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LEGISLATIVE ACTION

Senate

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House

The Committee on Criminal Justice (Siplin) recommended the following:

Senate Amendment (with title amendment)

Delete lines 219 - 604

and insert:

458.3265 Pain-management clinics.-

(1) REGISTRATION.-

(a) A privately owned clinic that advertises in any medium for any type of pain-management services or employs one or more physicians who are primarily engaged in the treatment of pain by prescribing or dispensing controlled substances is exempt from the registration provisions in this subsection if:

1. The majority of the physicians who provide services in



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13 the clinic primarily provide surgical services;

14 2. The physicians provide services in a clinic that
15 primarily provides chiropractic services and does not dispense
16 controlled substances;

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

21 4. The clinic is affiliated with an accredited medical
22 school at which training is provided for medical students,
23 residents, or fellows;

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

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

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

31 (c) As a part of registration, a clinic must designate a
32 physician who is responsible for complying with all requirements
33 related to registration and operation of the clinic in
34 compliance with this section. Within 10 days after termination
35 of a designated physician, the clinic must notify the department
36 of the identity of another designated physician for that clinic.
37 The designated physician shall have a full, active, and
38 unencumbered license under this chapter or chapter 459 and shall
39 practice at the clinic location for which the physician has
40 assumed responsibility. Failing to have a licensed designated
41 physician practicing at the location of the registered clinic



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

45 (d) The department shall deny registration to any clinic
46 that is not fully owned by a physician licensed under this
47 chapter or chapter 459 or a group of physicians, each of whom is
48 licensed under this chapter or chapter 459; or that is not a
49 health care clinic licensed under part X of chapter 400.

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

53 1. Whose Drug Enforcement Administration number has ever
54 been revoked.

55 2. Whose application for a license to prescribe, dispense,
56 or administer a controlled substance has been denied by any
57 jurisdiction.

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

64 (f) If the department finds that a pain-management clinic
65 does not meet the requirement of paragraph (d) or is owned,
66 directly or indirectly, by a person meeting any criteria listed
67 in paragraph (e), the department shall revoke the certificate of
68 registration previously issued by the department. As determined
69 by rule, the department may grant an exemption to denying a
70 registration or revoking a previously issued registration if



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71 more than 10 years have elapsed since adjudication. As used in
72 this subsection, the term "convicted" includes an adjudication
73 of guilt following a plea of guilty or nolo contendere or the
74 forfeiture of a bond when charged with a crime.

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

80 (h) If the registration of a pain-management clinic is
81 revoked or suspended, the designated physician of the pain-
82 management clinic, the owner or lessor of the pain-management
83 clinic property, the manager, and the proprietor shall cease to
84 operate the facility as a pain-management clinic as of the
85 effective date of the suspension or revocation.

86 (i) If a pain-management clinic registration is revoked or
87 suspended, the designated physician of the pain-management
88 clinic, the owner or lessor of the clinic property, the manager,
89 or the proprietor is responsible for removing all signs and
90 symbols identifying the premises as a pain-management clinic.

91 (j) Upon the effective date of the suspension or
92 revocation, the designated physician of the pain-management
93 clinic shall advise the department of the disposition of the
94 medicinal drugs located on the premises. The disposition is
95 subject to the supervision and approval of the department.
96 Medicinal drugs that are purchased or held by a pain-management
97 clinic that is not registered may be deemed adulterated pursuant
98 to s. 499.006.

99 (k) If the clinic's registration is revoked, any person



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100 named in the registration documents of the pain-management
101 clinic, including persons owning or operating the pain-
102 management clinic, may not, as an individual or as a part of a
103 group, apply to operate a pain-management clinic for 5 years
104 after the date the registration is revoked.

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

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

110 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
111 apply to any physician who provides professional services in a
112 pain-management clinic that is required to be registered in
113 subsection (1).

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

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

118 2. Effective July 1, 2012, the physician has not
119 successfully completed a pain medicine fellowship that is
120 accredited by the Accreditation Council for Graduate Medical
121 Education or a pain medicine residency that is accredited by the
122 Accreditation Council for Graduate Medical Education unless
123 recognized as a specialist in pain medicine by an organization
124 approved by the Board of Medicine.

125
126 A physician who violates this paragraph is subject to
127 disciplinary action by his or her appropriate medical regulatory
128 board.



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

133 (c) A physician must perform a physical examination of a
134 patient on the same day that he or she dispenses or prescribes a
135 controlled substance to a patient at a pain-management clinic.
136 If the physician prescribes or dispenses more than a 72-hour
137 dose of controlled substances for the treatment of chronic
138 nonmalignant pain, the physician must document in the patient's
139 record the reason for prescribing or dispensing that quantity.

140 (d) A physician authorized to prescribe controlled
141 substances who practices at a pain-management clinic is
142 responsible for maintaining the control and security of his or
143 her prescription blanks and any other method used for
144 prescribing controlled substance pain medication. The physician
145 shall comply with the requirements for counterfeit-resistant
146 prescription blanks in s. 893.065 and the rules adopted pursuant
147 to that section. The physician shall notify in writing the
148 department within 24 hours following any theft or loss of a
149 prescription blank or breach of any other method for prescribing
150 pain medication.

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

156 (3) INSPECTION.—

157 (a) The department shall inspect the pain-management clinic



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158 annually, including a review of the patient records, to ensure
159 that it complies with this section and the rules of the Board of
160 Medicine adopted pursuant to subsection (4) unless the clinic is
161 accredited by a nationally recognized accrediting agency
162 approved by the Board of Medicine.

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

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

171 (4) RULEMAKING.—

172 (a) The department shall adopt rules necessary to
173 administer the registration and inspection of pain-management
174 clinics which establish the specific requirements, procedures,
175 forms, and fees.

176 (b) The department shall adopt a rule defining what
177 constitutes practice by a designated physician at the clinic
178 location for which the physician has assumed responsibility, as
179 set forth in subsection (1). When adopting the rule, the
180 department shall consider the number of clinic employees, the
181 location of the pain-management clinic, the clinic's hours of
182 operation, and the amount of controlled substances being
183 prescribed, dispensed, or administered at the pain-management
184 clinic.

185 (c) The Board of Medicine shall adopt a rule establishing
186 the maximum number of prescriptions for Schedule II or Schedule



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187 III controlled substances or the controlled substance Alprazolam
188 which may be written at any one registered pain-management
189 clinic during any 24-hour period.

190 (d) The Board of Medicine shall adopt rules setting forth
191 standards of practice for physicians practicing in privately
192 owned pain-management clinics that primarily engage in the
193 treatment of pain by prescribing or dispensing controlled
194 substance medications. Such rules shall address, but need not be
195 limited to:

- 196 1. Facility operations;
- 197 2. Physical operations;
- 198 3. Infection control requirements;
- 199 4. Health and safety requirements;
- 200 5. Quality assurance requirements;
- 201 6. Patient records;
- 202 7. Training requirements for all facility health care
203 practitioners who are not regulated by another board;
- 204 8. Inspections; and
- 205 9. Data collection and reporting requirements.

206
207 A physician is primarily engaged in the treatment of pain by
208 prescribing or dispensing controlled substance medications when
209 the majority of the patients seen are prescribed or dispensed
210 controlled substance medications for the treatment of chronic
211 nonmalignant pain. Chronic nonmalignant pain is pain unrelated
212 to cancer which persists beyond the usual course of the disease
213 or the injury that is the cause of the pain or more than 90 days
214 after surgery.

215 (5) PENALTIES; ENFORCEMENT.-



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216 (a) The department may impose an administrative fine on the
217 clinic of up to \$5,000 per violation for violating the
218 requirements of this section; chapter 499, the Florida Drug and
219 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
220 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
221 Abuse Prevention and Control Act; chapter 893, the Florida
222 Comprehensive Drug Abuse Prevention and Control Act; or the
223 rules of the department. In determining whether a penalty is to
224 be imposed, and in fixing the amount of the fine, the department
225 shall consider the following factors:

226 1. The gravity of the violation, including the probability
227 that death or serious physical or emotional harm to a patient
228 has resulted, or could have resulted, from the pain-management
229 clinic's actions or the actions of the physician, the severity
230 of the action or potential harm, and the extent to which the
231 provisions of the applicable laws or rules were violated.

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

234 3. Whether there were any previous violations at the pain-
235 management clinic.

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

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

241 (c) The department may impose a fine and, in the case of an
242 owner-operated pain-management clinic, revoke or deny a pain-
243 management clinic's registration, if the clinic's designated
244 physician knowingly and intentionally misrepresents actions



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245 taken to correct a violation.

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

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

253 Section 5. Section 458.327, Florida Statutes, is amended to
254 read:

255 458.327 Penalty for violations.—

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

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

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

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

265 (d) Attempting to obtain or obtaining a position as a
266 medical practitioner or medical resident in a clinic or hospital
267 through knowing misrepresentation of education, training, or
268 experience.

269 (e) Knowingly operating, owning, or managing a
270 nonregistered pain-management clinic that is required to be
271 registered with the Department of Health pursuant to s.
272 458.3265(1).

273 (2) Each of the following acts constitutes a misdemeanor of



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274 the first degree, punishable as provided in s. 775.082 or s.
275 775.083:

276 (a) Knowingly concealing information relating to violations
277 of this chapter.

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

280 (c) Referring any patient, for health care goods or
281 services, to a partnership, firm, corporation, or other business
282 entity in which the physician or the physician's employer has an
283 equity interest of 10 percent or more unless, prior to such
284 referral, the physician notifies the patient of his or her
285 financial interest and of the patient's right to obtain such
286 goods or services at the location of the patient's choice. This
287 section does not apply to the following types of equity
288 interest:

289 1. The ownership of registered securities issued by a
290 publicly held corporation or the ownership of securities issued
291 by a publicly held corporation, the shares of which are traded
292 on a national exchange or the over-the-counter market;

293 2. A physician's own practice, whether he or she is a sole
294 practitioner or part of a group, when the health care good or
295 service is prescribed or provided solely for the physician's own
296 patients and is provided or performed by the physician or under
297 the physician's supervision; or

298 3. An interest in real property resulting in a landlord-
299 tenant relationship between the physician and the entity in
300 which the equity interest is held, unless the rent is
301 determined, in whole or in part, by the business volume or
302 profitability of the tenant or is otherwise unrelated to fair



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303 market value.

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

307 (e) Practicing medicine or attempting to practice medicine
308 with an inactive or delinquent license.

309 (f) Knowingly prescribing or dispensing, or causing to be
310 prescribed or dispensed, controlled substances in a
311 nonregistered pain-management clinic that is required to be
312 registered with the Department of Health pursuant to s.
313 458.3265(1).

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

316 458.331 Grounds for disciplinary action; action by the
317 board and department.—

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

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

323 1. Registering a pain-management clinic through
324 misrepresentation or fraud;

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

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



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332 Florida Comprehensive Drug Abuse Prevention and Control Act;

333 4. Being convicted or found guilty of, regardless of
334 adjudication to, a felony or any other crime involving moral
335 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
336 the courts of this state, of any other state, or of the United
337 States;

338 5. Being convicted of, or disciplined by a regulatory
339 agency of the Federal Government or a regulatory agency of
340 another state for any offense that would constitute a violation
341 of this chapter;

342 6. Being convicted of, or entering a plea of guilty or nolo
343 contendere to, regardless of adjudication, a crime in any
344 jurisdiction of the courts of this state, of any other state, or
345 of the United States which relates to the practice of, or the
346 ability to practice, a licensed health care profession;

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

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

356 9. Failing to timely notify the board of the date of his or
357 her termination from a pain-management clinic as required by s.
358 458.3265(2).

359 (pp) Failing to timely notify the department of the theft
360 of prescription blanks from a pain-management clinic or a breach



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361 of other methods for prescribing within 24 hours as required by
362 s. 458.3265(2).

363 Section 7. Subsections (3), (4), and (5) of section
364 459.005, Florida Statutes, are repealed.

365 Section 8. Section 459.0137, Florida Statutes, is created
366 to read:

367 459.0137 Pain-management clinics.-

368 (1) REGISTRATION.-

369 (a) A privately owned clinic that advertises in any medium
370 for any type of pain-management services or employs one or more
371 physicians who are primarily engaged in the treatment of pain by
372 prescribing or dispensing controlled substances is exempt from
373 the registration provisions in this subsection if:

374 1. The majority of the physicians who provide services in
375 the clinic, facility, or office primarily provide surgical
376 services;

377 2. The physicians provide services in a clinic, facility,
378 or office that primarily provides chiropractic services and does
379 not dispense controlled substances;

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

384 4. The clinic is affiliated with an accredited medical
385 school at which training is provided for medical students,
386 residents, or fellows;

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

389 6. The clinic is owned by a corporate entity exempt from



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390 federal taxation under 26 U.S.C. s. 501(c)(3).

391

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

393 And the title is amended as follows:

394 Delete lines 16 - 17

395 and insert:

396 requiring all privately owned pain-management clinics

397 that primarily engage in the treatment of