

Amendment No.

CHAMBER ACTION

Senate

House

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1 Representative Skidmore offered the following:

2

3 **Amendment (with title amendment)**

4 Remove everything after the enacting clause and insert:

5 Section 1. Subsection (5) of section 456.037, Florida

6 Statutes, is amended to read:

7 456.037 Business establishments; requirements for active
8 status licenses; delinquency; discipline; applicability.-

9 (5) This section applies to any business establishment
10 registered, permitted, or licensed by the department to do
11 business. Business establishments include, but are not limited
12 to, dental laboratories, electrology facilities, massage
13 establishments, ~~and~~ pharmacies, and pain-management clinics
14 required to be registered under s. 458.3265 or s. 459.0137.

15 Section 2. Paragraph (a) of subsection (9) of section
16 456.057, Florida Statutes, is amended to read:

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17 456.057 Ownership and control of patient records; report
18 or copies of records to be furnished.-

19 (9) (a) 1. The department may obtain patient records
20 pursuant to a subpoena without written authorization from the
21 patient if the department and the probable cause panel of the
22 appropriate board, if any, find reasonable cause to believe that
23 a health care practitioner has excessively or inappropriately
24 prescribed any controlled substance specified in chapter 893 in
25 violation of this chapter or any professional practice act or
26 that a health care practitioner has practiced his or her
27 profession below that level of care, skill, and treatment
28 required as defined by this chapter or any professional practice
29 act and also find that appropriate, reasonable attempts were
30 made to obtain a patient release. Notwithstanding the foregoing,
31 the department need not attempt to obtain a patient release when
32 investigating an offense involving the inappropriate
33 prescribing, overprescribing, or diversion of controlled
34 substances and the offense involves a pain-management clinic.
35 The department may obtain patient records without patient
36 authorization or subpoena from any pain-management clinic
37 required to be licensed if the department has probable cause to
38 believe that a violation of any provision of s. 458.3265 or s.
39 459.0137 is occurring or has occurred and reasonably believes
40 that obtaining such authorization is not feasible due to the
41 volume of the dispensing and prescribing activity involving
42 controlled substances and that obtaining patient authorization
43 or the issuance of a subpoena would jeopardize the
44 investigation.

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45 2. The department may obtain patient records and insurance
46 information pursuant to a subpoena without written authorization
47 from the patient if the department and the probable cause panel
48 of the appropriate board, if any, find reasonable cause to
49 believe that a health care practitioner has provided inadequate
50 medical care based on termination of insurance and also find
51 that appropriate, reasonable attempts were made to obtain a
52 patient release.

53 3. The department may obtain patient records, billing
54 records, insurance information, provider contracts, and all
55 attachments thereto pursuant to a subpoena without written
56 authorization from the patient if the department and probable
57 cause panel of the appropriate board, if any, find reasonable
58 cause to believe that a health care practitioner has submitted a
59 claim, statement, or bill using a billing code that would result
60 in payment greater in amount than would be paid using a billing
61 code that accurately describes the services performed, requested
62 payment for services that were not performed by that health care
63 practitioner, used information derived from a written report of
64 an automobile accident generated pursuant to chapter 316 to
65 solicit or obtain patients personally or through an agent
66 regardless of whether the information is derived directly from
67 the report or a summary of that report or from another person,
68 solicited patients fraudulently, received a kickback as defined
69 in s. 456.054, violated the patient brokering provisions of s.
70 817.505, or presented or caused to be presented a false or
71 fraudulent insurance claim within the meaning of s.
72 817.234(1)(a), and also find that, within the meaning of s.

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73 817.234(1)(a), patient authorization cannot be obtained because
74 the patient cannot be located or is deceased, incapacitated, or
75 suspected of being a participant in the fraud or scheme, and if
76 the subpoena is issued for specific and relevant records.

77 4. Notwithstanding subparagraphs 1.-3., when the
78 department investigates a professional liability claim or
79 undertakes action pursuant to s. 456.049 or s. 627.912, the
80 department may obtain patient records pursuant to a subpoena
81 without written authorization from the patient if the patient
82 refuses to cooperate or if the department attempts to obtain a
83 patient release and the failure to obtain the patient records
84 would be detrimental to the investigation.

85 Section 3. Subsections (4), (5), and (6) of section
86 458.309, Florida Statutes, are repealed.

87 Section 4. Section 458.3265, Florida Statutes, is created
88 to read:

89 458.3265 Pain-management clinics.-

90 (1) REGISTRATION.-

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

97 1. That clinic is licensed as a facility pursuant to
98 chapter 395;

99 2. The majority of the physicians who provide services in
100 the clinic primarily provide surgical services;

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101 3. The physicians who provide services in the clinic
102 primarily provide chiropractic services and do not dispense
103 controlled substances.

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

108 5. The clinic is affiliated with an accredited medical
109 school at which training is provided for medical students,
110 residents, or fellows;

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

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

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

118 (c) As a part of registration, a clinic must designate a
119 physician who is responsible for complying with all requirements
120 related to registration and operation of the clinic in
121 compliance with this section. Within 10 days after termination
122 of a designated physician, the clinic must notify the department
123 of the identity of another designated physician for that clinic.
124 The designated physician shall have a full, active, and
125 unencumbered license under this chapter or chapter 459 and shall
126 practice at the clinic location for which the physician has
127 assumed responsibility. Failing to have a licensed designated
128 physician practicing at the location of the registered clinic

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129 may be the basis for a summary suspension of the clinic
130 registration certificate as described in s. 456.073(8) for a
131 license or s. 120.60(6).

132 (d) The department shall deny registration to any clinic
133 that is not fully owned by a physician licensed under this
134 chapter or chapter 459 or a group of physicians, each of whom is
135 licensed under this chapter or chapter 459; or that is not a
136 health care clinic licensed under part X of chapter 400.

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

140 1. Whose Drug Enforcement Administration number has ever
141 been revoked.

142 2. Whose application for a license to prescribe, dispense,
143 or administer a controlled substance has been denied by any
144 jurisdiction.

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

151 (f) If the department finds that a pain-management clinic
152 does not meet the requirement of paragraph (d) or is owned,
153 directly or indirectly, by a person meeting any criteria listed
154 in paragraph (e), the department shall revoke the certificate of
155 registration previously issued by the department. As determined
156 by rule, the department may grant an exemption to denying a

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157 registration or revoking a previously issued registration if
158 more than 10 years have elapsed since adjudication. As used in
159 this subsection, the term "convicted" includes an adjudication
160 of guilt following a plea of guilty or nolo contendere or the
161 forfeiture of a bond when charged with a crime.

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

167 (h) If the registration of a pain-management clinic is
168 revoked or suspended, the designated physician of the pain-
169 management clinic, the owner or lessor of the pain-management
170 clinic property, the manager, and the proprietor shall cease to
171 operate the facility as a pain-management clinic as of the
172 effective date of the suspension or revocation.

173 (i) If a pain-management clinic registration is revoked or
174 suspended, the designated physician of the pain-management
175 clinic, the owner or lessor of the clinic property, the manager,
176 or the proprietor is responsible for removing all signs and
177 symbols identifying the premises as a pain-management clinic.

178 (j) Upon the effective date of the suspension or
179 revocation, the designated physician of the pain-management
180 clinic shall advise the department of the disposition of the
181 medicinal drugs located on the premises. The disposition is
182 subject to the supervision and approval of the department.
183 Medicinal drugs that are purchased or held by a pain-management

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184 clinic that is not registered may be deemed adulterated pursuant
185 to s. 499.006.

186 (k) If the clinic's registration is revoked, any person
187 named in the registration documents of the pain-management
188 clinic, including persons owning or operating the pain-
189 management clinic, may not, as an individual or as a part of a
190 group, apply to operate a pain-management clinic for 5 years
191 after the date the registration is revoked.

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

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

197 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
198 apply to any physician who provides professional services in a
199 pain-management clinic that is required to be registered in
200 subsection (1).

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

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

205 2. Effective July 1, 2012, the physician has not
206 successfully completed a pain medicine fellowship that is
207 accredited by the Accreditation Council for Graduate Medical
208 Education or a pain medicine residency that is accredited by the
209 Accreditation Council for Graduate Medical Education or does not
210 comply with rules adopted by the Board of Medicine.

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212 A physician who violates this paragraph is subject to
213 disciplinary action by his or her appropriate medical regulatory
214 board.

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

219 (c) A physician must perform a physical examination of a
220 patient on the same day that he or she dispenses or prescribes a
221 controlled substance to a patient at a pain-management clinic.
222 If the physician prescribes or dispenses more than a 72-hour
223 dose of controlled substances for the treatment of chronic
224 nonmalignant pain, the physician must document in the patient's
225 record the reason for prescribing or dispensing that quantity.

226 (d) A physician authorized to prescribe controlled
227 substances who practices at a pain-management clinic is
228 responsible for maintaining the control and security of his or
229 her prescription blanks and any other method used for
230 prescribing controlled substance pain medication. The physician
231 shall comply with the requirements for counterfeit-resistant
232 prescription blanks in s. 893.065 and the rules adopted pursuant
233 to that section. The physician shall notify in writing the
234 department within 24 hours following any theft or loss of a
235 prescription blank or breach of any other method for prescribing
236 pain medication.

237 (e) The designated physician of a pain-management clinic
238 shall notify the applicable board in writing of the date of
239 termination of employment within 10 days after terminating his

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240 or her employment with a pain-management clinic that is required
241 to be registered under subsection (1).

242 (3) INSPECTION.-

243 (a) The department shall inspect the pain-management
244 clinic annually, including a review of the patient records, to
245 ensure that it complies with this section and the rules of the
246 Board of Medicine adopted pursuant to subsection (4) unless the
247 clinic is accredited by a nationally recognized accrediting
248 agency approved by the Board of Medicine.

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

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

257 (4) RULEMAKING.-

258 (a) The department shall adopt rules necessary to
259 administer the registration and inspection of pain-management
260 clinics which establish the specific requirements, procedures,
261 forms, and fees.

262 (b) The department shall adopt a rule defining what
263 constitutes practice by a designated physician at the clinic
264 location for which the physician has assumed responsibility, as
265 set forth in subsection (1). When adopting the rule, the
266 department shall consider the number of clinic employees, the
267 location of the pain-management clinic, the clinic's hours of

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268 operation, and the amount of controlled substances being
269 prescribed, dispensed, or administered at the pain-management
270 clinic.

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

276 (d) The Board of Medicine shall adopt rules setting forth
277 standards of practice for physicians practicing in privately
278 owned pain-management clinics that primarily engage in the
279 treatment of pain by prescribing or dispensing controlled
280 substance medications. Such rules shall address, but need not be
281 limited to:

- 282 1. Facility operations;
- 283 2. Physical operations;
- 284 3. Infection control requirements;
- 285 4. Health and safety requirements;
- 286 5. Quality assurance requirements;
- 287 6. Patient records;
- 288 7. Training requirements for all facility health care
289 practitioners who are not regulated by another board;
- 290 8. Inspections; and
- 291 9. Data collection and reporting requirements.

292
293 A physician is primarily engaged in the treatment of pain by
294 prescribing or dispensing controlled substance medications when
295 the majority of the patients seen are prescribed or dispensed

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296 controlled substance medications for the treatment of chronic
297 nonmalignant pain. Chronic nonmalignant pain is pain unrelated
298 to cancer which persists beyond the usual course of the disease
299 or the injury that is the cause of the pain or more than 90 days
300 after surgery.

301 (5) PENALTIES; ENFORCEMENT.—

302 (a) The department may impose an administrative fine on
303 the clinic of up to \$5,000 per violation for violating the
304 requirements of this section; chapter 499, the Florida Drug and
305 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
306 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
307 Abuse Prevention and Control Act; chapter 893, the Florida
308 Comprehensive Drug Abuse Prevention and Control Act; or the
309 rules of the department. In determining whether a penalty is to
310 be imposed, and in fixing the amount of the fine, the department
311 shall consider the following factors:

312 1. The gravity of the violation, including the probability
313 that death or serious physical or emotional harm to a patient
314 has resulted, or could have resulted, from the pain-management
315 clinic's actions or the actions of the physician, the severity
316 of the action or potential harm, and the extent to which the
317 provisions of the applicable laws or rules were violated.

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

320 3. Whether there were any previous violations at the pain-
321 management clinic.

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

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

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

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

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

339 Section 5. Section 458.327, Florida Statutes, is amended
340 to read:

341 458.327 Penalty for violations.—

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

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

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

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

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351 (d) Attempting to obtain or obtaining a position as a
352 medical practitioner or medical resident in a clinic or hospital
353 through knowing misrepresentation of education, training, or
354 experience.

355 (e) Knowingly operating, owning, or managing a
356 nonregistered pain-management clinic that is required to be
357 registered with the Department of Health pursuant to s.
358 458.3265(1).

359 (2) Each of the following acts constitutes a misdemeanor
360 of the first degree, punishable as provided in s. 775.082 or s.
361 775.083:

362 (a) Knowingly concealing information relating to
363 violations of this chapter.

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

366 (c) Referring any patient, for health care goods or
367 services, to a partnership, firm, corporation, or other business
368 entity in which the physician or the physician's employer has an
369 equity interest of 10 percent or more unless, prior to such
370 referral, the physician notifies the patient of his or her
371 financial interest and of the patient's right to obtain such
372 goods or services at the location of the patient's choice. This
373 section does not apply to the following types of equity
374 interest:

375 1. The ownership of registered securities issued by a
376 publicly held corporation or the ownership of securities issued
377 by a publicly held corporation, the shares of which are traded
378 on a national exchange or the over-the-counter market;

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379 2. A physician's own practice, whether he or she is a sole
380 practitioner or part of a group, when the health care good or
381 service is prescribed or provided solely for the physician's own
382 patients and is provided or performed by the physician or under
383 the physician's supervision; or

384 3. An interest in real property resulting in a landlord-
385 tenant relationship between the physician and the entity in
386 which the equity interest is held, unless the rent is
387 determined, in whole or in part, by the business volume or
388 profitability of the tenant or is otherwise unrelated to fair
389 market value.

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

393 (e) Practicing medicine or attempting to practice medicine
394 with an inactive or delinquent license.

395 (f) Knowingly prescribing or dispensing, or causing to be
396 prescribed or dispensed, controlled substances in a
397 nonregistered pain-management clinic that is required to be
398 registered with the Department of Health pursuant to s.
399 458.3265(1).

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

402 458.331 Grounds for disciplinary action; action by the
403 board and department.—

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

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

409 1. Registering a pain-management clinic through
410 misrepresentation or fraud;

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

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

419 4. Being convicted or found guilty of, regardless of
420 adjudication to, a felony or any other crime involving moral
421 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
422 the courts of this state, of any other state, or of the United
423 States;

424 5. Being convicted of, or disciplined by a regulatory
425 agency of the Federal Government or a regulatory agency of
426 another state for any offense that would constitute a violation
427 of this chapter;

428 6. Being convicted of, or entering a plea of guilty or
429 nolo contendere to, regardless of adjudication, a crime in any
430 jurisdiction of the courts of this state, of any other state, or
431 of the United States which relates to the practice of, or the
432 ability to practice, a licensed health care profession;

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

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

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

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

449 Section 7. Subsections (3), (4), and (5) of section
450 459.005, Florida Statutes, are repealed.

451 Section 8. Section 459.0137, Florida Statutes, is created
452 to read:

453 459.0137 Pain-management clinics.—

454 (1) REGISTRATION.—

455 (a) All privately owned pain-management clinics,
456 facilities, or offices, hereinafter referred to as "clinics,"
457 which advertise in any medium for any type of pain-management
458 services, or employ an osteopathic physician who is primarily
459 engaged in the treatment of pain by prescribing or dispensing

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460 controlled substance medications, must register with the
461 department unless:

462 1. That clinic is licensed as a facility pursuant to
463 chapter 395;

464 2. The majority of the physicians who provide services in
465 the clinic primarily provide surgical services;

466 3. The physicians who provide services in the clinic
467 primarily provide chiropractic services and do not dispense
468 controlled substances.

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

473 5. The clinic is affiliated with an accredited medical
474 school at which training is provided for medical students,
475 residents, or fellows;

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

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

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

483 (c) As a part of registration, a clinic must designate an
484 osteopathic physician who is responsible for complying with all
485 requirements related to registration and operation of the clinic
486 in compliance with this section. Within 10 days after
487 termination of a designated osteopathic physician, the clinic

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488 must notify the department of the identity of another designated
489 physician for that clinic. The designated physician shall have a
490 full, active, and unencumbered license under chapter 458 or this
491 chapter and shall practice at the clinic location for which the
492 physician has assumed responsibility. Failing to have a licensed
493 designated osteopathic physician practicing at the location of
494 the registered clinic may be the basis for a summary suspension
495 of the clinic registration certificate as described in s.
496 456.073(8) for a license or s. 120.60(6).

497 (d) The department shall deny registration to any clinic
498 that is not fully owned by a physician licensed under chapter
499 458 or this chapter or a group of physicians, each of whom is
500 licensed under chapter 458 or this chapter; or that is not a
501 health care clinic licensed under part X of chapter 400.

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

505 1. Whose Drug Enforcement Administration number has ever
506 been revoked.

507 2. Whose application for a license to prescribe, dispense,
508 or administer a controlled substance has been denied by any
509 jurisdiction.

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

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516 (f) If the department finds that a pain-management clinic
517 does not meet the requirement of paragraph (d) or is owned,
518 directly or indirectly, by a person meeting any criteria listed
519 in paragraph (e), the department shall revoke the certificate of
520 registration previously issued by the department. As determined
521 by rule, the department may grant an exemption to denying a
522 registration or revoking a previously issued registration if
523 more than 10 years have elapsed since adjudication. As used in
524 this subsection, the term "convicted" includes an adjudication
525 of guilt following a plea of guilty or nolo contendere or the
526 forfeiture of a bond when charged with a crime.

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

532 (h) If the registration of a pain-management clinic is
533 revoked or suspended, the designated physician of the pain-
534 management clinic, the owner or lessor of the pain-management
535 clinic property, the manager, and the proprietor shall cease to
536 operate the facility as a pain-management clinic as of the
537 effective date of the suspension or revocation.

538 (i) If a pain-management clinic registration is revoked or
539 suspended, the designated physician of the pain-management
540 clinic, the owner or lessor of the clinic property, the manager,
541 or the proprietor is responsible for removing all signs and
542 symbols identifying the premises as a pain-management clinic.

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543 (j) Upon the effective date of the suspension or
544 revocation, the designated physician of the pain-management
545 clinic shall advise the department of the disposition of the
546 medicinal drugs located on the premises. The disposition is
547 subject to the supervision and approval of the department.
548 Medicinal drugs that are purchased or held by a pain-management
549 clinic that is not registered may be deemed adulterated pursuant
550 to s. 499.006.

551 (k) If the clinic's registration is revoked, any person
552 named in the registration documents of the pain-management
553 clinic, including persons owning or operating the pain-
554 management clinic, may not as an individual or as a part of a
555 group, make application for a permit to operate a pain-
556 management clinic for 5 years after the date the registration is
557 revoked.

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

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

563 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
564 apply to any osteopathic physician who provides professional
565 services in a pain-management clinic that is required to be
566 registered in subsection (1).

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

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

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571 2. Effective July 1, 2012, the physician has not
572 successfully completed a pain medicine fellowship that is
573 accredited by the Accreditation Council for Graduate Medical
574 Education or the American Osteopathic Association or a pain
575 medicine residency that is accredited by the Accreditation
576 Council for Graduate Medical Education or the American
577 Osteopathic Association or does not comply with rules adopted by
578 the Board of Osteopathic Medicine.

579
580 An osteopathic physician who violates this paragraph is subject
581 to disciplinary action by his or her appropriate medical
582 regulatory board.

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

587 (c) An osteopathic physician must perform a physical
588 examination of a patient on the same day that he or she
589 dispenses or prescribes a controlled substance to a patient at a
590 pain-management clinic. If the osteopathic physician prescribes
591 or dispenses more than a 72-hour dose of controlled substances
592 for the treatment of chronic nonmalignant pain, the osteopathic
593 physician must document in the patient's record the reason for
594 prescribing or dispensing that quantity.

595 (d) An osteopathic physician authorized to prescribe
596 controlled substances who practices at a pain-management clinic
597 is responsible for maintaining the control and security of his
598 or her prescription blanks and any other method used for

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599 prescribing controlled substance pain medication. The
600 osteopathic physician shall comply with the requirements for
601 counterfeit-resistant prescription blanks in s. 893.065 and the
602 rules adopted pursuant to that section. The osteopathic
603 physician shall notify in writing the department within 24 hours
604 following any theft or loss of a prescription blank or breach of
605 any other method for prescribing pain medication.

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

611 (3) INSPECTION.-

612 (a) The department shall inspect the pain-management
613 clinic annually, including a review of the patient records, to
614 ensure that it complies with this section and the rules of the
615 Board of Osteopathic Medicine adopted pursuant to subsection (4)
616 unless the clinic is accredited by a nationally recognized
617 accrediting agency approved by the Board of Osteopathic
618 Medicine.

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

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

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627 (4) RULEMAKING.-

628 (a) The department shall adopt rules necessary to
629 administer the registration and inspection of pain-management
630 clinics which establish the specific requirements, procedures,
631 forms, and fees.

632 (b) The department shall adopt a rule defining what
633 constitutes practice by a designated osteopathic physician at
634 the clinic location for which the physician has assumed
635 responsibility, as set forth in subsection (1). When adopting
636 the rule, the department shall consider the number of clinic
637 employees, the location of the pain-management clinic, the
638 clinic's hours of operation, and the amount of controlled
639 substances being prescribed, dispensed, or administered at the
640 pain-management clinic.

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

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

- 652 1. Facility operations;
- 653 2. Physical operations;
- 654 3. Infection control requirements;

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- 655 4. Health and safety requirements;
656 5. Quality assurance requirements;
657 6. Patient records;
658 7. Training requirements for all facility health care
659 practitioners who are not regulated by another board;
660 8. Inspections; and
661 9. Data collection and reporting requirements.
662

663 An osteopathic physician is primarily engaged in the treatment
664 of pain by prescribing or dispensing controlled substance
665 medications when the majority of the patients seen are
666 prescribed or dispensed controlled substance medications for the
667 treatment of chronic nonmalignant pain. Chronic nonmalignant
668 pain is pain unrelated to cancer which persists beyond the usual
669 course of the disease or the injury that is the cause of the
670 pain or more than 90 days after surgery.

671 (5) PENALTIES; ENFORCEMENT.—

672 (a) The department may impose an administrative fine on
673 the clinic of up to \$5,000 per violation for violating the
674 requirements of this section; chapter 499, the Florida Drug and
675 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
676 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
677 Abuse Prevention and Control Act; chapter 893, the Florida
678 Comprehensive Drug Abuse Prevention and Control Act; or the
679 rules of the department. In determining whether a penalty is to
680 be imposed, and in fixing the amount of the fine, the department
681 shall consider the following factors:

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682 1. The gravity of the violation, including the probability
683 that death or serious physical or emotional harm to a patient
684 has resulted, or could have resulted, from the pain-management
685 clinic's actions or the actions of the osteopathic physician,
686 the severity of the action or potential harm, and the extent to
687 which the provisions of the applicable laws or rules were
688 violated.

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

691 3. Whether there were any previous violations at the pain-
692 management clinic.

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

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

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

703 (d) An owner or designated osteopathic physician of a pain-
704 management clinic who concurrently operates an unregistered
705 pain-management clinic is subject to an administrative fine of
706 \$5,000 per day.

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

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

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

713 459.013 Penalty for violations.—

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

717 (a) The practice of osteopathic medicine, or an attempt to
718 practice osteopathic medicine, without an active license or
719 certificate issued pursuant to this chapter.

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

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

726 (d) Attempting to obtain or obtaining a position as an
727 osteopathic medical practitioner or osteopathic medical resident
728 in a clinic or hospital through knowing misrepresentation of
729 education, training, or experience.

730 (e) Knowingly operating, owning, or managing a
731 nonregistered pain-management clinic that is required to be
732 registered with the Department of Health pursuant to s.
733 459.0137(1).

734 (2) Each of the following acts constitutes a misdemeanor
735 of the first degree, punishable as provided in s. 775.082 or s.
736 775.083:

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737 (a) Knowingly concealing information relating to
738 violations of this chapter.

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

741 (c) The practice of medicine as a resident or intern
742 without holding a valid current registration pursuant to s.
743 459.021.

744 (d) Knowingly prescribing or dispensing, or causing to be
745 prescribed or dispensed, controlled substances in a
746 nonregistered pain-management clinic that is required to be
747 registered with the Department of Health pursuant to s.
748 459.0137(1).

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

751 459.015 Grounds for disciplinary action; action by the
752 board and department.—

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

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

758 1. Registering a pain-management clinic through
759 misrepresentation or fraud;

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

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

768 4. Being convicted or found guilty of, regardless of
769 adjudication to, a felony or any other crime involving moral
770 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
771 the courts of this state, of any other state, or of the United
772 States;

773 5. Being convicted of, or disciplined by a regulatory
774 agency of the Federal Government or a regulatory agency of
775 another state for any offense that would constitute a violation
776 of this chapter;

777 6. Being convicted of, or entering a plea of guilty or
778 nolo contendere to, regardless of adjudication, a crime in any
779 jurisdiction of the courts of this state, of any other state, or
780 of the United States which relates to the practice of, or the
781 ability to practice, a licensed health care profession;

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

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

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

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

798 Section 11. Paragraph (b) of subsection (7) of section
799 893.055, Florida Statutes, is amended to read:

800 893.055 Prescription drug monitoring program.—

801 (7)

802 (b)1. A pharmacy, prescriber, or dispenser shall have
803 access to information in the prescription drug monitoring
804 program's database which relates to a patient of that pharmacy,
805 prescriber, or dispenser in a manner established by the
806 department as needed for the purpose of reviewing the patient's
807 controlled substance prescription history.

808 2. The prescription drug monitoring program's database
809 shall report information directly to applicable law enforcement
810 agencies to investigate whether any violation of s.
811 893.13(7)(a)8., s. 893.13(8)(a), or s. 893.13(8)(b), has
812 occurred regarding controlled substances in Schedule II,
813 Schedule III, or Schedule IV. The department shall adopt rules
814 to identify the factors that might be indicative of a violation
815 of s. 893.13(7)(a)8., s. 893.13(8)(a), or s. 893.13(8)(b), based
816 on input from the Department of Law Enforcement and
817 representatives of local law enforcement, the Florida Medical

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818 Association, the Florida Osteopathic Medical Association, the
819 Florida Pharmacy Association, and other relevant stakeholders.

820 3. Other access to the program's database shall be limited
821 to the program's manager and to the designated program and
822 support staff, who may act only at the direction of the program
823 manager or, in the absence of the program manager, as
824 authorized. Access by the program manager or such designated
825 staff is for prescription drug program management only or for
826 management of the program's database and its system in support
827 of the requirements of this section and in furtherance of the
828 prescription drug monitoring program. Confidential and exempt
829 information in the database shall be released only as provided
830 in paragraph (c) and s. 893.0551.

831 Section 12. Subsections (4), (5), and (6) of section
832 893.0551, Florida Statutes, are renumbered as subsections (5),
833 (6), and (7), respectively, and subsection (4) is added to that
834 section, to read:

835 893.0551 Public records exemption for the prescription
836 drug monitoring program.—

837 (4) The department shall disclose such confidential and
838 exempt information to the applicable law enforcement agency in
839 accordance with s. 893.055(7)(b)2. The law enforcement agency
840 may disclose the confidential and exempt information received
841 from the department to a criminal justice agency as defined in
842 s. 119.011 as part of an active investigation that is specific
843 to a violation of s. 893.13(7)(a)8., s. 893.13(8)(a), or s.
844 893.13(8)(b).

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

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T I T L E A M E N D M E N T

Remove the entire title and insert:

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

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874 to registration and operation of the clinic; requiring the
875 department to deny registration or revoke the registration
876 of a pain-management clinic for certain conditions;
877 authorizing the department to revoke a clinic's
878 certificate of registration and prohibit physicians
879 associated with the clinic from practicing at the clinic's
880 location; requiring a pain-management clinic to cease
881 operating if its registration certificate is revoked or
882 suspended; requiring certain named persons to remove all
883 signs and symbols identifying the premises as a pain-
884 management clinic; requiring a pain-management clinic that
885 has had its registration revoked or suspended to advise
886 the department of the disposition of the medicinal drugs
887 located on the premises; providing that medicinal drugs
888 that are purchased or held by a pain-management clinic
889 that is not registered may be deemed adulterated;
890 prohibiting any person acting as an individual or as part
891 of a group from applying for a certificate to operate a
892 pain-management clinic for a certain period after the date
893 the person's registration certificate is revoked;
894 providing that a change of ownership of a registered pain-
895 management clinic requires submission of a new
896 registration application; providing the responsibilities
897 of a physician who provides professional services at a
898 pain-management clinic; requiring the department to
899 inspect pain-management clinics and its patient records;
900 providing an exception to inspection by the department;
901 requiring a pain-management clinic to document corrective

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902 action; requiring the department and the Board of Medicine
903 to adopt rules; authorizing the department to impose
904 fines, deny a clinic's registration, or revoke a clinic's
905 registration; amending s. 458.327, F.S.; providing that
906 the commission of certain specified acts involving a
907 nonregistered pain-management clinic constitutes a felony
908 of the third degree or a misdemeanor of the first degree;
909 amending s. 458.331, F.S.; providing additional acts that
910 constitute grounds for disciplinary actions against health
911 professional licensees; repealing s. 459.005(3), (4), and
912 (5), F.S., relating to pain-management clinics; creating
913 s. 459.0137, F.S.; requiring all privately owned pain-
914 management clinics, or offices that primarily engage in
915 the treatment of pain by prescribing or dispensing
916 controlled substance medications or by employing an
917 osteopathic physician who is primarily engaged in the
918 treatment of pain by prescribing or dispensing controlled
919 substance medications, to register with the department;
920 providing exceptions; requiring each location of a pain-
921 management clinic to register separately; requiring a
922 clinic to designate an osteopathic physician who is
923 responsible for complying with requirements related to
924 registration and operation of the clinic; requiring the
925 department to deny registration or revoke the registration
926 of a pain-management clinic for certain conditions;
927 authorizing the department to revoke a clinic's
928 certificate of registration and prohibit osteopathic
929 physicians associated with the clinic from practicing at

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930 the clinic's location; requiring a pain-management clinic
931 to cease operating if its registration certificate is
932 revoked or suspended; requiring certain named persons to
933 remove all signs and symbols identifying the premises as a
934 pain-management clinic; requiring a pain-management clinic
935 that has had its registration revoked or suspended to
936 advise the department of the disposition of the medicinal
937 drugs located on the premises; providing that medicinal
938 drugs that are purchased or held by a pain-management
939 clinic that is not registered may be deemed adulterated;
940 prohibiting any person acting as an individual or as part
941 of a group from applying for a certificate to operate a
942 pain-management clinic for a certain period after the date
943 the person's registration certificate is revoked;
944 providing that a change of ownership of a registered pain-
945 management clinic requires submission of a new
946 registration application; providing the responsibilities
947 of an osteopathic physician who provides professional
948 services at a pain-management clinic; requiring the
949 department to inspect pain-management clinics and its
950 patient records; providing an exception to inspection by
951 the department; requiring a pain-management clinic to
952 document corrective action; requiring the department and
953 the Board of Osteopathic Medicine to adopt rules;
954 authorizing the department to impose fines, deny a
955 clinic's registration, or revoke a clinic's registration;
956 amending s. 459.013, F.S.; providing that the commission
957 of certain specified acts involving a nonregistered pain-

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958 management clinic constitutes a felony of the third degree
959 or a misdemeanor of the first degree; amending s. 459.015,
960 F.S.; providing additional acts that constitute grounds
961 for disciplinary actions against health professional
962 licensees; amending s. 893.055, F.S.; providing for the
963 prescription drug monitoring program's database to report
964 certain information directly to applicable law enforcement
965 agencies for investigation; requiring the department to
966 adopt rules; amending s. 893.0551, F.S.; providing for
967 disclosure of confidential and exempt information to
968 applicable law enforcement; providing an effective date.

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