

Amendment No.

CHAMBER ACTION

Senate

House

.

Representative Boyd offered the following:

Amendment to Amendment (872398) (with title amendment)

Remove lines 5-732 of the amendment and insert:

Section 1. Section 456.0301, Florida Statutes, is created to read:

456.0301 Requirement for instruction on controlled substance prescribing.-

(1) (a) The appropriate board shall require each person registered with the United States Drug Enforcement Administration and authorized to prescribe controlled substances pursuant to 21 U.S.C. s. 822 to complete a board-approved 2-hour continuing education course on prescribing controlled substances

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14 offered by a statewide professional association of physicians in
15 this state that is accredited to provide educational activities
16 designated for the American Medical Association Physician's
17 Recognition Award Category 1 Credit or the American Osteopathic
18 Category 1-A continuing medical education credit as part of
19 biennial license renewal. The course must include information on
20 the current standards for prescribing controlled substances,
21 particularly opiates; alternatives to these standards;
22 nonpharmacological therapies; prescribing emergency opioid
23 antagonists; and the risks of opioid addiction following all
24 stages of treatment in the management of acute pain. The course
25 may be offered in a distance learning format and must be
26 included within the number of continuing education hours
27 required by law. The department may not renew the license of any
28 prescriber registered with the United States Drug Enforcement
29 Administration to prescribe controlled substances who has failed
30 to complete the course. The course must be completed by January
31 31, 2019, and at each subsequent renewal. This paragraph does
32 not apply to a licensee who is required by his or her applicable
33 practice act to complete a minimum of 2 hours of continuing
34 education on the safe and effective prescribing of controlled
35 substances.

36 (b) Each practitioner required to complete the course
37 required in paragraph (a) shall submit confirmation of having

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38 completed such course when applying for biennial license
39 renewal.

40 (c) Each licensing board that requires a licensee to
41 complete an educational course pursuant to this subsection must
42 include the hours required for completion of the course in the
43 total hours of continuing education required by law for such
44 profession unless the continuing education requirements for such
45 profession consist of fewer than 30 hours biennially.

46 (2) Each board may adopt rules to administer this section.

47 Section 2. Paragraph (gg) of subsection (1) of section
48 456.072, Florida Statutes, is amended to read:

49 456.072 Grounds for discipline; penalties; enforcement.—

50 (1) The following acts shall constitute grounds for which
51 the disciplinary actions specified in subsection (2) may be
52 taken:

53 (gg) Engaging in a pattern of practice when prescribing
54 medicinal drugs or controlled substances which demonstrates a
55 lack of reasonable skill or safety to patients, a violation of
56 ~~any provision of this chapter~~ or ss. 893.055 and 893.0551, a
57 violation of the applicable practice act, or a violation of any
58 rules adopted under this chapter or the applicable practice act
59 of the prescribing practitioner. Notwithstanding s. 456.073(13),
60 the department may initiate an investigation and establish such
61 a pattern from billing records, data, or any other information
62 obtained by the department.

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63 Section 3. Paragraphs (a) through (g) of subsection (1) of
64 section 456.44, Florida Statutes, are redesignated as paragraphs
65 (b) through (h), respectively, a new paragraph (a) is added to
66 that subsection, subsection (3) of that section is amended, and
67 subsections (4), (5), and (6) are added to that section, to
68 read:

69 456.44 Controlled substance prescribing.—

70 (1) DEFINITIONS.—As used in this section, the term:

71 (a) "Acute pain" means the normal, predicted,
72 physiological, and time-limited response to an adverse chemical,
73 thermal, or mechanical stimulus associated with surgery, trauma,
74 or acute illness. The term does not include pain related to:

75 1. Cancer.

76 2. A terminal condition. For purposes of this
77 subparagraph, the term "terminal condition" means a progressive
78 disease or medical or surgical condition that causes significant
79 functional impairment, is not considered by a treating physician
80 to be reversible without the administration of life-sustaining
81 procedures, and will result in death within 1 year after
82 diagnosis if the condition runs its normal course.

83 3. Palliative care to provide relief of symptoms related
84 to an incurable, progressive illness or injury.

85 4. A traumatic injury with an Injury Severity Score of 9
86 or greater.

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87 (3) STANDARDS OF PRACTICE FOR TREATMENT OF CHRONIC
88 NONMALIGNANT PAIN.—The standards of practice in this section do
89 not supersede the level of care, skill, and treatment recognized
90 in general law related to health care licensure.

91 (a) A complete medical history and a physical examination
92 must be conducted before beginning any treatment and must be
93 documented in the medical record. The exact components of the
94 physical examination shall be left to the judgment of the
95 registrant who is expected to perform a physical examination
96 proportionate to the diagnosis that justifies a treatment. The
97 medical record must, at a minimum, document the nature and
98 intensity of the pain, current and past treatments for pain,
99 underlying or coexisting diseases or conditions, the effect of
100 the pain on physical and psychological function, a review of
101 previous medical records, previous diagnostic studies, and
102 history of alcohol and substance abuse. The medical record shall
103 also document the presence of one or more recognized medical
104 indications for the use of a controlled substance. Each
105 registrant must develop a written plan for assessing each
106 patient's risk of aberrant drug-related behavior, which may
107 include patient drug testing. Registrants must assess each
108 patient's risk for aberrant drug-related behavior and monitor
109 that risk on an ongoing basis in accordance with the plan.

110 (b) Each registrant must develop a written individualized
111 treatment plan for each patient. The treatment plan shall state

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112 objectives that will be used to determine treatment success,
113 such as pain relief and improved physical and psychosocial
114 function, and shall indicate if any further diagnostic
115 evaluations or other treatments are planned. After treatment
116 begins, the registrant shall adjust drug therapy to the
117 individual medical needs of each patient. Other treatment
118 modalities, including a rehabilitation program, shall be
119 considered depending on the etiology of the pain and the extent
120 to which the pain is associated with physical and psychosocial
121 impairment. The interdisciplinary nature of the treatment plan
122 shall be documented.

123 (c) The registrant shall discuss the risks and benefits of
124 the use of controlled substances, including the risks of abuse
125 and addiction, as well as physical dependence and its
126 consequences, with the patient, persons designated by the
127 patient, or the patient's surrogate or guardian if the patient
128 is incompetent. The registrant shall use a written controlled
129 substance agreement between the registrant and the patient
130 outlining the patient's responsibilities, including, but not
131 limited to:

132 1. Number and frequency of controlled substance
133 prescriptions and refills.

134 2. Patient compliance and reasons for which drug therapy
135 may be discontinued, such as a violation of the agreement.

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136 3. An agreement that controlled substances for the
137 treatment of chronic nonmalignant pain shall be prescribed by a
138 single treating registrant unless otherwise authorized by the
139 treating registrant and documented in the medical record.

140 (d) The patient shall be seen by the registrant at regular
141 intervals, not to exceed 3 months, to assess the efficacy of
142 treatment, ensure that controlled substance therapy remains
143 indicated, evaluate the patient's progress toward treatment
144 objectives, consider adverse drug effects, and review the
145 etiology of the pain. Continuation or modification of therapy
146 shall depend on the registrant's evaluation of the patient's
147 progress. If treatment goals are not being achieved, despite
148 medication adjustments, the registrant shall reevaluate the
149 appropriateness of continued treatment. The registrant shall
150 monitor patient compliance in medication usage, related
151 treatment plans, controlled substance agreements, and
152 indications of substance abuse or diversion at a minimum of 3-
153 month intervals.

154 (e) The registrant shall refer the patient as necessary
155 for additional evaluation and treatment in order to achieve
156 treatment objectives. Special attention shall be given to those
157 patients who are at risk for misusing their medications and
158 those whose living arrangements pose a risk for medication
159 misuse or diversion. The management of pain in patients with a
160 history of substance abuse or with a comorbid psychiatric

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161 disorder requires extra care, monitoring, and documentation and
162 requires consultation with or referral to an addiction medicine
163 specialist or a psychiatrist.

164 (f) A registrant must maintain accurate, current, and
165 complete records that are accessible and readily available for
166 review and comply with the requirements of this section, the
167 applicable practice act, and applicable board rules. The medical
168 records must include, but are not limited to:

- 169 1. The complete medical history and a physical
170 examination, including history of drug abuse or dependence.
- 171 2. Diagnostic, therapeutic, and laboratory results.
- 172 3. Evaluations and consultations.
- 173 4. Treatment objectives.
- 174 5. Discussion of risks and benefits.
- 175 6. Treatments.
- 176 7. Medications, including date, type, dosage, and quantity
177 prescribed.
- 178 8. Instructions and agreements.
- 179 9. Periodic reviews.
- 180 10. Results of any drug testing.
- 181 11. A photocopy of the patient's government-issued photo
182 identification.
- 183 12. If a written prescription for a controlled substance
184 is given to the patient, a duplicate of the prescription.

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185 13. The registrant's full name presented in a legible
186 manner.

187 (g) A registrant shall immediately refer patients with
188 signs or symptoms of substance abuse to a board-certified pain
189 management physician, an addiction medicine specialist, or a
190 mental health addiction facility as it pertains to drug abuse or
191 addiction unless the registrant is a physician who is board-
192 certified or board-eligible in pain management. Throughout the
193 period of time before receiving the consultant's report, a
194 prescribing registrant shall clearly and completely document
195 medical justification for continued treatment with controlled
196 substances and those steps taken to ensure medically appropriate
197 use of controlled substances by the patient. Upon receipt of the
198 consultant's written report, the prescribing registrant shall
199 incorporate the consultant's recommendations for continuing,
200 modifying, or discontinuing controlled substance therapy. The
201 resulting changes in treatment shall be specifically documented
202 in the patient's medical record. Evidence or behavioral
203 indications of diversion shall be followed by discontinuation of
204 controlled substance therapy, and the patient shall be
205 discharged, and all results of testing and actions taken by the
206 registrant shall be documented in the patient's medical record.

207
208 This subsection does not apply to a board-eligible or board-
209 certified anesthesiologist, physiatrist, rheumatologist, or

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210 neurologist, or to a board-certified physician who has surgical
211 privileges at a hospital or ambulatory surgery center and
212 primarily provides surgical services. This subsection does not
213 apply to a board-eligible or board-certified medical specialist
214 who has also completed a fellowship in pain medicine approved by
215 the Accreditation Council for Graduate Medical Education or the
216 American Osteopathic Association, or who is board eligible or
217 board certified in pain medicine by the American Board of Pain
218 Medicine, the American Board of Interventional Pain Physicians,
219 the American Association of Physician Specialists, or a board
220 approved by the American Board of Medical Specialties or the
221 American Osteopathic Association and performs interventional
222 pain procedures of the type routinely billed using surgical
223 codes. This subsection does not apply to a registrant who
224 prescribes medically necessary controlled substances for a
225 patient during an inpatient stay in a hospital licensed under
226 chapter 395.

227 (4) STANDARDS OF PRACTICE FOR TREATMENT OF ACUTE PAIN.—The
228 applicable boards shall adopt rules establishing guidelines for
229 prescribing controlled substances for acute pain, including
230 evaluation of the patient, creation and maintenance of a
231 treatment plan, obtaining informed consent and agreement for
232 treatment, periodic review of the treatment plan, consultation,
233 medical record review, and compliance with controlled substance
234 laws and regulations. Failure of a prescriber to follow such

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235 guidelines constitutes grounds for disciplinary action pursuant
236 to s. 456.072(1)(gg), punishable as provided in s. 456.072(2).

237 (5) PRESCRIPTION SUPPLY.—

238 (a) For the treatment of acute pain, a prescription for an
239 opioid drug listed as a Schedule II controlled substance in s.
240 893.03 or 21 U.S.C. s. 812 may not exceed a 3-day supply, except
241 that up to a 7-day supply may be prescribed if:

242 1. The prescriber, in his or her professional judgment,
243 believes that more than a 3-day supply of such an opioid is
244 medically necessary to treat the patient's pain as an acute
245 medical condition;

246 2. The prescriber indicates "ACUTE PAIN EXCEPTION" on the
247 prescription; and

248 3. The prescriber adequately documents in the patient's
249 medical records the acute medical condition and lack of
250 alternative treatment options that justify deviation from the 3-
251 day supply limit established in this subsection.

252 (b) For the treatment of pain other than acute pain, a
253 prescriber must indicate "NONACUTE PAIN" on a prescription for
254 an opioid drug listed as a Schedule II controlled substance in
255 s. 893.03 or 21 U.S.C. s. 812.

256 (6) EMERGENCY OPIOID ANTAGONIST.—For the treatment of pain
257 related to a traumatic injury with an Injury Severity Score of 9
258 or greater, a prescriber who prescribes a Schedule II controlled
259 substance listed in s. 893.03 or 21 U.S.C. s. 812 must

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260 concurrently prescribe an emergency opioid antagonist, as
261 defined in s. 381.887(1).

262 Section 4. Effective January 1, 2019, present subsections
263 (2) through (5) of section 458.3265, Florida Statutes, are
264 renumbered as subsections (3) through (6), respectively,
265 paragraphs (a) and (g) of subsection (1), paragraph (a) of
266 present subsection (2), paragraph (a) of present subsection (3),
267 and paragraph (a) of present subsection (4) of that section are
268 amended, and a new subsection (2) is added to that section, to
269 read:

270 458.3265 Pain-management clinics.—

271 (1) REGISTRATION.—

272 (a)1. As used in this section, the term:

273 a. "Board eligible" means successful completion of an
274 anesthesia, physical medicine and rehabilitation, rheumatology,
275 or neurology residency program approved by the Accreditation
276 Council for Graduate Medical Education or the American
277 Osteopathic Association for a period of 6 years from successful
278 completion of such residency program.

279 b. "Chronic nonmalignant pain" means pain unrelated to
280 cancer which persists beyond the usual course of disease or the
281 injury that is the cause of the pain or more than 90 days after
282 surgery.

283 c. "Pain-management clinic" or "clinic" means any publicly
284 or privately owned facility:

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285 (I) That advertises in any medium for any type of pain-
286 management services; or

287 (II) Where in any month a majority of patients are
288 prescribed opioids, benzodiazepines, barbiturates, or
289 carisoprodol for the treatment of chronic nonmalignant pain.

290 2. Each pain-management clinic must register with the
291 department or hold a valid certificate of exemption pursuant to
292 subsection (2).

293 3. The following clinics are exempt from the registration
294 requirement of paragraphs (c)-(m) and must apply to the
295 department for a certificate of exemption unless:

296 a. A ~~The~~ clinic ~~is~~ licensed as a facility pursuant to
297 chapter 395;

298 b. A clinic in which the majority of the physicians who
299 provide services in the clinic primarily provide surgical
300 services;

301 c. A ~~The~~ clinic ~~is~~ owned by a publicly held corporation
302 whose shares are traded on a national exchange or on the over-
303 the-counter market and whose total assets at the end of the
304 corporation's most recent fiscal quarter exceeded \$50 million;

305 d. A ~~The~~ clinic ~~is~~ affiliated with an accredited medical
306 school at which training is provided for medical students,
307 residents, or fellows;

308 e. A ~~The~~ clinic that does not prescribe controlled
309 substances for the treatment of pain;

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310 f. A ~~The~~ clinic ~~is~~ owned by a corporate entity exempt from
311 federal taxation under 26 U.S.C. s. 501(c)(3);

312 g. A ~~The~~ clinic ~~is~~ wholly owned and operated by one or
313 more board-eligible or board-certified anesthesiologists,
314 physiatrists, rheumatologists, or neurologists; or

315 h. A ~~The~~ clinic ~~is~~ wholly owned and operated by a
316 physician multispecialty practice where one or more board-
317 eligible or board-certified medical specialists, who have also
318 completed fellowships in pain medicine approved by the
319 Accreditation Council for Graduate Medical Education or who are
320 also board-certified in pain medicine by the American Board of
321 Pain Medicine or a board approved by the American Board of
322 Medical Specialties, the American Association of Physician
323 Specialists, or the American Osteopathic Association, perform
324 interventional pain procedures of the type routinely billed
325 using surgical codes.

326 (g) The department may revoke the clinic's certificate of
327 registration and prohibit all physicians associated with that
328 pain-management clinic from practicing at that clinic location
329 based upon an annual inspection and evaluation of the factors
330 described in subsection (4) ~~(3)~~.

331 (2) CERTIFICATE OF EXEMPTION.—

332 (a) A pain management clinic claiming an exemption from
333 the registration requirements of subsection (1) must apply for a

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334 certificate of exemption on a form adopted in rule by the
335 department. The form must require the applicant to provide:
336 1. The name or names under which the applicant does
337 business.
338 2. The address at which the pain management clinic is
339 located.
340 3. The specific exemption the applicant is claiming with
341 supporting documentation.
342 4. Any other information deemed necessary by the
343 department.
344 (b) The department must approve or deny the certificate
345 within 30 days after the receipt of a complete application.
346 (c) The certificate of exemption must be renewed
347 biennially, except that the department may issue the initial
348 certificates of exemption for up to 3 years in order to stagger
349 renewal dates.
350 (d) A certificateholder must prominently display the
351 certificate of exemption and make it available to the department
352 or the board upon request.
353 (e) A new certificate of exemption is required for a
354 change of address and is not transferable. A certificate of
355 exemption is valid only for the applicant, qualifying owners,
356 licenses, registrations, certifications, and services provided
357 under a specific statutory exemption and is valid only to the
358 specific exemption claimed and granted.

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359 (f) A certificateholder must notify the department at
360 least 60 days before any anticipated relocation or name change
361 of the pain management clinic or a change of ownership.

362 (g) If a pain management clinic no longer qualifies for a
363 certificate of exemption, the certificateholder must notify the
364 department within 3 days after becoming aware that the clinic no
365 longer qualifies for a certificate of exemption and register as
366 a pain management clinic under subsection (1) or cease
367 operations.

368 (3)~~(2)~~ PHYSICIAN RESPONSIBILITIES.—These responsibilities
369 apply to any physician who provides professional services in a
370 pain-management clinic that is required to be registered in
371 subsection (1).

372 (a) A physician may not practice medicine in a pain-
373 management clinic, as described in subsection (5) ~~(4)~~, if the
374 pain-management clinic is not registered with the department as
375 required by this section. Any physician who qualifies to
376 practice medicine in a pain-management clinic pursuant to rules
377 adopted by the Board of Medicine as of July 1, 2012, may
378 continue to practice medicine in a pain-management clinic as
379 long as the physician continues to meet the qualifications set
380 forth in the board rules. A physician who violates this
381 paragraph is subject to disciplinary action by his or her
382 appropriate medical regulatory board.

383 (4)~~(3)~~ INSPECTION.—

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384 (a) The department shall inspect the pain-management
385 clinic annually, including a review of the patient records, to
386 ensure that it complies with this section and the rules of the
387 Board of Medicine adopted pursuant to subsection (5) ~~(4)~~ unless
388 the clinic is accredited by a nationally recognized accrediting
389 agency approved by the Board of Medicine.

390 (5)~~(4)~~ RULEMAKING.—

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

395 Section 5. Effective January 1, 2019, present subsections
396 (2) through (5) of section 459.0137, Florida Statutes, are
397 renumbered as subsections (3) through (6), respectively,
398 paragraphs (a) and (g) of subsection (1), paragraph (a) of
399 present subsection (2), paragraph (a) of present subsection (3),
400 and paragraph (a) of present subsection (4) of that section are
401 amended, and a new subsection (2) is added to that section, to
402 read:

403 459.0137 Pain-management clinics.—

404 (1) REGISTRATION.—

405 (a)1. As used in this section, the term:

406 a. "Board eligible" means successful completion of an
407 anesthesia, physical medicine and rehabilitation, rheumatology,
408 or neurology residency program approved by the Accreditation

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409 Council for Graduate Medical Education or the American
410 Osteopathic Association for a period of 6 years from successful
411 completion of such residency program.

412 b. "Chronic nonmalignant pain" means pain unrelated to
413 cancer which persists beyond the usual course of disease or the
414 injury that is the cause of the pain or more than 90 days after
415 surgery.

416 c. "Pain-management clinic" or "clinic" means any publicly
417 or privately owned facility:

418 (I) That advertises in any medium for any type of pain-
419 management services; or

420 (II) Where in any month a majority of patients are
421 prescribed opioids, benzodiazepines, barbiturates, or
422 carisoprodol for the treatment of chronic nonmalignant pain.

423 2. Each pain-management clinic must register with the
424 department or hold a valid certificate of exemption pursuant to
425 subsection (2).

426 3. The following clinics are exempt from the registration
427 requirement of paragraphs (c)-(m) and must apply to the
428 department for a certificate of exemption unless:

429 a. A ~~That~~ clinic ~~is~~ licensed as a facility pursuant to
430 chapter 395;

431 b. A clinic in which the majority of the physicians who
432 provide services in the clinic primarily provide surgical
433 services;

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434 c. A ~~The~~ clinic ~~is~~ owned by a publicly held corporation
435 whose shares are traded on a national exchange or on the over-
436 the-counter market and whose total assets at the end of the
437 corporation's most recent fiscal quarter exceeded \$50 million;

438 d. A ~~The~~ clinic ~~is~~ affiliated with an accredited medical
439 school at which training is provided for medical students,
440 residents, or fellows;

441 e. A ~~The~~ clinic that does not prescribe controlled
442 substances for the treatment of pain;

443 f. A ~~The~~ clinic ~~is~~ owned by a corporate entity exempt from
444 federal taxation under 26 U.S.C. s. 501(c) (3);

445 g. A ~~The~~ clinic ~~is~~ wholly owned and operated by one or
446 more board-eligible or board-certified anesthesiologists,
447 physiatrists, rheumatologists, or neurologists; or

448 h. A ~~The~~ clinic ~~is~~ wholly owned and operated by a
449 physician multispecialty practice where one or more board-
450 eligible or board-certified medical specialists, who have also
451 completed fellowships in pain medicine approved by the
452 Accreditation Council for Graduate Medical Education or the
453 American Osteopathic Association or who are also board-certified
454 in pain medicine by the American Board of Pain Medicine or a
455 board approved by the American Board of Medical Specialties, the
456 American Association of Physician Specialists, or the American
457 Osteopathic Association, perform interventional pain procedures
458 of the type routinely billed using surgical codes.

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459 (g) The department may revoke the clinic's certificate of
460 registration and prohibit all physicians associated with that
461 pain-management clinic from practicing at that clinic location
462 based upon an annual inspection and evaluation of the factors
463 described in subsection (4) ~~(3)~~.

464 (2) CERTIFICATE OF EXEMPTION.—

465 (a) A pain management clinic claiming an exemption from
466 the registration requirements of subsection (1) must apply for a
467 certificate of exemption on a form adopted in rule by the
468 department. The form must require the applicant to provide:

469 1. The name or names under which the applicant does
470 business.

471 2. The address at which the pain management clinic is
472 located.

473 3. The specific exemption the applicant is claiming with
474 supporting documentation.

475 4. Any other information deemed necessary by the
476 department.

477 (b) The department must approve or deny the certificate
478 within 30 days after the receipt of a complete application.

479 (c) The certificate of exemption must be renewed
480 biennially, except that the department may issue the initial
481 certificates of exemption for up to 3 years in order to stagger
482 renewal dates.

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483 (d) A certificateholder must prominently display the
484 certificate of exemption and make it available to the department
485 or the board upon request.

486 (e) A new certificate of exemption is required for a
487 change of address and is not transferable. A certificate of
488 exemption is valid only for the applicant, qualifying owners,
489 licenses, registrations, certifications, and services provided
490 under a specific statutory exemption and is valid only to the
491 specific exemption claimed and granted.

492 (f) A certificateholder must notify the department at
493 least 60 days before any anticipated relocation or name change
494 of the pain management clinic or a change of ownership.

495 (g) If a pain management clinic no longer qualifies for a
496 certificate of exemption, the certificateholder must notify the
497 department within 3 days after becoming aware that the clinic no
498 longer qualifies for a certificate of exemption and register as
499 a pain management clinic under subsection (1) or cease
500 operations.

501 (3) ~~(2)~~ PHYSICIAN RESPONSIBILITIES.—These responsibilities
502 apply to any osteopathic physician who provides professional
503 services in a pain-management clinic that is required to be
504 registered in subsection (1).

505 (a) An osteopathic physician may not practice medicine in
506 a pain-management clinic, as described in subsection (5) ~~(4)~~, if
507 the pain-management clinic is not registered with the department

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508 as required by this section. Any physician who qualifies to
509 practice medicine in a pain-management clinic pursuant to rules
510 adopted by the Board of Osteopathic Medicine as of July 1, 2012,
511 may continue to practice medicine in a pain-management clinic as
512 long as the physician continues to meet the qualifications set
513 forth in the board rules. An osteopathic physician who violates
514 this paragraph is subject to disciplinary action by his or her
515 appropriate medical regulatory board.

516 ~~(4)~~⁽³⁾ INSPECTION.—

517 (a) The department shall inspect the pain-management
518 clinic annually, including a review of the patient records, to
519 ensure that it complies with this section and the rules of the
520 Board of Osteopathic Medicine adopted pursuant to subsection (5)
521 ~~(4)~~ unless the clinic is accredited by a nationally recognized
522 accrediting agency approved by the Board of Osteopathic
523 Medicine.

524 ~~(5)~~⁽⁴⁾ RULEMAKING.—

525 (a) The department shall adopt rules necessary to
526 administer the registration, exemption, and inspection of pain-
527 management clinics which establish the specific requirements,
528 procedures, forms, and fees.

529 Section 6. Section 465.0155, Florida Statutes, is amended
530 to read:

531 465.0155 Standards of practice.—

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532 (1) Consistent with the provisions of this act, the board
533 shall adopt by rule standards of practice relating to the
534 practice of pharmacy which shall be binding on every state
535 agency and shall be applied by such agencies when enforcing or
536 implementing any authority granted by any applicable statute,
537 rule, or regulation, whether federal or state.

538 (2) (a) Before dispensing a controlled substance to a
539 person not known to the pharmacist, the pharmacist must require
540 the person purchasing, receiving, or otherwise acquiring the
541 controlled substance to present valid photographic
542 identification or other verification of his or her identity. If
543 the person does not have proper identification, the pharmacist
544 may verify the validity of the prescription and the identity of
545 the patient with the prescriber or his or her authorized agent.
546 Verification of health plan eligibility through a real-time
547 inquiry or adjudication system is considered to be proper
548 identification.

549 (b) This subsection does not apply in an institutional
550 setting or to a long-term care facility, including, but not
551 limited to, an assisted living facility or a hospital to which
552 patients are admitted.

553 (c) As used in this subsection, the term "proper
554 identification" means an identification that is issued by a
555 state or the Federal Government containing the person's

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556 photograph, printed name, and signature or a document considered
557 acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).

558 Section 7. Paragraph (b) of subsection (1) of section
559 465.0276, Florida Statutes, is amended, and paragraph (d) is
560 added to subsection (2) of that section, to read:

561 465.0276 Dispensing practitioner.—

562 (1)

563 (b) A practitioner registered under this section may not
564 dispense a controlled substance listed in Schedule II or
565 Schedule III as provided in s. 893.03. This paragraph does not
566 apply to:

567 1. The dispensing of complimentary packages of medicinal
568 drugs which are labeled as a drug sample or complimentary drug
569 as defined in s. 499.028 to the practitioner's own patients in
570 the regular course of her or his practice without the payment of
571 a fee or remuneration of any kind, whether direct or indirect,
572 as provided in subsection (4).

573 2. The dispensing of controlled substances in the health
574 care system of the Department of Corrections.

575 3. The dispensing of a controlled substance listed in
576 Schedule II or Schedule III in connection with the performance
577 of a surgical procedure.

578 a. For an opioid drug listed as a Schedule II controlled
579 substance in s. 893.03 or 21 U.S.C. s. 812:

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580 (I) For the treatment of acute pain, the amount dispensed
581 pursuant to this subparagraph may not exceed a 3-day supply, or
582 a 7-day supply if the criteria in s. 456.44(5) (a) are met.

583 (II) For the treatment of pain other than acute pain, a
584 practitioner must indicate "NONACUTE PAIN" on a prescription.

585 (III) For the treatment of pain related to a traumatic
586 injury with an Injury Severity Score of 9 or greater, a
587 practitioner must concurrently prescribe an emergency opioid
588 antagonist, as defined in s. 381.887(1).

589 b. For a controlled substance listed in Schedule III, the
590 amount dispensed pursuant to ~~this~~ the subparagraph may not
591 exceed a 14-day supply.

592 c. The exception in this subparagraph ~~exception~~ does not
593 allow for the dispensing of a controlled substance listed in
594 Schedule II or Schedule III more than 14 days after the
595 performance of the surgical procedure.

596 d. For purposes of this subparagraph, the term "surgical
597 procedure" means any procedure in any setting which involves, or
598 reasonably should involve:

599 (I)~~a.~~ Perioperative medication and sedation that allows
600 the patient to tolerate unpleasant procedures while maintaining
601 adequate cardiorespiratory function and the ability to respond
602 purposefully to verbal or tactile stimulation and makes intra-
603 and postoperative monitoring necessary; or

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604 ~~(II) b.~~ The use of general anesthesia or major conduction
605 anesthesia and preoperative sedation.

606 4. The dispensing of a controlled substance listed in
607 Schedule II or Schedule III pursuant to an approved clinical
608 trial. For purposes of this subparagraph, the term "approved
609 clinical trial" means a clinical research study or clinical
610 investigation that, in whole or in part, is state or federally
611 funded or is conducted under an investigational new drug
612 application that is reviewed by the United States Food and Drug
613 Administration.

614 5. The dispensing of methadone in a facility licensed
615 under s. 397.427 where medication-assisted treatment for opiate
616 addiction is provided.

617 6. The dispensing of a controlled substance listed in
618 Schedule II or Schedule III to a patient of a facility licensed
619 under part IV of chapter 400.

620 7. The dispensing of controlled substances listed in
621 Schedule II or Schedule III which have been approved by the
622 United States Food and Drug Administration for the purpose of
623 treating opiate addictions, including, but not limited to,
624 buprenorphine and buprenorphine combination products, by a
625 practitioner authorized under 21 U.S.C. s. 823, as amended, to
626 the practitioner's own patients for the medication-assisted
627 treatment of opiate addiction.

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628 (2) A practitioner who dispenses medicinal drugs for human
629 consumption for fee or remuneration of any kind, whether direct
630 or indirect, must:

631 (d)1. Before dispensing a controlled substance to a person
632 not known to the dispenser, require the person purchasing,
633 receiving, or otherwise acquiring the controlled substance to
634 present valid photographic identification or other verification
635 of his or her identity. If the person does not have proper
636 identification, the dispenser may verify the validity of the
637 prescription and the identity of the patient with the prescriber
638 or his or her authorized agent. Verification of health plan
639 eligibility through a real-time inquiry or adjudication system
640 is considered to be proper identification.

641 2. This paragraph does not apply in an institutional
642 setting or to a long-term care facility, including, but not
643 limited to, an assisted living facility or a hospital to which
644 patients are admitted.

645 3. As used in this paragraph, the term "proper
646 identification" means an identification that is issued by a
647 state or the Federal Government containing the person's
648 photograph, printed name, and signature or a document considered
649 acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).

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

Remove lines 3869-3935 of the amendment and insert:
An act relating to controlled substances; creating s. 456.0301, F.S.; requiring certain boards to require certain registered practitioners to complete a specified board-approved continuing education course to obtain authorization to prescribe controlled substances as part of biennial license renewal and before a specified date; providing course requirements; providing that the course may be offered in a distance learning format and requiring that it be included within required continuing education hours; prohibiting the Department of Health from renewing the license of a prescriber under specified circumstances; specifying a deadline for course completion; providing an exception from the course requirements for certain licensees; requiring such licensees to submit confirmation of course completion; authorizing certain boards to adopt rules; amending s. 456.072, F.S.; authorizing disciplinary action against practitioners for violating specified provisions relating to controlled substances; amending s. 456.44, F.S.; defining the term "acute pain"; requiring the applicable boards to adopt rules establishing certain guidelines for prescribing controlled substances for acute pain; providing that the failure of a prescriber to follow specified guidelines is grounds for disciplinary action;

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678 limiting opioid drug prescriptions for the treatment of
679 acute pain to a specified period under certain
680 circumstances; authorizing such prescriptions for an
681 extended period if specified requirements are met;
682 requiring a prescriber who prescribes an opioid drug for
683 the treatment of pain other than acute pain to include a
684 specific indication on the prescription; requiring a
685 prescriber who prescribes an opioid drug for the treatment
686 of pain related to a traumatic injury with a specified
687 Injury Severity Score to concurrently prescribe an
688 emergency opioid antagonist; amending ss. 458.3265 and
689 459.0137, F.S.; requiring pain management clinics to
690 register with the department or hold a valid certificate of
691 exemption; requiring certain clinics to apply to the
692 department for a certificate of exemption; providing
693 requirements for such certificates; requiring the
694 department to adopt rules necessary to administer such
695 exemptions; amending s. 465.0155, F.S.; providing
696 requirements for pharmacists for the dispensing of
697 controlled substances to persons not known to them;
698 defining the term "proper identification"; amending s.
699 465.0276, F.S.; prohibiting the dispensing of certain
700 controlled substances in an amount that exceeds a 3-day
701 supply unless certain criteria are met; providing an
702 exception for the dispensing of certain controlled

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703 substances by a practitioner to the practitioner's own
704 patients for the medication-assisted treatment of opiate
705 addiction; providing requirements for practitioners for the
706 dispensing of controlled substances to persons not known to
707 them; defining the term "proper identification"; amending
708 s. 893.03, F.S.;

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