356 patient on the same day that he or she dispenses or prescribes a
357 controlled substance to a patient at a pain-management clinic.
358 If the physician prescribes or dispenses more than a 72-hour
359 dose of controlled substances for the treatment of chronic
360 nonmalignant pain, the physician must document in the patient's
361 record the reason for prescribing or dispensing that quantity.
362 (d) A physician authorized to prescribe controlled
363 substances who practices at a pain-management clinic is
364 responsible for maintaining the control and security of his or
365 her prescription blanks and any other method used for
366 prescribing controlled substance pain medication. The physician
367 shall comply with the requirements for counterfeit-resistant
368 prescription blanks in s. 893.065 and the rules adopted pursuant
369 to that section. The physician shall notify in writing the
370 department within 24 hours following any theft or loss of a
371 prescription blank or breach of any other method for prescribing
372 pain medication.
373 (e) The designated physician of a pain-management clinic
374 shall notify the applicable board in writing of the date of
375 termination of employment within 10 days after terminating his
376 or her employment with a pain-management clinic that is required
377 to be registered under subsection (1).

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

378 (3) INSPECTION.—
379 (a) The department shall inspect the pain-management clinic
380 annually, including a review of the patient records, to ensure
381 that it complies with this section and the rules of the Board of
382 Medicine adopted pursuant to subsection (4) unless the clinic is
383 accredited by a nationally recognized accrediting agency
384 approved by the Board of Medicine.
385 (b) During an onsite inspection, the department shall make
386 a reasonable attempt to discuss each violation with the owner or
387 designated physician of the pain-management clinic before
388 issuing a formal written notification.
389 (c) Any action taken to correct a violation shall be
390 documented in writing by the owner or designated physician of
391 the pain-management clinic and verified by followup visits by
392 departmental personnel.
393 (4) RULEMAKING.—
394 (a) The department shall adopt rules necessary to
395 administer the registration and inspection of pain-management
396 clinics which establish the specific requirements, procedures,
397 forms, and fees.
398 (b) The department shall adopt a rule defining what
399 constitutes practice by a designated physician at the clinic
400 location for which the physician has assumed responsibility, as
401 set forth in subsection (1). When adopting the rule, the
402 department shall consider the number of clinic employees, the
403 location of the pain-management clinic, the clinic's hours of
404 operation, and the amount of controlled substances being
405 prescribed, dispensed, or administered at the pain-management
406 clinic.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

407 (c) The Board of Medicine shall adopt a rule establishing
408 the maximum number of prescriptions for Schedule II or Schedule
409 III controlled substances or the controlled substance Alprazolam
410 which may be written at any one registered pain-management
411 clinic during any 24-hour period.
412 (d) The Board of Medicine shall adopt rules setting forth
413 standards of practice for physicians practicing in privately
414 owned pain-management clinics that primarily engage in the
415 treatment of pain by prescribing or dispensing controlled
416 substance medications. Such rules shall address, but need not be
417 limited to:
418 1. Facility operations;
419 2. Physical operations;
420 3. Infection control requirements;
421 4. Health and safety requirements;
422 5. Quality assurance requirements;
423 6. Patient records;
424 7. Training requirements for all facility health care
425 practitioners who are not regulated by another board;
426 8. Inspections; and
427 9. Data collection and reporting requirements.
428
429 A physician is primarily engaged in the treatment of pain by
430 prescribing or dispensing controlled substance medications when
431 the majority of the patients seen are prescribed or dispensed
432 controlled substance medications for the treatment of chronic
433 nonmalignant pain. Chronic nonmalignant pain is pain unrelated
434 to cancer which persists beyond the usual course of the disease
435 or the injury that is the cause of the pain or more than 90 days

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

436 after surgery.
437 (5) PENALTIES; ENFORCEMENT.—
438 (a) The department may impose an administrative fine on the
439 clinic of up to $5,000 per violation for violating the
440 requirements of this section; chapter 499, the Florida Drug and
441 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
442 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
443 Abuse Prevention and Control Act; chapter 893, the Florida
444 Comprehensive Drug Abuse Prevention and Control Act; or the
445 rules of the department. In determining whether a penalty is to
446 be imposed, and in fixing the amount of the fine, the department
447 shall consider the following factors:
448 1. The gravity of the violation, including the probability
449 that death or serious physical or emotional harm to a patient
450 has resulted, or could have resulted, from the pain-management
451 clinic's actions or the actions of the physician, the severity
452 of the action or potential harm, and the extent to which the
453 provisions of the applicable laws or rules were violated.
454 2. What actions, if any, the owner or designated physician
455 took to correct the violations.
456 3. Whether there were any previous violations at the pain-
457 management clinic.
458 4. The financial benefits that the pain-management clinic
459 derived from committing or continuing to commit the violation.
460 (b) Each day a violation continues after the date fixed for
461 termination of the violation as ordered by the department
462 constitutes an additional, separate, and distinct violation.
463 (c) The department may impose a fine and, in the case of an
464 owner-operated pain-management clinic, revoke or deny a pain-

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

465 management clinic's registration, if the clinic's designated
466 physician knowingly and intentionally misrepresents actions
467 taken to correct a violation.
468 (d) An owner or designated physician of a pain-management
469 clinic who concurrently operates an unregistered pain-management
470 clinic is subject to an administrative fine of $5,000 per day.
471 (e) If the owner of a pain-management clinic that requires
472 registration fails to apply to register the clinic upon a
473 change-of-ownership and operates the clinic under the new
474 ownership, the owner is subject to a fine of $5,000.
475 Section 5. Section 458.327, Florida Statutes, is amended to
476 read:
477 458.327 Penalty for violations.—
478 (1) Each of the following acts constitutes a felony of the
479 third degree, punishable as provided in s. 775.082, s. 775.083,
480 or s. 775.084:
481 (a) The practice of medicine or an attempt to practice
482 medicine without a license to practice in Florida.
483 (b) The use or attempted use of a license which is
484 suspended or revoked to practice medicine.
485 (c) Attempting to obtain or obtaining a license to practice
486 medicine by knowing misrepresentation.
487 (d) Attempting to obtain or obtaining a position as a
488 medical practitioner or medical resident in a clinic or hospital
489 through knowing misrepresentation of education, training, or
490 experience.
491 (e) Knowingly operating, owning, or managing a
492 nonregistered pain-management clinic that is required to be
493 registered with the Department of Health pursuant to s.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

494 458.3265(1).
495 (2) Each of the following acts constitutes a misdemeanor of
496 the first degree, punishable as provided in s. 775.082 or s.
497 775.083:
498 (a) Knowingly concealing information relating to violations
499 of this chapter.
500 (b) Making any willfully false oath or affirmation whenever
501 an oath or affirmation is required by this chapter.
502 (c) Referring any patient, for health care goods or
503 services, to a partnership, firm, corporation, or other business
504 entity in which the physician or the physician's employer has an
505 equity interest of 10 percent or more unless, prior to such
506 referral, the physician notifies the patient of his or her
507 financial interest and of the patient's right to obtain such
508 goods or services at the location of the patient's choice. This
509 section does not apply to the following types of equity
510 interest:
511 1. The ownership of registered securities issued by a
512 publicly held corporation or the ownership of securities issued
513 by a publicly held corporation, the shares of which are traded
514 on a national exchange or the over-the-counter market;
515 2. A physician's own practice, whether he or she is a sole
516 practitioner or part of a group, when the health care good or
517 service is prescribed or provided solely for the physician's own
518 patients and is provided or performed by the physician or under
519 the physician's supervision; or
520 3. An interest in real property resulting in a landlord-
521 tenant relationship between the physician and the entity in
522 which the equity interest is held, unless the rent is

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

523 determined, in whole or in part, by the business volume or
524 profitability of the tenant or is otherwise unrelated to fair
525 market value.
526 (d) Leading the public to believe that one is licensed as a
527 medical doctor, or is engaged in the licensed practice of
528 medicine, without holding a valid, active license.
529 (e) Practicing medicine or attempting to practice medicine
530 with an inactive or delinquent license.
531 (f) Knowingly prescribing or dispensing, or causing to be
532 prescribed or dispensed, controlled substances in a
533 nonregistered pain-management clinic that is required to be
534 registered with the Department of Health pursuant to s.
535 458.3265(1).
536 Section 6. Paragraphs (oo), (pp), and (qq) are added to
537 subsection (1) of section 458.331, Florida Statutes, to read:
538 458.331 Grounds for disciplinary action; action by the
539 board and department.—
540 (1) The following acts constitute grounds for denial of a
541 license or disciplinary action, as specified in s. 456.072(2):
542 (oo) Applicable to a licensee who serves as the designated
543 physician of a pain-management clinic as defined in s. 458.3265
544 or s. 459.0137:
545 1. Registering a pain-management clinic through
546 misrepresentation or fraud;
547 2. Procuring, or attempting to procure, the registration of
548 a pain-management clinic for any other person by making or
549 causing to be made, any false representation;
550 3. Failing to comply with any requirement of chapter 499,
551 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

552 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
553 the Drug Abuse Prevention and Control Act; or chapter 893, the
554 Florida Comprehensive Drug Abuse Prevention and Control Act;
555 4. Being convicted or found guilty of, regardless of
556 adjudication to, a felony or any other crime involving moral
557 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
558 the courts of this state, of any other state, or of the United
559 States;
560 5. Being convicted of, or disciplined by a regulatory
561 agency of the Federal Government or a regulatory agency of
562 another state for any offense that would constitute a violation
563 of this chapter;
564 6. Being convicted of, or entering a plea of guilty or nolo
565 contendere to, regardless of adjudication, a crime in any
566 jurisdiction of the courts of this state, of any other state, or
567 of the United States which relates to the practice of, or the
568 ability to practice, a licensed health care profession;
569 7. Being convicted of, or entering a plea of guilty or nolo
570 contendere to, regardless of adjudication, a crime in any
571 jurisdiction of the courts of this state, of any other state, or
572 of the United States which relates to health care fraud;
573 8. Dispensing any medicinal drug based upon a communication
574 that purports to be a prescription as defined in s. 465.003(14)
575 or s. 893.02 if the dispensing practitioner knows or has reason
576 to believe that the purported prescription is not based upon a
577 valid practitioner-patient relationship; or
578 9. Failing to timely notify the board of the date of his or
579 her termination from a pain-management clinic as required by s.
580 458.3265(2).

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

581 (pp) Failing to timely notify the department of the theft
582 of prescription blanks from a pain-management clinic or a breach
583 of other methods for prescribing within 24 hours as required by
584 s. 458.3265(2).
585 (qq) Promoting or advertising through any communication
586 media the use, sale, or dispensing of any controlled substance
587 appearing on any schedule in chapter 893.
588 Section 7. Subsections (3), (4), and (5) of section
589 459.005, Florida Statutes, are repealed.
590 Section 8. Section 459.0137, Florida Statutes, is created
591 to read:
592 459.0137 Pain-management clinics.—
593 (1) REGISTRATION.—
594 (a) All privately owned pain-management clinics,
595 facilities, or offices, hereinafter referred to as "clinics,"
596 which advertise in any medium for any type of pain-management
597 services, or employ an osteopathic physician who is primarily
598 engaged in the treatment of pain by prescribing or dispensing
599 controlled substance medications, must register with the
600 department unless:
601 1. That clinic is licensed as a facility pursuant to
602 chapter 395;
603 2. The majority of the physicians who provide services in
604 the clinic primarily provide surgical services;
605 3. The clinic is owned by a publicly held corporation whose
606 shares are traded on a national exchange or on the over-the-
607 counter market and whose total assets at the end of the
608 corporation's most recent fiscal quarter exceeded $50 million;
609 4. The clinic is affiliated with an accredited medical

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

610 school at which training is provided for medical students,
611 residents, or fellows;
612 5. The clinic does not prescribe or dispense controlled
613 substances for the treatment of pain; or
614 6. The clinic is owned by a corporate entity exempt from
615 federal taxation under 26 U.S.C. s. 501(c)(3).
616 (b) Each clinic location shall be registered separately
617 regardless of whether the clinic is operated under the same
618 business name or management as another clinic.
619 (c) As a part of registration, a clinic must designate an
620 osteopathic physician who is responsible for complying with all
621 requirements related to registration and operation of the clinic
622 in compliance with this section. Within 10 days after
623 termination of a designated osteopathic physician, the clinic
624 must notify the department of the identity of another designated
625 physician for that clinic. The designated physician shall have a
626 full, active, and unencumbered license under chapter 458 or this
627 chapter and shall practice at the clinic location for which the
628 physician has assumed responsibility. Failing to have a licensed
629 designated osteopathic physician practicing at the location of
630 the registered clinic may be the basis for a summary suspension
631 of the clinic registration certificate as described in s.
632 456.073(8) for a license or s. 120.60(6).
633 (d) The department shall deny registration to any clinic
634 that is not fully owned by a physician licensed under chapter
635 458 or this chapter or a group of physicians, each of whom is
636 licensed under chapter 458 or this chapter; or that is not a
637 health care clinic licensed under part X of chapter 400.
638 (e) The department shall deny registration to any pain-

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

639 management clinic owned by or with any contractual or employment
640 relationship with a physician:
641 1. Whose Drug Enforcement Administration number has ever
642 been revoked.
643 2. Whose application for a license to prescribe, dispense,
644 or administer a controlled substance has been denied by any
645 jurisdiction.
646 3. Who has been convicted of or plead guilty or nolo
647 contendere to, regardless of adjudication, an offense that
648 constitutes a felony for receipt of illicit and diverted drugs,
649 including a controlled substance listed in Schedule I, Schedule
650 II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in
651 this state, any other state, or the United States.
652 (f) If the department finds that a pain-management clinic
653 does not meet the requirement of paragraph (d) or is owned,
654 directly or indirectly, by a person meeting any criteria listed
655 in paragraph (e), the department shall revoke the certificate of
656 registration previously issued by the department. As determined
657 by rule, the department may grant an exemption to denying a
658 registration or revoking a previously issued registration if
659 more than 10 years have elapsed since adjudication. As used in
660 this subsection, the term "convicted" includes an adjudication
661 of guilt following a plea of guilty or nolo contendere or the
662 forfeiture of a bond when charged with a crime.
663 (g) The department may revoke the clinic's certificate of
664 registration and prohibit all physicians associated with that
665 pain-management clinic from practicing at that clinic location
666 based upon an annual inspection and evaluation of the factors
667 described in subsection (3).

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

668 (h) If the registration of a pain-management clinic is
669 revoked or suspended, the designated physician of the pain-
670 management clinic, the owner or lessor of the pain-management
671 clinic property, the manager, and the proprietor shall cease to
672 operate the facility as a pain-management clinic as of the
673 effective date of the suspension or revocation.
674 (i) If a pain-management clinic registration is revoked or
675 suspended, the designated physician of the pain-management
676 clinic, the owner or lessor of the clinic property, the manager,
677 or the proprietor is responsible for removing all signs and
678 symbols identifying the premises as a pain-management clinic.
679 (j) Upon the effective date of the suspension or
680 revocation, the designated physician of the pain-management
681 clinic shall advise the department of the disposition of the
682 medicinal drugs located on the premises. The disposition is
683 subject to the supervision and approval of the department.
684 Medicinal drugs that are purchased or held by a pain-management
685 clinic that is not registered may be deemed adulterated pursuant
686 to s. 499.006.
687 (k) If the clinic's registration is revoked, any person
688 named in the registration documents of the pain-management
689 clinic, including persons owning or operating the pain-
690 management clinic, may not as an individual or as a part of a
691 group, make application for a permit to operate a pain-
692 management clinic for 5 years after the date the registration is
693 revoked.
694 (l) The period of suspension for the registration of a pain
695 management clinic shall be prescribed by the department, but may
696 not exceed 1 year.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

697 (m) A change of ownership of a registered pain-management
698 clinic requires submission of a new registration application.
699 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
700 apply to any osteopathic physician who provides professional
701 services in a pain-management clinic that is required to be
702 registered in subsection (1).
703 (a) An osteopathic physician may not practice medicine in a
704 pain-management clinic, as described in subsection (4), if:
705 1. The pain-management clinic is not registered with the
706 department as required by this section; or
707 2. Effective July 1, 2012, the physician has not
708 successfully completed a pain medicine fellowship that is
709 accredited by the Accreditation Council for Graduate Medical
710 Education or the American Osteopathic Association or a pain
711 medicine residency that is accredited by the Accreditation
712 Council for Graduate Medical Education or the American
713 Osteopathic Association or, prior to July 1, 2012, does not
714 comply with rules adopted by the board.
715
716 Any physician who qualifies to practice medicine in a pain-
717 management clinic pursuant to rules adopted by the Board of
718 Osteopathic Medicine as of July 1, 2012, may continue to
719 practice medicine in a pain-management clinic as long as the
720 physician continues to meet the qualifications set forth in the
721 board rules. An osteopathic physician who violates this
722 paragraph is subject to disciplinary action by his or her
723 appropriate medical regulatory board.
724 (b) A person may not dispense any medication, including a
725 controlled substance, on the premises of a registered pain-

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

726 management clinic unless he or she is a physician licensed under
727 this chapter or chapter 458.
728 (c) An osteopathic physician must perform a physical
729 examination of a patient on the same day that he or she
730 dispenses or prescribes a controlled substance to a patient at a
731 pain-management clinic. If the osteopathic physician prescribes
732 or dispenses more than a 72-hour dose of controlled substances
733 for the treatment of chronic nonmalignant pain, the osteopathic
734 physician must document in the patient's record the reason for
735 prescribing or dispensing that quantity.
736 (d) An osteopathic physician authorized to prescribe
737 controlled substances who practices at a pain-management clinic
738 is responsible for maintaining the control and security of his
739 or her prescription blanks and any other method used for
740 prescribing controlled substance pain medication. The
741 osteopathic physician shall comply with the requirements for
742 counterfeit-resistant prescription blanks in s. 893.065 and the
743 rules adopted pursuant to that section. The osteopathic
744 physician shall notify in writing the department within 24 hours
745 following any theft or loss of a prescription blank or breach of
746 any other method for prescribing pain medication.
747 (e) The designated osteopathic physician of a pain-
748 management clinic shall notify the applicable board in writing
749 of the date of termination of employment within 10 days after
750 terminating his or her employment with a pain-management clinic
751 that is required to be registered under subsection (1).
752 (3) INSPECTION.—
753 (a) The department shall inspect the pain-management clinic
754 annually, including a review of the patient records, to ensure

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

755 that it complies with this section and the rules of the Board of
756 Osteopathic Medicine adopted pursuant to subsection (4) unless
757 the clinic is accredited by a nationally recognized accrediting
758 agency approved by the Board of Osteopathic Medicine.
759 (b) During an onsite inspection, the department shall make
760 a reasonable attempt to discuss each violation with the owner or
761 designated physician of the pain-management clinic before
762 issuing a formal written notification.
763 (c) Any action taken to correct a violation shall be
764 documented in writing by the owner or designated physician of
765 the pain-management clinic and verified by followup visits by
766 departmental personnel.
767 (4) RULEMAKING.—
768 (a) The department shall adopt rules necessary to
769 administer the registration and inspection of pain-management
770 clinics which establish the specific requirements, procedures,
771 forms, and fees.
772 (b) The department shall adopt a rule defining what
773 constitutes practice by a designated osteopathic physician at
774 the clinic location for which the physician has assumed
775 responsibility, as set forth in subsection (1). When adopting
776 the rule, the department shall consider the number of clinic
777 employees, the location of the pain-management clinic, the
778 clinic’s hours of operation, and the amount of controlled
779 substances being prescribed, dispensed, or administered at the
780 pain-management clinic.
781 (c) The Board of Osteopathic Medicine shall adopt a rule
782 establishing the maximum number of prescriptions for Schedule II
783 or Schedule III controlled substances or the controlled

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

784 substance Alprazolam which may be written at any one registered
785 pain-management clinic during any 24-hour period.
786 (d) The Board of Osteopathic Medicine shall adopt rules
787 setting forth standards of practice for osteopathic physicians
788 practicing in privately owned pain-management clinics that
789 primarily engage in the treatment of pain by prescribing or
790 dispensing controlled substance medications. Such rules shall
791 address, but need not be limited to:
792 1. Facility operations;
793 2. Physical operations;
794 3. Infection control requirements;
795 4. Health and safety requirements;
796 5. Quality assurance requirements;
797 6. Patient records;
798 7. Training requirements for all facility health care
799 practitioners who are not regulated by another board;
800 8. Inspections; and
801 9. Data collection and reporting requirements.
802
803 An osteopathic physician is primarily engaged in the treatment
804 of pain by prescribing or dispensing controlled substance
805 medications when the majority of the patients seen are
806 prescribed or dispensed controlled substance medications for the
807 treatment of chronic nonmalignant pain. Chronic nonmalignant
808 pain is pain unrelated to cancer which persists beyond the usual
809 course of the disease or the injury that is the cause of the
810 pain or more than 90 days after surgery.
811 (5) PENALTIES; ENFORCEMENT.—
812 (a) The department may impose an administrative fine on the

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

813 clinic of up to $5,000 per violation for violating the
814 requirements of this section; chapter 499, the Florida Drug and
815 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
816 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
817 Abuse Prevention and Control Act; chapter 893, the Florida
818 Comprehensive Drug Abuse Prevention and Control Act; or the
819 rules of the department. In determining whether a penalty is to
820 be imposed, and in fixing the amount of the fine, the department
821 shall consider the following factors:
822 1. The gravity of the violation, including the probability
823 that death or serious physical or emotional harm to a patient
824 has resulted, or could have resulted, from the pain-management
825 clinic's actions or the actions of the osteopathic physician,
826 the severity of the action or potential harm, and the extent to
827 which the provisions of the applicable laws or rules were
828 violated.
829 2. What actions, if any, the owner or designated
830 osteopathic physician took to correct the violations.
831 3. Whether there were any previous violations at the pain-
832 management clinic.
833 4. The financial benefits that the pain-management clinic
834 derived from committing or continuing to commit the violation.
835 (b) Each day a violation continues after the date fixed for
836 termination of the violation as ordered by the department
837 constitutes an additional, separate, and distinct violation.
838 (c) The department may impose a fine and, in the case of an
839 owner-operated pain-management clinic, revoke or deny a pain-
840 management clinic's registration, if the clinic's designated
841 osteopathic physician knowingly and intentionally misrepresents

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

842 actions taken to correct a violation.
843 (d) An owner or designated osteopathic physician of a pain-
844 management clinic who concurrently operates an unregistered
845 pain-management clinic is subject to an administrative fine of
846 $5,000 per day.
847 (e) If the owner of a pain-management clinic that requires
848 registration fails to apply to register the clinic upon a
849 change-of-ownership and operates the clinic under the new
850 ownership, the owner is subject to a fine of $5,000.
851 Section 9. Subsections (1) and (2) of section 459.013,
852 Florida Statutes, are amended to read:
853 459.013 Penalty for violations.—
854 (1) Each of the following acts constitutes a felony of the
855 third degree, punishable as provided in s. 775.082, s. 775.083,
856 or s. 775.084:
857 (a) The practice of osteopathic medicine, or an attempt to
858 practice osteopathic medicine, without an active license or
859 certificate issued pursuant to this chapter.
860 (b) The practice of osteopathic medicine by a person
861 holding a limited license, osteopathic faculty certificate, or
862 other certificate issued under this chapter beyond the scope of
863 practice authorized for such licensee or certificateholder.
864 (c) Attempting to obtain or obtaining a license to practice
865 osteopathic medicine by knowing misrepresentation.
866 (d) Attempting to obtain or obtaining a position as an
867 osteopathic medical practitioner or osteopathic medical resident
868 in a clinic or hospital through knowing misrepresentation of
869 education, training, or experience.
870 (e) Knowingly operating, owning, or managing a

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

871 nonregistered pain-management clinic that is required to be
872 registered with the Department of Health pursuant to s.
873 459.0137(1).
874 (2) Each of the following acts constitutes a misdemeanor of
875 the first degree, punishable as provided in s. 775.082 or s.
876 775.083:
877 (a) Knowingly concealing information relating to violations
878 of this chapter.
879 (b) Making any willfully false oath or affirmation whenever
880 an oath or affirmation is required by this chapter.
881 (c) The practice of medicine as a resident or intern
882 without holding a valid current registration pursuant to s.
883 459.021.
884 (d) Knowingly prescribing or dispensing, or causing to be
885 prescribed or dispensed, controlled substances in a
886 nonregistered pain-management clinic that is required to be
887 registered with the Department of Health pursuant to s.
888 459.0137(1).
889 Section 10. Paragraphs (qq), (rr), and (ss) are added to
890 subsection (1) of section 459.015, Florida Statutes, to read:
891 459.015 Grounds for disciplinary action; action by the
892 board and department.—
893 (1) The following acts constitute grounds for denial of a
894 license or disciplinary action, as specified in s. 456.072(2):
895 (qq) Applicable to a licensee who serves as the designated
896 physician of a pain-management clinic as defined in s. 458.3265
897 or s. 459.0137:
898 1. Registering a pain-management clinic through
899 misrepresentation or fraud;

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

900 2. Procuring, or attempting to procure, the registration of
901 a pain-management clinic for any other person by making or
902 causing to be made, any false representation;
903 3. Failing to comply with any requirement of chapter 499,
904 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
905 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
906 the Drug Abuse Prevention and Control Act; or chapter 893, the
907 Florida Comprehensive Drug Abuse Prevention and Control Act;
908 4. Being convicted or found guilty of, regardless of
909 adjudication to, a felony or any other crime involving moral
910 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
911 the courts of this state, of any other state, or of the United
912 States;
913 5. Being convicted of, or disciplined by a regulatory
914 agency of the Federal Government or a regulatory agency of
915 another state for any offense that would constitute a violation
916 of this chapter;
917 6. Being convicted of, or entering a plea of guilty or nolo
918 contendere to, regardless of adjudication, a crime in any
919 jurisdiction of the courts of this state, of any other state, or
920 of the United States which relates to the practice of, or the
921 ability to practice, a licensed health care profession;
922 7. Being convicted of, or entering a plea of guilty or nolo
923 contendere to, regardless of adjudication, a crime in any
924 jurisdiction of the courts of this state, of any other state, or
925 of the United States which relates to health care fraud;
926 8. Dispensing any medicinal drug based upon a communication
927 that purports to be a prescription as defined in s. 465.003(14)
928 or s. 893.02 if the dispensing practitioner knows or has reason

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

929 to believe that the purported prescription is not based upon a
930 valid practitioner-patient relationship; or
931 9. Failing to timely notify the board of the date of his or
932 her termination from a pain-management clinic as required by s.
933 459.0137(2).
934 (rr) Failing to timely notify the department of the theft
935 of prescription blanks from a pain-management clinic or a breach
936 of other methods for prescribing within 24 hours as required by
937 s. 459.0137(2).
938 (ss) Promoting or advertising through any communication
939 media the use, sale, or dispensing of any controlled substance
940 appearing on any schedule in chapter 893.
941 Section 11. Subsection (1) of section 465.0276, Florida
942 Statutes, is amended to read:
943 465.0276 Dispensing practitioner.—
944 (1)(a) A person may not dispense medicinal drugs unless
945 licensed as a pharmacist or otherwise authorized under this
946 chapter to do so, except that a practitioner authorized by law
947 to prescribe drugs may dispense such drugs to her or his
948 patients in the regular course of her or his practice in
949 compliance with this section.
950 (b) A practitioner registered under this section may not
951 dispense more than a 72-hour supply of a controlled substance
952 listed in Schedule II, Schedule III, Schedule IV, or Schedule V
953 of s. 893.03 for any patient who pays for the medication by
954 cash, check, or credit card in a clinic registered under s.
955 458.3265 or s. 459.0137. A practitioner who violates this
956 paragraph commits a felony of the third degree, punishable as
957 provided in s. 775.082, s. 775.083, or s. 775.084. This

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

958 paragraph does not apply to:
959 1. A practitioner who dispenses medication to a workers'
960 compensation patient pursuant to chapter 440.
961 2. A practitioner who dispenses medication to an insured
962 patient who pays by cash, check, or credit card to cover any
963 applicable copayment or deductible.
964 3. The dispensing of complimentary packages of medicinal
965 drugs to the practitioner's own patients in the regular course
966 of her or his practice without the payment of a fee or
967 remuneration of any kind, whether direct or indirect, as
968 provided in subsection (5).
969 Section 12. Paragraph (j) is added to subsection (1),
970 paragraph (d) is added to subsection (2), and paragraph (f) is
971 added to subsection (7) of section 893.055, Florida Statutes, to
972 read:
973 893.055 Prescription drug monitoring program.—
974 (1) As used in this section, the term:
975 (j) "Program manager" means an employee of or a person
976 contracted by the Department of Health who is designated to
977 ensure the integrity of the prescription drug monitoring program
978 in accordance with the requirements established in paragraphs
979 (2)(a) and (b).
980 (2)
981 (d) The program manager shall work with professional health
982 care licensure boards and the stakeholders listed in paragraph
983 (b) to develop rules appropriate for identifying indicators of
984 controlled substance abuse.
985 (7)
986 (f) The program manager, upon determining a pattern

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

987 consistent with the rules established under paragraph (2)(c) and
988 having cause to believe a violation of s. 893.13(7)(a)8.,
989 (8)(a), or (8)(b) has occurred, may provide relevant information
990 to the applicable law enforcement agency.
991 Section 13. Subsections (4), (5), and (6) of section
992 893.0551, Florida Statutes, are renumbered as subsections (5),
993 (6), and (7), respectively, and subsection (4) is added to that
994 section, to read:
995 893.0551 Public records exemption for the prescription drug
996 monitoring program.—
997 (4) The department shall disclose such confidential and
998 exempt information to the applicable law enforcement agency in
999 accordance with s. 893.055(7)(b)2. The law enforcement agency
1000 may disclose the confidential and exempt information received
1001 from the department to a criminal justice agency as defined in
1002 s. 119.011 as part of an active investigation that is specific
1003 to a violation of s. 893.13(7)(a)8., s. 893.13(8)(a), or s.
1004 893.13(8)(b).
1005 Section 14. This act shall take effect October 1, 2010.

CODING: Words ~~stricken~~ are deletions; words underlined are additions.