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LEGISLATIVE ACTION

Senate . House

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Senator Fasano moved the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Paragraph (mm) is added to subsection (1) of
section 456.072, Florida Statutes, subsection (7) is
redesignated as subsection (8), and a new subsection (7) is
added to that section, to read:

456.072 Grounds for discipline; penalties; enforcement.—

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

(mm) Failure to comply with controlled substance



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14 prescribing requirements of s. 456.44.

15 (7) Notwithstanding subsection (2), upon a finding that a
16 physician has prescribed or dispensed a controlled substance, or
17 caused a controlled substance to be prescribed or dispensed, in
18 a manner that violates the standard of practice set forth in s.
19 458.331(1)(q) or (t), s. 459.015(1)(t) or (x), s. 461.013(1)(o)
20 or (s), or s. 466.028(1)(p) or (x), the physician shall be
21 suspended for a period of not less than 6 months and pay a fine
22 of not less than \$10,000 per count. Repeated violations shall
23 result in increased penalties.

24 Section 2. Section 456.42, Florida Statutes, is amended to
25 read:

26 456.42 Written prescriptions for medicinal drugs.—

27 (1) A written prescription for a medicinal drug issued by a
28 health care practitioner licensed by law to prescribe such drug
29 must be legibly printed or typed so as to be capable of being
30 understood by the pharmacist filling the prescription; must
31 contain the name of the prescribing practitioner, the name and
32 strength of the drug prescribed, the quantity of the drug
33 prescribed, and the directions for use of the drug; must be
34 dated; and must be signed by the prescribing practitioner on the
35 day when issued. ~~A written prescription for a controlled~~
36 ~~substance listed in chapter 893 must have the quantity of the~~
37 ~~drug prescribed in both textual and numerical formats and must~~
38 ~~be dated with the abbreviated month written out on the face of~~
39 ~~the prescription.~~ However, a prescription that is electronically
40 generated and transmitted must contain the name of the
41 prescribing practitioner, the name and strength of the drug
42 prescribed, the quantity of the drug prescribed in numerical



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43 format, and the directions for use of the drug and must be dated
44 and signed by the prescribing practitioner only on the day
45 issued, which signature may be in an electronic format as
46 defined in s. 668.003(4).

47 (2) A written prescription for a controlled substance
48 listed in chapter 893 must have the quantity of the drug
49 prescribed in both textual and numerical formats, must be dated
50 with the abbreviated month written out on the face of the
51 prescription, and must be either written on a standardized
52 counterfeit-proof prescription pad produced by a vendor approved
53 by the department or electronically prescribed as that term is
54 used in s. 408.0611. As a condition of being an approved vendor,
55 a prescription pad vendor must submit a monthly report to the
56 department which, at a minimum, documents the number of
57 prescription pads sold and identifies the purchasers. The
58 department may, by rule, require the reporting of additional
59 information.

60 Section 3. Section 456.44, Florida Statutes, is created to
61 read:

62 456.44 Controlled substance prescribing.-

63 (1) DEFINITIONS.-

64 (a) "Addiction medicine specialist" means a board-certified
65 physiatrist with a subspecialty certification in addiction
66 medicine or who is eligible for such subspecialty certification
67 in addiction medicine, an addiction medicine physician certified
68 or eligible for certification by the American Society of
69 Addiction Medicine, or an osteopathic physician who holds a
70 certificate of added qualification in Addiction Medicine through
71 the American Osteopathic Association.



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72 (b) "Adverse incident" means any incident set forth in s.
73 458.351(4)(a)-(e) or s. 459.026(4)(a)-(e).

74 (c) "Board-certified pain management physician" means a
75 physician who possesses board certification in pain medicine by
76 the American Board of Pain Medicine, board certification by the
77 American Board of Interventional Pain Physicians, or board
78 certification or subcertification in pain management by a
79 specialty board recognized by the American Association of
80 Physician Specialists or an osteopathic physician who holds a
81 certificate in Pain Management by the American Osteopathic
82 Association.

83 (d) "Chronic nonmalignant pain" means pain unrelated to
84 cancer or rheumatoid arthritis which persists beyond the usual
85 course of disease or the injury that is the cause of the pain or
86 more than 90 days after surgery.

87 (e) "Mental health addiction facility" means a facility
88 licensed under chapter 394 or chapter 397.

89 (2) REGISTRATION.—Effective January 1, 2012, a physician
90 licensed under chapter 458, chapter 459, chapter 461, or chapter
91 466 who prescribes any controlled substance, as defined in s.
92 893.03, for the treatment of chronic nonmalignant pain, must:

93 (a) Designate himself or herself as a controlled substance
94 prescribing practitioner on the physician's practitioner
95 profile.

96 (b) Comply with the requirements of this section and
97 applicable board rules.

98 (3) STANDARDS OF PRACTICE.—The standards of practice in
99 this section do not supersede the level of care, skill, and
100 treatment recognized in general law related to healthcare



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101 licensure.

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

121 (b) Each registrant must develop a written individualized
122 treatment plan for each patient. The treatment plan shall state
123 objectives that will be used to determine treatment success,
124 such as pain relief and improved physical and psychosocial
125 function, and shall indicate if any further diagnostic
126 evaluations or other treatments are planned. After treatment
127 begins, the physician shall adjust drug therapy to the
128 individual medical needs of each patient. Other treatment
129 modalities, including a rehabilitation program, shall be



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130 considered depending on the etiology of the pain and the extent
131 to which the pain is associated with physical and psychosocial
132 impairment. The interdisciplinary nature of the treatment plan
133 shall be documented.

134 (c) The physician shall discuss the risks and benefits of
135 the use of controlled substances, including the risks of abuse
136 and addiction, as well as physical dependence and its
137 consequences, with the patient, persons designated by the
138 patient, or the patient's surrogate or guardian if the patient
139 is incompetent. The physician shall use a written controlled
140 substance agreement between the physician and the patient
141 outlining the patient's responsibilities, including, but not
142 limited to:

143 1. Number and frequency of controlled substance
144 prescriptions and refills.

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

147 3. An agreement that controlled substances for the
148 treatment of chronic nonmalignant pain shall be prescribed by a
149 single treating physician unless otherwise authorized by the
150 treating physician and documented in the medical record.

151 (d) The patient shall be seen by the physician at regular
152 intervals, not to exceed 3 months, to assess the efficacy of
153 treatment, ensure that controlled substance therapy remains
154 indicated, evaluate the patient's progress toward treatment
155 objectives, consider adverse drug effects, and review the
156 etiology of the pain. Continuation or modification of therapy
157 shall depend on the physician's evaluation of the patient's
158 progress. If treatment goals are not being achieved, despite



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159 medication adjustments, the physician shall reevaluate the
160 appropriateness of continued treatment. The physician shall
161 monitor patient compliance in medication usage, related
162 treatment plans, controlled substance agreements, and
163 indications of substance abuse or diversion at a minimum of 3-
164 month intervals.

165 (e) The physician shall refer the patient as necessary for
166 additional evaluation and treatment in order to achieve
167 treatment objectives. Special attention shall be given to those
168 patients who are at risk for misusing their medications and
169 those whose living arrangements pose a risk for medication
170 misuse or diversion. The management of pain in patients with a
171 history of substance abuse or with a comorbid psychiatric
172 disorder requires extra care, monitoring, and documentation and
173 requires consultation with or referral to an addictionologist or
174 physiatrist.

175 (f) A physician registered under this section must maintain
176 accurate, current, and complete records that are accessible and
177 readily available for review and comply with the requirements of
178 this section, the applicable practice act, and applicable board
179 rules. The medical records must include, but are not limited to:

- 180 1. The complete medical history and a physical examination,
181 including history of drug abuse or dependence.
- 182 2. Diagnostic, therapeutic, and laboratory results.
- 183 3. Evaluations and consultations.
- 184 4. Treatment objectives.
- 185 5. Discussion of risks and benefits.
- 186 6. Treatments.
- 187 7. Medications, including date, type, dosage, and quantity



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188 prescribed.

189 8. Instructions and agreements.

190 9. Periodic reviews.

191 10. Results of any drug testing.

192 11. A photocopy of the patient's government-issued photo
193 identification.

194 12. If a written prescription for a controlled substance is
195 given to the patient, a duplicate of the prescription.

196 13. The physician's full name presented in a legible
197 manner.

198 (g) Patients with signs or symptoms of substance abuse
199 shall be immediately referred to a board-certified pain
200 management physician, an addiction medicine specialist, or a
201 mental health addiction facility as it pertains to drug abuse or
202 addiction unless the physician is board-certified or board-
203 eligible in pain management. Throughout the period of time
204 before receiving the consultant's report, a prescribing
205 physician shall clearly and completely document medical
206 justification for continued treatment with controlled substances
207 and those steps taken to ensure medically appropriate use of
208 controlled substances by the patient. Upon receipt of the
209 consultant's written report, the prescribing physician shall
210 incorporate the consultant's recommendations for continuing,
211 modifying, or discontinuing controlled substance therapy. The
212 resulting changes in treatment shall be specifically documented
213 in the patient's medical record. Evidence or behavioral
214 indications of diversion shall be followed by discontinuation of
215 controlled substance therapy and the patient shall be discharged
216 and all results of testing and actions taken by the physician



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217 shall be documented in the patient's medical record.

218

219 This subsection does not apply to a board-certified
220 anesthesiologist, physiatrist, or neurologist, or to a board-
221 certified physician who has surgical privileges at a hospital or
222 ambulatory surgery center and primarily provides surgical
223 services. This subsection does not apply to a board-certified
224 medical specialist who has also completed a fellowship in pain
225 medicine approved by the Accreditation Council for Graduate
226 Medical Education or the American Osteopathic Association, or
227 who is board certified in pain medicine by a board approved by
228 the American Board of Medical Specialties or the American
229 Osteopathic Association and performs interventional pain
230 procedures of the type routinely billed using surgical codes.

231 Section 4. Section 458.3265, Florida Statutes, is amended
232 to read:

233 458.3265 Pain-management clinics.-

234 (1) REGISTRATION.-

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

236 a. "Chronic nonmalignant pain" means pain unrelated to
237 cancer or rheumatoid arthritis which persists beyond the usual
238 course of disease or the injury that is the cause of the pain or
239 more than 90 days after surgery.

240 b. "Pain-management clinic" or "clinic" means any publicly
241 or privately owned facility:

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

244 (II) Where in any month a majority of patients are
245 prescribed opioids, benzodiazepines, barbiturates, or



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246 carisoprodol for the treatment of chronic nonmalignant pain. ~~All~~
247 ~~privately owned pain-management clinics, facilities, or offices,~~
248 ~~hereinafter referred to as "clinics," which advertise in any~~
249 ~~medium for any type of pain-management services, or employ a~~
250 ~~physician who is primarily engaged in the treatment of pain by~~
251 ~~prescribing or dispensing controlled substance medications,~~

252 2. Each pain-management clinic must register with the
253 department unless:

254 a.1. ~~That clinic is licensed as a facility pursuant to~~
255 ~~chapter 395;~~

256 b.2. ~~The majority of the physicians who provide services in~~
257 ~~the clinic primarily provide surgical services;~~

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

262 d.4. ~~The clinic is affiliated with an accredited medical~~
263 ~~school at which training is provided for medical students,~~
264 ~~residents, or fellows;~~

265 e.5. ~~The clinic does not prescribe or dispense controlled~~
266 ~~substances for the treatment of pain; or~~

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

269 g. The clinic is wholly owned and operated by one or more
270 board-certified anesthesiologists, physiatrists, or
271 neurologists; or

272 h. The clinic is wholly owned and operated by one or more
273 board-certified medical specialists who have also completed
274 fellowships in pain medicine approved by the Accreditation



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275 Council for Graduate Medical Education, or who are also board-
276 certified in pain medicine by a board approved by the American
277 Board of Medical Specialties and perform interventional pain
278 procedures of the type routinely billed using surgical codes.

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

282 (c) As a part of registration, a clinic must designate a
283 physician who is responsible for complying with all requirements
284 related to registration and operation of the clinic in
285 compliance with this section. Within 10 days after termination
286 of a designated physician, the clinic must notify the department
287 of the identity of another designated physician for that clinic.
288 The designated physician shall have a full, active, and
289 unencumbered license under this chapter or chapter 459 and shall
290 practice at the clinic location for which the physician has
291 assumed responsibility. Failing to have a licensed designated
292 physician practicing at the location of the registered clinic
293 may be the basis for a summary suspension of the clinic
294 registration certificate as described in s. 456.073(8) for a
295 license or s. 120.60(6).

296 (d) The department shall deny registration to any clinic
297 that is not fully owned by a physician licensed under this
298 chapter or chapter 459 or a group of physicians, each of whom is
299 licensed under this chapter or chapter 459; or that is not a
300 health care clinic licensed under part X of chapter 400.

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



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304 1. Whose Drug Enforcement Administration number has ever
305 been revoked.

306 2. Whose application for a license to prescribe, dispense,
307 or administer a controlled substance has been denied by any
308 jurisdiction.

309 3. Who has been convicted of or pleaded guilty or nolo
310 contendere to, regardless of adjudication, an offense that
311 constitutes a felony for receipt of illicit and diverted drugs,
312 including a controlled substance listed in Schedule I, Schedule
313 II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in
314 this state, any other state, or the United States.

315 (f) If the department finds that a pain-management clinic
316 does not meet the requirement of paragraph (d) or is owned,
317 directly or indirectly, by a person meeting any criteria listed
318 in paragraph (e), the department shall revoke the certificate of
319 registration previously issued by the department. As determined
320 by rule, the department may grant an exemption to denying a
321 registration or revoking a previously issued registration if
322 more than 10 years have elapsed since adjudication. As used in
323 this subsection, the term "convicted" includes an adjudication
324 of guilt following a plea of guilty or nolo contendere or the
325 forfeiture of a bond when charged with a crime.

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 (3).

331 (h) If the registration of a pain-management clinic is
332 revoked or suspended, the designated physician of the pain-



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333 management clinic, the owner or lessor of the pain-management
334 clinic property, the manager, and the proprietor shall cease to
335 operate the facility as a pain-management clinic as of the
336 effective date of the suspension or revocation.

337 (i) If a pain-management clinic registration is revoked or
338 suspended, the designated physician of the pain-management
339 clinic, the owner or lessor of the clinic property, the manager,
340 or the proprietor is responsible for removing all signs and
341 symbols identifying the premises as a pain-management clinic.

342 (j) Upon the effective date of the suspension or
343 revocation, the designated physician of the pain-management
344 clinic shall advise the department of the disposition of the
345 medicinal drugs located on the premises. The disposition is
346 subject to the supervision and approval of the department.
347 Medicinal drugs that are purchased or held by a pain-management
348 clinic that is not registered may be deemed adulterated pursuant
349 to s. 499.006.

350 (k) If the clinic's registration is revoked, any person
351 named in the registration documents of the pain-management
352 clinic, including persons owning or operating the pain-
353 management clinic, may not, as an individual or as a part of a
354 group, apply to operate a pain-management clinic for 5 years
355 after the date the registration is revoked.

356 (l) The period of suspension for the registration of a
357 pain-management clinic shall be prescribed by the department,
358 but may not exceed 1 year.

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

361 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities



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362 apply to any physician who provides professional services in a
363 pain-management clinic that is required to be registered in
364 subsection (1).

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

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

369 ~~2. Effective July 1, 2012, the physician has not~~
370 ~~successfully completed a pain-medicine fellowship that is~~
371 ~~accredited by the Accreditation Council for Graduate Medical~~
372 ~~Education or a pain-medicine residency that is accredited by the~~
373 ~~Accreditation Council for Graduate Medical Education or, prior~~
374 ~~to July 1, 2012, does not comply with rules adopted by the~~
375 ~~board.~~

376
377 Any physician who qualifies to practice medicine in a pain-
378 management clinic pursuant to rules adopted by the Board of
379 Medicine as of July 1, 2012, may continue to practice medicine
380 in a pain-management clinic as long as the physician continues
381 to meet the qualifications set forth in the board rules. A
382 physician who violates this paragraph is subject to disciplinary
383 action by his or her appropriate medical regulatory board.

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

388 (c) A physician, a physician assistant, or an advanced
389 registered nurse practitioner must perform a physical
390 examination of a patient on the same day that the physician ~~he~~



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391 ~~or she dispenses or~~ prescribes a controlled substance to a
392 patient at a pain-management clinic. If the physician prescribes
393 ~~or dispenses~~ more than a 72-hour dose of controlled substances
394 for the treatment of chronic nonmalignant pain, the physician
395 must document in the patient's record the reason for prescribing
396 ~~or dispensing~~ that quantity.

397 (d) A physician authorized to prescribe controlled
398 substances who practices at a pain-management clinic is
399 responsible for maintaining the control and security of his or
400 her prescription blanks and any other method used for
401 prescribing controlled substance pain medication. The physician
402 shall comply with the requirements for counterfeit-resistant
403 prescription blanks in s. 893.065 and the rules adopted pursuant
404 to that section. The physician shall notify, in writing, the
405 department within 24 hours following any theft or loss of a
406 prescription blank or breach of any other method for prescribing
407 pain medication.

408 (e) The designated physician of a pain-management clinic
409 shall notify the applicable board in writing of the date of
410 termination of employment within 10 days after terminating his
411 or her employment with a pain-management clinic that is required
412 to be registered under subsection (1). Each physician practicing
413 in a pain-management clinic shall advise the Board of Medicine,
414 in writing, within 10 calendar days after beginning or ending
415 his or her practice at a pain-management clinic.

416 (f) Each physician practicing in a pain-management clinic
417 is responsible for ensuring compliance with the following
418 facility and physical operations requirements:

419 1. A pain-management clinic shall be located and operated



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- 420 at a publicly accessible fixed location and must:
- 421 a. Display a sign that can be viewed by the public that
- 422 contains the clinic name, hours of operations, and a street
- 423 address.
- 424 b. Have a publicly listed telephone number and a dedicated
- 425 phone number to send and receive faxes with a fax machine that
- 426 shall be operational 24 hours per day.
- 427 c. Have emergency lighting and communications.
- 428 d. Have a reception and waiting area.
- 429 e. Provide a restroom.
- 430 f. Have an administrative area, including room for storage
- 431 of medical records, supplies, and equipment.
- 432 g. Have private patient examination rooms.
- 433 h. Have treatment rooms, if treatment is being provided to
- 434 the patients.
- 435 i. Display a printed sign located in a conspicuous place in
- 436 the waiting room viewable by the public with the name and
- 437 contact information of the clinic's designated physician and the
- 438 names of all physicians practicing in the clinic.
- 439 j. If the clinic stores and dispenses prescription drugs,
- 440 comply with ss. 499.0121 and 893.07.
- 441 2. This section does not excuse a physician from providing
- 442 any treatment or performing any medical duty without the proper
- 443 equipment and materials as required by the standard of care.
- 444 This section does not supersede the level of care, skill, and
- 445 treatment recognized in general law related to healthcare
- 446 licensure.
- 447 (g) Each physician practicing in a pain-management clinic
- 448 is responsible for ensuring compliance with the following



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449 infection control requirements.
450 1. The clinic shall maintain equipment and supplies to
451 support infection prevention and control activities.
452 2. The clinic shall identify infection risks based on the
453 following:
454 a. Geographic location, community, and population served.
455 b. The care, treatment, and services it provides.
456 c. An analysis of its infection surveillance and control
457 data.
458 3. The clinic shall maintain written infection prevention
459 policies and procedures that address the following:
460 a. Prioritized risks.
461 b. Limiting unprotected exposure to pathogens.
462 c. Limiting the transmission of infections associated with
463 procedures performed in the clinic.
464 d. Limiting the transmission of infections associated with
465 the clinic's use of medical equipment, devices, and supplies.
466 (h) Each physician practicing in a pain-management clinic
467 is responsible for ensuring compliance with the following health
468 and safety requirements:
469 1. The clinic, including its grounds, buildings, furniture,
470 appliances, and equipment shall be structurally sound, in good
471 repair, clean, and free from health and safety hazards.
472 2. The clinic shall have evacuation procedures in the event
473 of an emergency, which shall include provisions for the
474 evacuation of disabled patients and employees.
475 3. The clinic shall have a written facility-specific
476 disaster plan setting forth actions that will be taken in the
477 event of clinic closure due to unforeseen disasters and shall



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478 include provisions for the protection of medical records and any
479 controlled substances.

480 4. Each clinic shall have at least one employee on the
481 premises during patient care hours who is certified in Basic
482 Life Support and is trained in reacting to accidents and medical
483 emergencies until emergency medical personnel arrive.

484 (i) The designated physician is responsible for ensuring
485 compliance with the following quality assurance requirements.
486 Each pain-management clinic shall have an ongoing quality
487 assurance program that objectively and systematically monitors
488 and evaluates the quality and appropriateness of patient care,
489 evaluates methods to improve patient care, identifies and
490 corrects deficiencies within the facility, alerts the designated
491 physician to identify and resolve recurring problems, and
492 provides for opportunities to improve the facility's performance
493 and to enhance and improve the quality of care provided to the
494 public. The designated physician shall establish a quality
495 assurance program that includes the following components:

496 1. The identification, investigation, and analysis of the
497 frequency and causes of adverse incidents to patients.

498 2. The identification of trends or patterns of incidents.

499 3. The development of measures to correct, reduce,
500 minimize, or eliminate the risk of adverse incidents to
501 patients.

502 4. The documentation of these functions and periodic review
503 no less than quarterly of such information by the designated
504 physician.

505 (j) The designated physician is responsible for ensuring
506 compliance with the following data collection and reporting



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507 requirements:

508 1. The designated physician for each pain-management clinic
509 shall report all adverse incidents to the department as set
510 forth in s. 458.351.

511 2. The designated physician shall also report to the Board
512 of Medicine, in writing, on a quarterly basis the following
513 data:

514 a. Number of new and repeat patients seen and treated at
515 the clinic who are prescribed controlled substance medications
516 for the treatment of chronic, nonmalignant pain.

517 b. The number of patients discharged due to drug abuse.

518 c. The number of patients discharged due to drug diversion.

519 d. The number of patients treated at the pain clinic whose
520 domicile is located somewhere other than in this state. A
521 patient's domicile is the patient's fixed or permanent home to
522 which he or she intends to return even though he or she may
523 temporarily reside elsewhere.

524 (3) INSPECTION.—

525 (a) The department shall inspect the pain-management clinic
526 annually, including a review of the patient records, to ensure
527 that it complies with this section and the rules of the Board of
528 Medicine adopted pursuant to subsection (4) unless the clinic is
529 accredited by a nationally recognized accrediting agency
530 approved by the Board of Medicine.

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

535 (c) Any action taken to correct a violation shall be



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536 documented in writing by the owner or designated physician of
537 the pain-management clinic and verified by followup visits by
538 departmental personnel.

539 (4) RULEMAKING.—

540 (a) The department shall adopt rules necessary to
541 administer the registration and inspection of pain-management
542 clinics which establish the specific requirements, procedures,
543 forms, and fees.

544 ~~(b) The department shall adopt a rule defining what~~
545 ~~constitutes practice by a designated physician at the clinic~~
546 ~~location for which the physician has assumed responsibility, as~~
547 ~~set forth in subsection (1). When adopting the rule, the~~
548 ~~department shall consider the number of clinic employees, the~~
549 ~~location of the pain-management clinic, the clinic's hours of~~
550 ~~operation, and the amount of controlled substances being~~
551 ~~prescribed, dispensed, or administered at the pain-management~~
552 ~~clinic.~~

553 ~~(c) The Board of Medicine shall adopt a rule establishing~~
554 ~~the maximum number of prescriptions for Schedule II or Schedule~~
555 ~~III controlled substances or the controlled substance Alprazolam~~
556 ~~which may be written at any one registered pain-management~~
557 ~~clinic during any 24-hour period.~~

558 ~~(b)(d)~~ The Board of Medicine shall adopt rules setting
559 forth standards of practice for physicians practicing in
560 privately owned pain-management clinics that primarily engage in
561 the treatment of pain by prescribing or dispensing controlled
562 substance medications. Such rules shall address, but need not be
563 limited to:

564 1. Facility operations;



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- 565 ~~2. Physical operations;~~
566 ~~3. Infection control requirements;~~
567 ~~4. Health and safety requirements;~~
568 ~~5. Quality assurance requirements;~~
569 ~~6. Patient records;~~
570 ~~7. training requirements for all facility health care~~
571 ~~practitioners who are not regulated by another board.~~
572 ~~8. Inspections; and~~
573 ~~9. Data collection and reporting requirements.~~
574

575 ~~A physician is primarily engaged in the treatment of pain by~~
576 ~~prescribing or dispensing controlled substance medications when~~
577 ~~the majority of the patients seen are prescribed or dispensed~~
578 ~~controlled substance medications for the treatment of chronic~~
579 ~~nonmalignant pain. Chronic nonmalignant pain is pain unrelated~~
580 ~~to cancer which persists beyond the usual course of the disease~~
581 ~~or the injury that is the cause of the pain or more than 90 days~~
582 ~~after surgery.~~

583 (5) PENALTIES; ENFORCEMENT.—

584 (a) The department may impose an administrative fine on the
585 clinic of up to \$5,000 per violation for violating the
586 requirements of this section; chapter 499, the Florida Drug and
587 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
588 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
589 Abuse Prevention and Control Act; chapter 893, the Florida
590 Comprehensive Drug Abuse Prevention and Control Act; or the
591 rules of the department. In determining whether a penalty is to
592 be imposed, and in fixing the amount of the fine, the department
593 shall consider the following factors:



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594 1. The gravity of the violation, including the probability
595 that death or serious physical or emotional harm to a patient
596 has resulted, or could have resulted, from the pain-management
597 clinic's actions or the actions of the physician, the severity
598 of the action or potential harm, and the extent to which the
599 provisions of the applicable laws or rules were violated.

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

602 3. Whether there were any previous violations at the pain-
603 management clinic.

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

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

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

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

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

621 (6) EXPIRATION.—This section expires January 1, 2016.

622 Section 5. Paragraph (f) is added to subsection (1) of



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623 section 458.327, Florida Statutes, to read:

624 458.327 Penalty for violations.—

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

628 (f) Dispensing a controlled substance listed in Schedule II
629 or Schedule III in violation of s. 465.0276.

630 Section 6. Paragraph (rr) is added to subsection (1) of
631 section 458.331, Florida Statutes, to read:

632 458.331 Grounds for disciplinary action; action by the
633 board and department.—

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

636 (rr) Dispensing a controlled substance listed in Schedule
637 II or Schedule III in violation of s. 465.0276.

638 Section 7. Section 459.0137, Florida Statutes, is amended
639 to read:

640 459.0137 Pain-management clinics.—

641 (1) REGISTRATION.—

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

643 a. "Chronic nonmalignant pain" means pain unrelated to
644 cancer or rheumatoid arthritis which persists beyond the usual
645 course of disease or the injury that is the cause of the pain or
646 more than 90 days after surgery.

647 b. "Pain-management clinic" or "clinic" means any publicly
648 or privately owned facility:

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

651 (II) Where in any month a majority of patients are



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652 prescribed opioids, benzodiazepines, barbiturates, or
653 carisoprodol for the treatment of chronic nonmalignant pain. All
654 privately owned pain-management clinics, facilities, or offices,
655 hereinafter referred to as "clinics," which advertise in any
656 medium for any type of pain-management services, or employ an
657 osteopathic physician who is primarily engaged in the treatment
658 of pain by prescribing or dispensing controlled substance
659 medications,

660 2. Each pain-management clinic must register with the
661 department unless:

662 a.1. That clinic is licensed as a facility pursuant to
663 chapter 395;

664 b.2. The majority of the physicians who provide services in
665 the clinic primarily provide surgical services;

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

670 d.4. The clinic is affiliated with an accredited medical
671 school at which training is provided for medical students,
672 residents, or fellows;

673 e.5. The clinic does not prescribe ~~or dispense~~ controlled
674 substances for the treatment of pain; ~~or~~

675 f.6. The clinic is owned by a corporate entity exempt from
676 federal taxation under 26 U.S.C. s. 501(c)(3); ~~or~~

677 g. The clinic is wholly owned and operated by one or more
678 board-certified anesthesiologists, physiatrists, or
679 neurologists; or

680 h. The clinic is wholly owned and operated by one or more



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681 board-certified medical specialists who have also completed
682 fellowships in pain medicine approved by the Accreditation
683 Council for Graduate Medical Education or the American
684 Osteopathic Association, or who are also board-certified in pain
685 medicine by a board approved by the American Board of Medical
686 Specialties or the American Osteopathic Association and perform
687 interventional pain procedures of the type routinely billed
688 using surgical codes.

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

692 (c) As a part of registration, a clinic must designate an
693 osteopathic physician who is responsible for complying with all
694 requirements related to registration and operation of the clinic
695 in compliance with this section. Within 10 days after
696 termination of a designated osteopathic physician, the clinic
697 must notify the department of the identity of another designated
698 physician for that clinic. The designated physician shall have a
699 full, active, and unencumbered license under chapter 458 or this
700 chapter and shall practice at the clinic location for which the
701 physician has assumed responsibility. Failing to have a licensed
702 designated osteopathic physician practicing at the location of
703 the registered clinic may be the basis for a summary suspension
704 of the clinic registration certificate as described in s.
705 456.073(8) for a license or s. 120.60(6).

706 (d) The department shall deny registration to any clinic
707 that is not fully owned by a physician licensed under chapter
708 458 or this chapter or a group of physicians, each of whom is
709 licensed under chapter 458 or this chapter; or that is not a



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710 health care clinic licensed under part X of chapter 400.

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

714 1. Whose Drug Enforcement Administration number has ever
715 been revoked.

716 2. Whose application for a license to prescribe, dispense,
717 or administer a controlled substance has been denied by any
718 jurisdiction.

719 3. Who has been convicted of or pleaded guilty or nolo
720 contendere to, regardless of adjudication, an offense that
721 constitutes a felony for receipt of illicit and diverted drugs,
722 including a controlled substance listed in Schedule I, Schedule
723 II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in
724 this state, any other state, or the United States.

725 (f) If the department finds that a pain-management clinic
726 does not meet the requirement of paragraph (d) or is owned,
727 directly or indirectly, by a person meeting any criteria listed
728 in paragraph (e), the department shall revoke the certificate of
729 registration previously issued by the department. As determined
730 by rule, the department may grant an exemption to denying a
731 registration or revoking a previously issued registration if
732 more than 10 years have elapsed since adjudication. As used in
733 this subsection, the term "convicted" includes an adjudication
734 of guilt following a plea of guilty or nolo contendere or the
735 forfeiture of a bond when charged with a crime.

736 (g) The department may revoke the clinic's certificate of
737 registration and prohibit all physicians associated with that
738 pain-management clinic from practicing at that clinic location



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739 based upon an annual inspection and evaluation of the factors
740 described in subsection (3).

741 (h) If the registration of a pain-management clinic is
742 revoked or suspended, the designated physician of the pain-
743 management clinic, the owner or lessor of the pain-management
744 clinic property, the manager, and the proprietor shall cease to
745 operate the facility as a pain-management clinic as of the
746 effective date of the suspension or revocation.

747 (i) If a pain-management clinic registration is revoked or
748 suspended, the designated physician of the pain-management
749 clinic, the owner or lessor of the clinic property, the manager,
750 or the proprietor is responsible for removing all signs and
751 symbols identifying the premises as a pain-management clinic.

752 (j) Upon the effective date of the suspension or
753 revocation, the designated physician of the pain-management
754 clinic shall advise the department of the disposition of the
755 medicinal drugs located on the premises. The disposition is
756 subject to the supervision and approval of the department.
757 Medicinal drugs that are purchased or held by a pain-management
758 clinic that is not registered may be deemed adulterated pursuant
759 to s. 499.006.

760 (k) If the clinic's registration is revoked, any person
761 named in the registration documents of the pain-management
762 clinic, including persons owning or operating the pain-
763 management clinic, may not, as an individual or as a part of a
764 group, make application for a permit to operate a pain-
765 management clinic for 5 years after the date the registration is
766 revoked.

767 (l) The period of suspension for the registration of a



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768 pain-management clinic shall be prescribed by the department,
769 but may not exceed 1 year.

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

772 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
773 apply to any osteopathic physician who provides professional
774 services in a pain-management clinic that is required to be
775 registered in subsection (1).

776 (a) An osteopathic physician may not practice medicine in a
777 pain-management clinic, as described in subsection (4), if+

778 ~~1. the pain-management clinic is not registered with the~~
779 ~~department as required by this section.~~;

780 ~~2. Effective July 1, 2012, the physician has not~~
781 ~~successfully completed a pain-medicine fellowship that is~~
782 ~~accredited by the Accreditation Council for Graduate Medical~~
783 ~~Education or the American Osteopathic Association or a pain-~~
784 ~~medicine residency that is accredited by the Accreditation~~
785 ~~Council for Graduate Medical Education or the American~~
786 ~~Osteopathic Association or, prior to July 1, 2012, does not~~
787 ~~comply with rules adopted by the board.~~

788
789 Any physician who qualifies to practice medicine in a pain-
790 management clinic pursuant to rules adopted by the Board of
791 Osteopathic Medicine as of July 1, 2012, may continue to
792 practice medicine in a pain-management clinic as long as the
793 physician continues to meet the qualifications set forth in the
794 board rules. An osteopathic physician who violates this
795 paragraph is subject to disciplinary action by his or her
796 appropriate medical regulatory board.



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

801 (c) An osteopathic physician, a physician assistant, or an
802 advanced registered nurse practitioner must perform a physical
803 examination of a patient on the same day that the physician ~~he~~
804 ~~or she dispenses or~~ prescribes a controlled substance to a
805 patient at a pain-management clinic. If the osteopathic
806 physician prescribes ~~or dispenses~~ more than a 72-hour dose of
807 controlled substances for the treatment of chronic nonmalignant
808 pain, the osteopathic physician must document in the patient's
809 record the reason for prescribing ~~or dispensing~~ that quantity.

810 (d) An osteopathic physician authorized to prescribe
811 controlled substances who practices at a pain-management clinic
812 is responsible for maintaining the control and security of his
813 or her prescription blanks and any other method used for
814 prescribing controlled substance pain medication. The
815 osteopathic physician shall comply with the requirements for
816 counterfeit-resistant prescription blanks in s. 893.065 and the
817 rules adopted pursuant to that section. The osteopathic
818 physician shall notify, in writing, the department within 24
819 hours following any theft or loss of a prescription blank or
820 breach of any other method for prescribing pain medication.

821 (e) The designated osteopathic physician of a pain-
822 management clinic shall notify the applicable board in writing
823 of the date of termination of employment within 10 days after
824 terminating his or her employment with a pain-management clinic
825 that is required to be registered under subsection (1). Each



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826 osteopathic physician practicing in a pain-management clinic
827 shall advise the Board of Osteopathic Medicine in writing within
828 10 calendar days after beginning or ending his or her practice
829 at a pain-management clinic.

830 (f) Each osteopathic physician practicing in a pain-
831 management clinic is responsible for ensuring compliance with
832 the following facility and physical operations requirements:

833 1. A pain-management clinic shall be located and operated
834 at a publicly accessible fixed location and must:

835 a. Display a sign that can be viewed by the public that
836 contains the clinic name, hours of operations, and a street
837 address.

838 b. Have a publicly listed telephone number and a dedicated
839 phone number to send and receive faxes with a fax machine that
840 shall be operational 24 hours per day.

841 c. Have emergency lighting and communications.

842 d. Have a reception and waiting area.

843 e. Provide a restroom.

844 f. Have an administrative area including room for storage
845 of medical records, supplies and equipment.

846 g. Have private patient examination rooms.

847 h. Have treatment rooms, if treatment is being provided to
848 the patient.

849 i. Display a printed sign located in a conspicuous place in
850 the waiting room viewable by the public with the name and
851 contact information of the clinic-designated physician and the
852 names of all physicians practicing in the clinic.

853 j. If the clinic stores and dispenses prescription drug,
854 comply with ss. 499.0121 and 893.07.



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855 2. This section does not excuse an osteopathic physician
856 from providing any treatment or performing any medical duty
857 without the proper equipment and materials as required by the
858 standard of care. This section does not supersede the level of
859 care, skill, and treatment recognized in general law related to
860 healthcare licensure.

861 (g) Each osteopathic physician practicing in a pain-
862 management clinic is responsible for ensuring compliance with
863 the following infection control requirements.

864 1. The clinic shall maintain equipment and supplies to
865 support infection prevention and control activities.

866 2. The clinic shall identify infection risks based on the
867 following:

868 a. Geographic location, community, and population served.

869 b. The care, treatment and services it provides.

870 c. An analysis of its infection surveillance and control
871 data.

872 3. The clinic shall maintain written infection prevention
873 policies and procedures that address the following:

874 a. Prioritized risks.

875 b. Limiting unprotected exposure to pathogen.

876 c. Limiting the transmission of infections associated with
877 procedures performed in the clinic.

878 d. Limiting the transmission of infections associated with
879 the clinic's use of medical equipment, devices, and supplies.

880 (h) Each osteopathic physician practicing in a pain-
881 management clinic is responsible for ensuring compliance with
882 the following health and safety requirements.

883 1. The clinic, including its grounds, buildings, furniture,



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884 appliances, and equipment shall be structurally sound, in good
885 repair, clean, and free from health and safety hazards.

886 2. The clinic shall have evacuation procedures in the event
887 of an emergency which shall include provisions for the
888 evacuation of disabled patients and employees.

889 3. The clinic shall have a written facility-specific
890 disaster plan which sets forth actions that will be taken in the
891 event of clinic closure due to unforeseen disasters and shall
892 include provisions for the protection of medical records and any
893 controlled substances.

894 4. Each clinic shall have at least one employee on the
895 premises during patient care hours who is certified in Basic
896 Life Support and is trained in reacting to accidents and medical
897 emergencies until emergency medical personnel arrive.

898 (i) The designated physician is responsible for ensuring
899 compliance with the following quality assurance requirements.
900 Each pain-management clinic shall have an ongoing quality
901 assurance program that objectively and systematically monitors
902 and evaluates the quality and appropriateness of patient care,
903 evaluates methods to improve patient care, identifies and
904 corrects deficiencies within the facility, alerts the designated
905 physician to identify and resolve recurring problems, and
906 provides for opportunities to improve the facility's performance
907 and to enhance and improve the quality of care provided to the
908 public. The designated physician shall establish a quality
909 assurance program that includes the following components:

910 1. The identification, investigation, and analysis of the
911 frequency and causes of adverse incidents to patients.

912 2. The identification of trends or patterns of incidents.



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913 3. The development of measures to correct, reduce,
914 minimize, or eliminate the risk of adverse incidents to
915 patients.

916 4. The documentation of these functions and periodic review
917 no less than quarterly of such information by the designated
918 physician.

919 (j) The designated physician is responsible for ensuring
920 compliance with the following data collection and reporting
921 requirements:

922 1. The designated physician for each pain-management clinic
923 shall report all adverse incidents to the department as set
924 forth in s. 459.026.

925 2. The designated physician shall also report to the Board
926 of Osteopathic Medicine, in writing, on a quarterly basis, the
927 following data:

928 a. Number of new and repeat patients seen and treated at
929 the clinic who are prescribed controlled substance medications
930 for the treatment of chronic, nonmalignant pain.

931 b. The number of patients discharged due to drug abuse.

932 c. The number of patients discharged due to drug diversion.

933 d. The number of patients treated at the pain clinic whose
934 domicile is located somewhere other than in this state. A
935 patient's domicile is the patient's fixed or permanent home to
936 which he or she intends to return even though he or she may
937 temporarily reside elsewhere.

938 (3) INSPECTION.—

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



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942 Osteopathic Medicine adopted pursuant to subsection (4) unless
943 the clinic is accredited by a nationally recognized accrediting
944 agency approved by the Board of Osteopathic Medicine.

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

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

953 (4) RULEMAKING.—

954 (a) The department shall adopt rules necessary to
955 administer the registration and inspection of pain-management
956 clinics which establish the specific requirements, procedures,
957 forms, and fees.

958 ~~(b) The department shall adopt a rule defining what~~
959 ~~constitutes practice by a designated osteopathic physician at~~
960 ~~the clinic location for which the physician has assumed~~
961 ~~responsibility, as set forth in subsection (1). When adopting~~
962 ~~the rule, the department shall consider the number of clinic~~
963 ~~employees, the location of the pain-management clinic, the~~
964 ~~clinic's hours of operation, and the amount of controlled~~
965 ~~substances being prescribed, dispensed, or administered at the~~
966 ~~pain-management clinic.~~

967 ~~(c) The Board of Osteopathic Medicine shall adopt a rule~~
968 ~~establishing the maximum number of prescriptions for Schedule II~~
969 ~~or Schedule III controlled substances or the controlled~~
970 ~~substance Alprazolam which may be written at any one registered~~



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971 ~~pain management clinic during any 24-hour period.~~

972 ~~(b)(d) The Board of Osteopathic Medicine shall adopt rules~~
973 ~~setting forth standards of practice for osteopathic physicians~~
974 ~~practicing in privately owned pain management clinics that~~
975 ~~primarily engage in the treatment of pain by prescribing or~~
976 ~~dispensing controlled substance medications. Such rules shall~~
977 ~~address, but need not be limited to:~~

978 ~~1. Facility operations;~~

979 ~~2. Physical operations;~~

980 ~~3. Infection control requirements;~~

981 ~~4. Health and safety requirements;~~

982 ~~5. Quality assurance requirements;~~

983 ~~6. Patient records;~~

984 ~~7. training requirements for all facility health care~~
985 ~~practitioners who are not regulated by another board.~~

986 ~~8. Inspections; and~~

987 ~~9. Data collection and reporting requirements.~~

988

989 ~~An osteopathic physician is primarily engaged in the treatment~~
990 ~~of pain by prescribing or dispensing controlled substance~~
991 ~~medications when the majority of the patients seen are~~
992 ~~prescribed or dispensed controlled substance medications for the~~
993 ~~treatment of chronic nonmalignant pain. Chronic nonmalignant~~
994 ~~pain is pain unrelated to cancer which persists beyond the usual~~
995 ~~course of the disease or the injury that is the cause of the~~
996 ~~pain or more than 90 days after surgery.~~

997 (5) PENALTIES; ENFORCEMENT.—

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



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1000 requirements of this section; chapter 499, the Florida Drug and
1001 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
1002 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
1003 Abuse Prevention and Control Act; chapter 893, the Florida
1004 Comprehensive Drug Abuse Prevention and Control Act; or the
1005 rules of the department. In determining whether a penalty is to
1006 be imposed, and in fixing the amount of the fine, the department
1007 shall consider the following factors:

1008 1. The gravity of the violation, including the probability
1009 that death or serious physical or emotional harm to a patient
1010 has resulted, or could have resulted, from the pain-management
1011 clinic's actions or the actions of the osteopathic physician,
1012 the severity of the action or potential harm, and the extent to
1013 which the provisions of the applicable laws or rules were
1014 violated.

1015 2. What actions, if any, the owner or designated
1016 osteopathic physician took to correct the violations.

1017 3. Whether there were any previous violations at the pain-
1018 management clinic.

1019 4. The financial benefits that the pain-management clinic
1020 derived from committing or continuing to commit the violation.

1021 (b) Each day a violation continues after the date fixed for
1022 termination of the violation as ordered by the department
1023 constitutes an additional, separate, and distinct violation.

1024 (c) The department may impose a fine and, in the case of an
1025 owner-operated pain-management clinic, revoke or deny a pain-
1026 management clinic's registration, if the clinic's designated
1027 osteopathic physician knowingly and intentionally misrepresents
1028 actions taken to correct a violation.



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1029 (d) An owner or designated osteopathic physician of a pain-
1030 management clinic who concurrently operates an unregistered
1031 pain-management clinic is subject to an administrative fine of
1032 \$5,000 per day.

1033 (e) If the owner of a pain-management clinic that requires
1034 registration fails to apply to register the clinic upon a change
1035 of ownership and operates the clinic under the new ownership,
1036 the owner is subject to a fine of \$5,000.

1037 (6) EXPIRATION.—This section expires January 1, 2016.

1038 Section 8. Paragraph (f) is added to subsection (1) of
1039 section 459.013, Florida Statutes, to read:

1040 459.013 Penalty for violations.—

1041 (1) Each of the following acts constitutes a felony of the
1042 third degree, punishable as provided in s. 775.082, s. 775.083,
1043 or s. 775.084:

1044 (f) Dispensing a controlled substance listed in Schedule II
1045 or Schedule III in violation of s. 465.0276.

1046 Section 9. Paragraph (tt) is added to subsection (1) of
1047 section 459.015, Florida Statutes, to read:

1048 459.015 Grounds for disciplinary action; action by the
1049 board and department.—

1050 (1) The following acts constitute grounds for denial of a
1051 license or disciplinary action, as specified in s. 456.072(2):

1052 (tt) Dispensing a controlled substance listed in Schedule
1053 II or Schedule III in violation of s. 465.0276.

1054 Section 10. Subsections (3) and (4) of section 465.015,
1055 Florida Statutes, are renumbered as subsections (4) and (5),
1056 respectively, a new subsection (3) is added to that section, and
1057 present subsection (4) of that section is amended, to read:



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1058 465.015 Violations and penalties.-

1059 (3) It is unlawful for any pharmacist to knowingly fail to
1060 report to the sheriff or other chief law enforcement agency of
1061 the county where the pharmacy is located within 24 hours after
1062 learning of any instance in which a person obtained or attempted
1063 to obtain a controlled substance, as defined in s. 893.02, or at
1064 the close of business on the next business day, whichever is
1065 later, that the pharmacist knew or believed was obtained or
1066 attempted to be obtained through fraudulent methods or
1067 representations from the pharmacy at which the pharmacist
1068 practiced pharmacy. Any pharmacist who knowingly fails to make
1069 such a report within 24 hours after learning of the fraud or
1070 attempted fraud or at the close of business on the next business
1071 day, whichever is later, commits a misdemeanor of the first
1072 degree, punishable as provided in s. 775.082 or s. 775.083. A
1073 sufficient report of the fraudulent obtaining of controlled
1074 substances under this subsection must contain, at a minimum, a
1075 copy of the prescription used or presented and a narrative,
1076 including all information available to the pharmacist concerning
1077 the transaction, such as the name and telephone number of the
1078 prescribing physician; the name, description, and any personal
1079 identification information pertaining to the person who
1080 presented the prescription; and all other material information,
1081 such as photographic or video surveillance of the transaction.

1082 (5)~~(4)~~ Any person who violates any provision of subsection
1083 (1) or subsection (4) ~~(3)~~ commits a misdemeanor of the first
1084 degree, punishable as provided in s. 775.082 or s. 775.083. Any
1085 person who violates any provision of subsection (2) commits a
1086 felony of the third degree, punishable as provided in s.



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1087 775.082, s. 775.083, or s. 775.084. In any warrant, information,
1088 or indictment, it shall not be necessary to negative any
1089 exceptions, and the burden of any exception shall be upon the
1090 defendant.

1091 Section 11. Paragraph (t) is added to subsection (1) of
1092 section 465.016, Florida Statutes, to read:

1093 465.016 Disciplinary actions.—

1094 (1) The following acts constitute grounds for denial of a
1095 license or disciplinary action, as specified in s. 456.072(2):

1096 (t) Committing an error or omission during the performance
1097 of a specific function of prescription drug processing, which
1098 includes, for purposes of this paragraph:

1099 1. Receiving, interpreting, or clarifying a prescription.

1100 2. Entering prescription data into the pharmacy's record.

1101 3. Verifying or validating a prescription.

1102 4. Performing pharmaceutical calculations.

1103 5. Performing prospective drug review as defined by the
1104 board.

1105 6. Obtaining refill and substitution authorizations.

1106 7. Interpreting or acting on clinical data.

1107 8. Performing therapeutic interventions.

1108 9. Providing drug information concerning a patient's
1109 prescription.

1110 10. Providing patient counseling.

1111 Section 12. Section 465.018, Florida Statutes, is amended
1112 to read:

1113 465.018 Community pharmacies; permits.—

1114 (1) Any person desiring a permit to operate a community
1115 pharmacy shall apply to the department.



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1116 (2) If the board office certifies that the application
1117 complies with the laws of the state and the rules of the board
1118 governing pharmacies, the department shall issue the permit. No
1119 permit shall be issued unless a licensed pharmacist is
1120 designated as the prescription department manager ~~responsible~~
1121 ~~for maintaining all drug records, providing for the security of~~
1122 ~~the prescription department, and following such other rules as~~
1123 ~~relate to the practice of the profession of pharmacy. The~~
1124 ~~permittee and the newly designated prescription department~~
1125 ~~manager shall notify the department within 10 days of any change~~
1126 ~~in prescription department manager.~~

1127 (3) The board may suspend or revoke the permit of, or may
1128 refuse to issue a permit to:

1129 (a) Any person who has been disciplined or who has
1130 abandoned a permit or allowed a permit to become void after
1131 written notice that disciplinary proceedings had been or would
1132 be brought against the permit;

1133 (b) Any person who is an officer, director, or person
1134 interested directly or indirectly in a person or business entity
1135 that has had a permit disciplined or abandoned or become void
1136 after written notice that disciplinary proceedings had been or
1137 would be brought against the permit; or

1138 (c) Any person who is or has been an officer of a business
1139 entity, or who was interested directly or indirectly in a
1140 business entity, the permit of which has been disciplined or
1141 abandoned or become null and void after written notice that
1142 disciplinary proceedings had been or would be brought against
1143 the permit.

1144 (4) In addition to any other remedies provided by law, the



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1145 board may deny the application or suspend or revoke the license,
1146 registration, or certificate of any entity regulated or licensed
1147 by it if the applicant, licensee, registrant, or licenseholder,
1148 or, in the case of a corporation, partnership, or other business
1149 entity, if any officer, director, agent, or managing employee of
1150 that business entity or any affiliated person, partner, or
1151 shareholder having an ownership interest equal to 5 percent or
1152 greater in that business entity, has failed to pay all
1153 outstanding fines, liens, or overpayments assessed by final
1154 order of the department, unless a repayment plan is approved by
1155 the department, or has failed to comply with any repayment plan.

1156 (5) In reviewing any application requesting a change of
1157 ownership or a change of licensee or registrant, the transferor
1158 shall, before board approval of the change, repay or make
1159 arrangements to repay any amounts owed to the department. If the
1160 transferor fails to repay or make arrangements to repay the
1161 amounts owed to the department, the license or registration may
1162 not be issued to the transferee until repayment or until
1163 arrangements for repayment are made.

1164 (6) Passing an onsite inspection is a prerequisite to the
1165 issuance of an initial permit or a permit for a change of
1166 location. The department must make the inspection within 90 days
1167 before issuance of the permit.

1168 (7) Community pharmacies that dispense controlled
1169 substances must maintain a record of all controlled substance
1170 dispensing consistent with the requirements of s. 893.07 and
1171 must make the record available to the department and law
1172 enforcement agencies upon request.

1173 Section 13. In order to dispense controlled substances



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1174 listed in Schedule II or Schedule III, as provided in s. 893.03,
1175 Florida Statutes, on or after July 1, 2012, a community pharmacy
1176 permittee must be permitted pursuant to chapter 465, Florida
1177 Statutes, as amended by this act and any rules adopted
1178 thereunder.

1179 Section 14. Section 465.022, Florida Statutes, is amended
1180 to read:

1181 465.022 Pharmacies; general requirements; fees.—

1182 (1) The board shall adopt rules pursuant to ss. 120.536(1)
1183 and 120.54 to implement the provisions of this chapter. Such
1184 rules shall include, but shall not be limited to, rules relating
1185 to:

1186 (a) General drug safety measures.

1187 (b) Minimum standards for the physical facilities of
1188 pharmacies.

1189 (c) Safe storage of floor-stock drugs.

1190 (d) Functions of a pharmacist in an institutional pharmacy,
1191 consistent with the size and scope of the pharmacy.

1192 (e) Procedures for the safe storage and handling of
1193 radioactive drugs.

1194 (f) Procedures for the distribution and disposition of
1195 medicinal drugs distributed pursuant to s. 499.028.

1196 (g) Procedures for transfer of prescription files and
1197 medicinal drugs upon the change of ownership or closing of a
1198 pharmacy.

1199 (h) Minimum equipment which a pharmacy shall at all times
1200 possess to fill prescriptions properly.

1201 (i) Procedures for the dispensing of controlled substances
1202 to minimize dispensing based on fraudulent representations or



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1203 invalid practitioner-patient relationships.

1204 (2) A pharmacy permit may ~~shall~~ be issued only to a natural
1205 person who is at least 18 years of age, to a partnership
1206 comprised of at least one natural person and all of whose
1207 partners are all at least 18 years of age, to a governmental
1208 agency, or to a business entity that is properly registered with
1209 the Secretary of State, if required by law, and has been issued
1210 a federal employer tax identification number ~~corporation that is~~
1211 ~~registered pursuant to chapter 607 or chapter 617 whose~~
1212 ~~officers, directors, and shareholders are at least 18 years of~~
1213 ~~age. Permits issued to business entities may be issued only to~~
1214 entities whose affiliated persons, members, partners, officers,
1215 directors, and agents, including persons required to be
1216 fingerprinted under subsection (3), are not less than 18 years
1217 of age.

1218 (3) Any person or business entity, partnership, or
1219 ~~corporation~~ before engaging in the operation of a pharmacy,
1220 shall file with the board a sworn application on forms provided
1221 by the department. For purposes of this section, any person
1222 required to provide fingerprints under this subsection is an
1223 affiliated person within the meaning of s. 465.023(1).

1224 (a) An application for a pharmacy permit must include a set
1225 of fingerprints from each person having an ownership interest of
1226 5 percent or greater and from any person who, directly or
1227 indirectly, manages, oversees, or controls the operation of the
1228 applicant, including officers and members of the board of
1229 directors of an applicant that is a corporation. The applicant
1230 must provide payment in the application for the cost of state
1231 and national criminal history records checks.



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1232 1. For corporations having more than \$100 million of
1233 business taxable assets in this state, in lieu of these
1234 fingerprint requirements, the department shall require the
1235 prescription department manager or consultant pharmacist of
1236 record who will be directly involved in the management and
1237 operation of the pharmacy to submit a set of fingerprints.

1238 2. A representative of a corporation described in
1239 subparagraph 1. satisfies the requirement to submit a set of his
1240 or her fingerprints if the fingerprints are on file with the
1241 department or the Agency for Health Care Administration, meet
1242 the fingerprint specifications for submission by the Department
1243 of Law Enforcement, and are available to the department.

1244 (b) The department shall annually submit the fingerprints
1245 provided by the applicant to the Department of Law Enforcement
1246 for a state criminal history records check. The Department of
1247 Law Enforcement shall annually forward the fingerprints to the
1248 Federal Bureau of Investigation for a national criminal history
1249 records check. The department shall report the results of annual
1250 criminal history records checks to wholesale distributors
1251 permitted under chapter 499 for the purposes of s. 499.0121(15).

1252 (c) In addition to those documents required by the
1253 department or board, each applicant having any financial or
1254 ownership interest greater than 5 percent in the subject of the
1255 application must submit a signed affidavit disclosing any
1256 financial or ownership interest greater than 5 percent in any
1257 pharmacy permitted in the past 5 years, which pharmacy has
1258 closed voluntarily or involuntarily, has filed a voluntary
1259 relinquishment of its permit, has had its permit suspended or
1260 revoked, or has had an injunction issued against it by a



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1261 regulatory agency. The affidavit must disclose the reason such
1262 entity was closed, whether voluntary or involuntary.

1263 (4) An application for a pharmacy permit must include the
1264 applicant's written policies and procedures for preventing
1265 controlled substance dispensing based on fraudulent
1266 representations or invalid practitioner-patient relationships.
1267 The board must review the policies and procedures and may deny a
1268 permit if the policies and procedures are insufficient to
1269 reasonably prevent such dispensing. The department may phase in
1270 the submission and review of policies and procedures over one
1271 18-month period beginning July 1, 2011.

1272 (5)~~(4)~~ The department or board shall deny an application
1273 for a pharmacy permit if the applicant or an affiliated person,
1274 partner, officer, director, or prescription department manager
1275 or consultant pharmacist of record of the applicant has:

1276 (a) Has obtained a permit by misrepresentation or fraud.~~†~~

1277 (b) Has attempted to procure, or has procured, a permit for
1278 any other person by making, or causing to be made, any false
1279 representation.~~†~~

1280 (c) Has been convicted of, or entered a plea of guilty or
1281 nolo contendere to, regardless of adjudication, a crime in any
1282 jurisdiction which relates to the practice of, or the ability to
1283 practice, the profession of pharmacy.~~†~~

1284 (d) Has been convicted of, or entered a plea of guilty or
1285 nolo contendere to, regardless of adjudication, a crime in any
1286 jurisdiction which relates to health care fraud.~~†~~

1287 (e) Has been convicted of, or entered a plea of guilty or
1288 nolo contendere to, regardless of adjudication, a felony under
1289 chapter 409, chapter 817, or chapter 893, or a similar felony



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1290 offense committed in another state or jurisdiction, since July
1291 1, 2009. ~~Been terminated for cause, pursuant to the appeals~~
1292 ~~procedures established by the state or Federal Government, from~~
1293 ~~any state Medicaid program or the federal Medicare program,~~
1294 ~~unless the applicant has been in good standing with a state~~
1295 ~~Medicaid program or the federal Medicare program for the most~~
1296 ~~recent 5 years and the termination occurred at least 20 years~~
1297 ~~ago; or~~

1298 (f) Has been convicted of, or entered a plea of guilty or
1299 nolo contendere to, regardless of adjudication, a felony under
1300 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1,
1301 2009.

1302 (g) Has been terminated for cause from the Florida Medicaid
1303 program pursuant to s. 409.913, unless the applicant has been in
1304 good standing with the Florida Medicaid program for the most
1305 recent 5-year period.

1306 (h) Has been terminated for cause, pursuant to the appeals
1307 procedures established by the state, from any other state
1308 Medicaid program, unless the applicant has been in good standing
1309 with a state Medicaid program for the most recent 5-year period
1310 and the termination occurred at least 20 years before the date
1311 of the application.

1312 (i) Is currently listed on the United States Department of
1313 Health and Human Services Office of Inspector General's List of
1314 Excluded Individuals and Entities.

1315 (j) ~~(f)~~ Has dispensed any medicinal drug based upon a
1316 communication that purports to be a prescription as defined by
1317 s. 465.003(14) or s. 893.02 when the pharmacist knows or has
1318 reason to believe that the purported prescription is not based



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1319 upon a valid practitioner-patient relationship that includes a
1320 documented patient evaluation, including history and a physical
1321 examination adequate to establish the diagnosis for which any
1322 drug is prescribed and any other requirement established by
1323 board rule under chapter 458, chapter 459, chapter 461, chapter
1324 463, chapter 464, or chapter 466.

1325

1326 For felonies in which the defendant entered a plea of guilty or
1327 nolo contendere in an agreement with the court to enter a
1328 pretrial intervention or drug diversion program, the department
1329 shall deny the application if upon final resolution of the case
1330 the licensee has failed to successfully complete the program.

1331 (6) The department or board may deny an application for a
1332 pharmacy permit if the applicant or an affiliated person,
1333 partner, officer, director, or prescription department manager
1334 or consultant pharmacist of record of the applicant has violated
1335 or failed to comply with any provision of this chapter; chapter
1336 499, the Florida Drug and Cosmetic Act; chapter 893; 21 U.S.C.
1337 ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C.
1338 ss. 821 et seq., the Comprehensive Drug Abuse Prevention and
1339 Control Act; or any rules or regulations promulgated thereunder
1340 unless the violation or noncompliance is technical.

1341 (7)~~(5)~~ After the application has been filed with the board
1342 and the permit fee provided in this section has been received,
1343 the board shall cause the application to be fully investigated,
1344 both as to the qualifications of the applicant and the
1345 prescription department manager or consultant pharmacist
1346 designated to be in charge and as to the premises and location
1347 described in the application.



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1348 (8)~~(6)~~ The Board of Pharmacy shall have the authority to
1349 determine whether a bona fide transfer of ownership is present
1350 and that the sale of a pharmacy is not being accomplished for
1351 the purpose of avoiding an administrative prosecution.

1352 (9)~~(7)~~ Upon the completion of the investigation of an
1353 application, the board shall approve or deny ~~disapprove~~ the
1354 application. If approved, the permit shall be issued by the
1355 department.

1356 (10)~~(8)~~ A permittee must notify the department, on a form
1357 approved by the board, within 10 days after any change in
1358 prescription department manager or consultant pharmacist of
1359 record. ~~Permits issued by the department are not transferable.~~

1360 (11) A permittee must notify the department of the identity
1361 of the prescription department manager within 10 days after
1362 employment. The prescription department manager must comply with
1363 the following requirements:

1364 (a) The prescription department manager of a permittee must
1365 obtain and maintain all drug records required by any state or
1366 federal law to be obtained by a pharmacy, including, but not
1367 limited to, records required by or under this chapter, chapter
1368 499, or chapter 893. The prescription department manager must
1369 ensure the permittee's compliance with all rules adopted under
1370 those chapters as they relate to the practice of the profession
1371 of pharmacy and the sale of prescription drugs.

1372 (b) The prescription department manager must ensure the
1373 security of the prescription department. The prescription
1374 department manager must notify the board of any theft or
1375 significant loss of any controlled substances within 1 business
1376 day after discovery of the theft or loss.



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1377 (c) A registered pharmacist may not serve as the
1378 prescription department manager in more than one location unless
1379 approved by the board.

1380 (12) The board shall adopt rules that require the keeping
1381 of such records of prescription drugs as are necessary for the
1382 protection of public health, safety, and welfare.

1383 (a) All required records documenting prescription drug
1384 distributions shall be readily available or immediately
1385 retrievable during an inspection by the department.

1386 (b) The records must be maintained for 4 years after the
1387 creation or receipt of the record, whichever is later.

1388 (13) Permits issued by the department are not transferable.

1389 (14) ~~(9)~~ The board shall set the fees for the following:

1390 (a) Initial permit fee not to exceed \$250.

1391 (b) Biennial permit renewal not to exceed \$250.

1392 (c) Delinquent fee not to exceed \$100.

1393 (d) Change of location fee not to exceed \$100.

1394 Section 15. Paragraph (b) of subsection (1) of section
1395 465.0276, Florida Statutes, is amended to read:

1396 465.0276 Dispensing practitioner.—

1397 (1)

1398 (b) 1. A practitioner registered under this section may not
1399 dispense ~~more than a 72-hour supply of~~ a controlled substance
1400 listed in Schedule II or, Schedule III as provided in, Schedule
1401 IV, ~~or~~ Schedule V of s. 893.03 ~~for any patient who pays for the~~
1402 ~~medication by cash, check, or credit card in a clinic registered~~
1403 ~~under s. 458.3265 or s. 459.0137. A practitioner who violates~~
1404 ~~this paragraph commits a felony of the third degree, punishable~~
1405 ~~as provided in s. 775.082, s. 775.083, or s. 775.084. This~~



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1406 paragraph does not apply to:

1407 ~~1. A practitioner who dispenses medication to a workers'~~
1408 ~~compensation patient pursuant to chapter 440.~~

1409 ~~2. A practitioner who dispenses medication to an insured~~
1410 ~~patient who pays by cash, check, or credit card to cover any~~
1411 ~~applicable copayment or deductible.~~

1412 1.3. The dispensing of complimentary packages of medicinal
1413 drugs which are labeled as a drug sample or complimentary drug
1414 as defined in s. 499.028 to the practitioner's own patients in
1415 the regular course of her or his practice without the payment of
1416 a fee or remuneration of any kind, whether direct or indirect,
1417 as provided in subsection (5).

1418 2. The dispensing of controlled substances in the health
1419 care system of the Department of Corrections.

1420 3. The dispensing of a controlled substance listed in
1421 Schedule II or Schedule III in connection with the performance
1422 of a surgical procedure. The amount dispensed pursuant to the
1423 subparagraph may not exceed a 14-day supply. This exception does
1424 not allow for the dispensing of a controlled substance listed in
1425 Schedule II or Schedule III more than 14 days after the
1426 performance of the surgical procedure. For purposes of this
1427 subparagraph, the term "surgical procedure" means any procedure
1428 in any setting which involves, or reasonably should involve:

1429 a. Perioperative medication and sedation that allows the
1430 patient to tolerate unpleasant procedures while maintaining
1431 adequate cardiorespiratory function and the ability to respond
1432 purposefully to verbal or tactile stimulation and makes intra-
1433 and post-operative monitoring necessary; or

1434 b. The use of general anesthesia or major conduction



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1435 anesthesia and preoperative sedation.

1436 4. The dispensing of a controlled substance listed in
1437 Schedule II or Schedule III pursuant to an approved clinical
1438 trial. For purposes of this subparagraph, the term "approved
1439 clinical trial" means a clinical research study or clinical
1440 investigation that, in whole or in part, is state or federally
1441 funded or is conducted under an investigational new drug
1442 application that is reviewed by the United States Food and Drug
1443 Administration.

1444 5. The dispensing of methadone in a facility licensed under
1445 s. 397.427 where medication-assisted treatment for opiate
1446 addiction is provided.

1447 6. The dispensing of a controlled substance listed in
1448 Schedule II or Schedule III to a patient of a facility licensed
1449 under part IV of chapter 400.

1450 Section 16. Subsections (16) and (17) are added to section
1451 499.0051, Florida Statutes, to read:

1452 499.0051 Criminal acts.—

1453 (16) FALSE REPORT.—Any person who submits a report required
1454 by s. 499.0121(14) knowing that such report contains a false
1455 statement commits a felony of the third degree, punishable as
1456 provided in s. 775.082, s. 775.083, or s. 775.084.

1457 (17) CONTROLLED SUBSTANCE DISTRIBUTION.—Any person who
1458 engages in the wholesale distribution of prescription drugs and
1459 who knowingly distributes controlled substances in violation of
1460 s. 499.0121(14) commits a felony of the third degree, punishable
1461 as provided in s. 775.082, s. 775.083, or s. 775.084. In
1462 addition to any other fine that may be imposed, a person
1463 convicted of such a violation may be sentenced to pay a fine



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1464 that does not exceed three times the gross monetary value gained
1465 from such violation, plus court costs and the reasonable costs
1466 of investigation and prosecution.

1467 Section 17. Paragraph (o) is added to subsection (8) of
1468 section 499.012, Florida Statutes, to read:

1469 499.012 Permit application requirements.—

1470 (8) An application for a permit or to renew a permit for a
1471 prescription drug wholesale distributor or an out-of-state
1472 prescription drug wholesale distributor submitted to the
1473 department must include:

1474 (o) Documentation of the credentialing policies and
1475 procedures required by s. 499.0121(14).

1476 Section 18. Subsections (14) and (15) are added to section
1477 499.0121, Florida Statutes, to read:

1478 499.0121 Storage and handling of prescription drugs;
1479 recordkeeping.—The department shall adopt rules to implement
1480 this section as necessary to protect the public health, safety,
1481 and welfare. Such rules shall include, but not be limited to,
1482 requirements for the storage and handling of prescription drugs
1483 and for the establishment and maintenance of prescription drug
1484 distribution records.

1485 (14) DISTRIBUTION REPORTING.—Each prescription drug
1486 wholesale distributor, out-of-state prescription drug wholesale
1487 distributor, retail pharmacy drug wholesale distributor,
1488 manufacturer, or repackager that engages in the wholesale
1489 distribution of controlled substances as defined in s. 893.02
1490 shall submit a report to the department of its receipts and
1491 distributions of controlled substances listed in Schedule II,
1492 Schedule III, Schedule IV, or Schedule V as provided in s.



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1493 893.03. Wholesale distributor facilities located within this
1494 state shall report all transactions involving controlled
1495 substances, and wholesale distributor facilities located outside
1496 this state shall report all distributions to entities located in
1497 this state. If the prescription drug wholesale distributor, out-
1498 of-state prescription drug wholesale distributor, retail
1499 pharmacy drug wholesale distributor, manufacturer, or repackager
1500 does not have any controlled substance distributions for the
1501 month, a report shall be sent indicating that no distributions
1502 occurred in the period. The report shall be submitted monthly by
1503 the 20th of the next month, in the electronic format used for
1504 controlled substance reporting to the Automation of Reports and
1505 Consolidated Orders System division of the federal Drug
1506 Enforcement Administration. Submission of electronic data must
1507 be made in a secured Internet environment that allows for manual
1508 or automated transmission. Upon successful transmission, an
1509 acknowledgement page must be displayed to confirm receipt. The
1510 report must contain the following information:

1511 (a) The federal Drug Enforcement Administration
1512 registration number of the wholesale distributing location.

1513 (b) The federal Drug Enforcement Administration
1514 registration number of the entity to which the drugs are
1515 distributed or from which the drugs are received.

1516 (c) The transaction code that indicates the type of
1517 transaction.

1518 (d) The National Drug Code identifier of the product and
1519 the quantity distributed or received.

1520 (e) The Drug Enforcement Administration Form 222 number or
1521 Controlled Substance Ordering System Identifier on all schedule



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1522 II transactions.

1523 (f) The date of the transaction.

1524

1525 The department must share the reported data with the Department
1526 of Law Enforcement and local law enforcement agencies upon
1527 request and must monitor purchasing to identify purchasing
1528 levels that are inconsistent with the purchasing entity's
1529 clinical needs. The Department of Law Enforcement shall
1530 investigate purchases at levels that are inconsistent with the
1531 purchasing entity's clinical needs to determine whether
1532 violations of chapter 893 have occurred.

1533 (15) DUE DILIGENCE OF PURCHASERS.—

1534 (a) Each prescription drug wholesale distributor, out-of-
1535 state prescription drug wholesale distributor, and retail
1536 pharmacy drug wholesale distributor must establish and maintain
1537 policies and procedures to credential physicians licensed under
1538 chapter 458, chapter 459, chapter 461, or chapter 466 and
1539 pharmacies that purchase or otherwise receive from the wholesale
1540 distributor controlled substances listed in Schedule II or
1541 Schedule III as provided in s. 893.03. The prescription drug
1542 wholesale distributor, out-of-state prescription drug wholesale
1543 distributor, or retail pharmacy drug wholesale distributor shall
1544 maintain records of such credentialing and make the records
1545 available to the department upon request. Such credentialing
1546 must, at a minimum, include:

1547 1. A determination of the clinical nature of the receiving
1548 entity, including any specialty practice area.

1549 2. A review of the receiving entity's history of Schedule
1550 II and Schedule III controlled substance purchasing from the



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1551 wholesale distributor.

1552 3. A determination that the receiving entity's Schedule II
1553 and Schedule III controlled substance purchasing history, if
1554 any, is consistent with and reasonable for that entity's
1555 clinical business needs.

1556 (b) A wholesale distributor must take reasonable measures
1557 to identify its customers, understand the normal and expected
1558 transactions conducted by those customers, and identify those
1559 transactions that are suspicious in nature. A wholesale
1560 distributor must establish internal policies and procedures for
1561 identifying suspicious orders and preventing suspicious
1562 transactions. A wholesale distributor must assess orders for
1563 greater than 5,000 unit doses of any one controlled substance in
1564 any one month to determine whether the purchase is reasonable.
1565 In making such assessments, a wholesale distributor may consider
1566 the purchasing entity's clinical business needs, location, and
1567 population served, in addition to other factors established in
1568 the distributor's policies and procedures. A wholesale
1569 distributor must report to the department any regulated
1570 transaction involving an extraordinary quantity of a listed
1571 chemical, an uncommon method of payment or delivery, or any
1572 other circumstance that the regulated person believes may
1573 indicate that the listed chemical will be used in violation of
1574 the law. The wholesale distributor shall maintain records that
1575 document the report submitted to the department in compliance
1576 with this paragraph.

1577 (c) A wholesale distributor may not distribute controlled
1578 substances to an entity if any criminal history record check for
1579 any person associated with that entity shows that the person has



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1580 been convicted of, or entered a plea of guilty or nolo
1581 contendere to, regardless of adjudication, a crime in any
1582 jurisdiction related to controlled substances, the practice of
1583 pharmacy, or the dispensing of medicinal drugs.

1584 (d) The department shall assess national data from the
1585 Automation of Reports and Consolidated Orders System of the
1586 federal Drug Enforcement Administration, excluding Florida data,
1587 and identify the national average of grams of hydrocodone,
1588 morphine, oxycodone, and methadone distributed per pharmacy
1589 registrant per month in the most recent year for which data is
1590 available. The department shall report the average for each of
1591 these drugs to the Governor, the President of the Senate, and
1592 the Speaker of the House of Representatives by November 1, 2011.
1593 The department shall assess the data reported pursuant to
1594 subsection (14) and identify the statewide average of grams of
1595 each benzodiazapine distributed per community pharmacy per
1596 month. The department shall report the average for each
1597 benzodiazapine to the Governor, the President of the Senate, and
1598 the Speaker of the House of Representatives by November 1, 2011.

1599 Section 19. Paragraphs (o) and (p) are added to subsection
1600 (1) of section 499.05, Florida Statutes, to read:

1601 499.05 Rules.—

1602 (1) The department shall adopt rules to implement and
1603 enforce this part with respect to:

1604 (o) Wholesale distributor reporting requirements of s.
1605 499.0121(14).

1606 (p) Wholesale distributor credentialing and distribution
1607 requirements of s. 499.0121(15).

1608 Section 20. Subsections (8) and (9) are added to section



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1609 499.067, Florida Statutes, to read:

1610 499.067 Denial, suspension, or revocation of permit,
1611 certification, or registration.-

1612 (8) The department may deny, suspend, or revoke a permit if
1613 it finds the permittee has not complied with the credentialing
1614 requirements of s. 499.0121(15).

1615 (9) The department may deny, suspend, or revoke a permit if
1616 it finds the permittee has not complied with the reporting
1617 requirements of, or knowingly made a false statement in a report
1618 required by, s. 499.0121(14).

1619 Section 21. Paragraph (f) is added to subsection (3) of
1620 section 810.02, Florida Statutes, to read:

1621 810.02 Burglary.-

1622 (3) Burglary is a felony of the second degree, punishable
1623 as provided in s. 775.082, s. 775.083, or s. 775.084, if, in the
1624 course of committing the offense, the offender does not make an
1625 assault or battery and is not and does not become armed with a
1626 dangerous weapon or explosive, and the offender enters or
1627 remains in a:

1628 (f) Structure or conveyance when the offense intended to be
1629 committed therein is theft of a controlled substance as defined
1630 in s. 893.02. Notwithstanding any other law, separate judgments
1631 and sentences for burglary with the intent to commit theft of a
1632 controlled substance under this paragraph and for any applicable
1633 possession of controlled substance offense under s. 893.13 or
1634 trafficking in controlled substance offense under s. 893.135 may
1635 be imposed when all such offenses involve the same amount or
1636 amounts of a controlled substance.

1637



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1638 However, if the burglary is committed within a county that is
1639 subject to a state of emergency declared by the Governor under
1640 chapter 252 after the declaration of emergency is made and the
1641 perpetration of the burglary is facilitated by conditions
1642 arising from the emergency, the burglary is a felony of the
1643 first degree, punishable as provided in s. 775.082, s. 775.083,
1644 or s. 775.084. As used in this subsection, the term "conditions
1645 arising from the emergency" means civil unrest, power outages,
1646 curfews, voluntary or mandatory evacuations, or a reduction in
1647 the presence of or response time for first responders or
1648 homeland security personnel. A person arrested for committing a
1649 burglary within a county that is subject to such a state of
1650 emergency may not be released until the person appears before a
1651 committing magistrate at a first appearance hearing. For
1652 purposes of sentencing under chapter 921, a felony offense that
1653 is reclassified under this subsection is ranked one level above
1654 the ranking under s. 921.0022 or s. 921.0023 of the offense
1655 committed.

1656 Section 22. Paragraph (c) of subsection (2) of section
1657 812.014, Florida Statutes, is amended to read:

1658 812.014 Theft.—

1659 (2)

1660 (c) It is grand theft of the third degree and a felony of
1661 the third degree, punishable as provided in s. 775.082, s.
1662 775.083, or s. 775.084, if the property stolen is:

1663 1. Valued at \$300 or more, but less than \$5,000.

1664 2. Valued at \$5,000 or more, but less than \$10,000.

1665 3. Valued at \$10,000 or more, but less than \$20,000.

1666 4. A will, codicil, or other testamentary instrument.



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- 1667 5. A firearm.
- 1668 6. A motor vehicle, except as provided in paragraph (a).
- 1669 7. Any commercially farmed animal, including any animal of
1670 the equine, bovine, or swine class, or other grazing animal, and
1671 including aquaculture species raised at a certified aquaculture
1672 facility. If the property stolen is aquaculture species raised
1673 at a certified aquaculture facility, then a \$10,000 fine shall
1674 be imposed.
- 1675 8. Any fire extinguisher.
- 1676 9. Any amount of citrus fruit consisting of 2,000 or more
1677 individual pieces of fruit.
- 1678 10. Taken from a designated construction site identified by
1679 the posting of a sign as provided for in s. 810.09(2)(d).
- 1680 11. Any stop sign.
- 1681 12. Anhydrous ammonia.
- 1682 13. Any amount of a controlled substance as defined in s.
1683 893.02. Notwithstanding any other law, separate judgments and
1684 sentences for theft of a controlled substance under this
1685 subparagraph and for any applicable possession of controlled
1686 substance offense under s. 893.13 or trafficking in controlled
1687 substance offense under s. 893.135 may be imposed when all such
1688 offenses involve the same amount or amounts of a controlled
1689 substance.

1690

1691 However, if the property is stolen within a county that is
1692 subject to a state of emergency declared by the Governor under
1693 chapter 252, the property is stolen after the declaration of
1694 emergency is made, and the perpetration of the theft is
1695 facilitated by conditions arising from the emergency, the



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1696 offender commits a felony of the second degree, punishable as
1697 provided in s. 775.082, s. 775.083, or s. 775.084, if the
1698 property is valued at \$5,000 or more, but less than \$10,000, as
1699 provided under subparagraph 2., or if the property is valued at
1700 \$10,000 or more, but less than \$20,000, as provided under
1701 subparagraph 3. As used in this paragraph, the term "conditions
1702 arising from the emergency" means civil unrest, power outages,
1703 curfews, voluntary or mandatory evacuations, or a reduction in
1704 the presence of or the response time for first responders or
1705 homeland security personnel. For purposes of sentencing under
1706 chapter 921, a felony offense that is reclassified under this
1707 paragraph is ranked one level above the ranking under s.
1708 921.0022 or s. 921.0023 of the offense committed.

1709 Section 23. Section 893.055, Florida Statutes, is amended
1710 to read:

1711 893.055 Prescription drug monitoring program.—

1712 (1) As used in this section, the term:

1713 (a) "Patient advisory report" or "advisory report" means
1714 information provided by the department in writing, or as
1715 determined by the department, to a prescriber, dispenser,
1716 pharmacy, or patient concerning the dispensing of controlled
1717 substances. All advisory reports are for informational purposes
1718 only and impose no obligations of any nature or any legal duty
1719 on a prescriber, dispenser, pharmacy, or patient. The patient
1720 advisory report shall be provided in accordance with s.
1721 893.13(7)(a)8. The advisory reports issued by the department are
1722 not subject to discovery or introduction into evidence in any
1723 civil or administrative action against a prescriber, dispenser,
1724 pharmacy, or patient arising out of matters that are the subject



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1725 of the report; and a person who participates in preparing,
1726 reviewing, issuing, or any other activity related to an advisory
1727 report may not be permitted or required to testify in any such
1728 civil action as to any findings, recommendations, evaluations,
1729 opinions, or other actions taken in connection with preparing,
1730 reviewing, or issuing such a report.

1731 (b) "Controlled substance" means a controlled substance
1732 listed in Schedule II, Schedule III, or Schedule IV in s.
1733 893.03.

1734 (c) "Dispenser" means a pharmacy, dispensing pharmacist, or
1735 dispensing health care practitioner.

1736 (d) "Health care practitioner" or "practitioner" means any
1737 practitioner who is subject to licensure or regulation by the
1738 department under chapter 458, chapter 459, chapter 461, chapter
1739 462, chapter 464, chapter 465, or chapter 466.

1740 (e) "Health care regulatory board" means any board for a
1741 practitioner or health care practitioner who is licensed or
1742 regulated by the department.

1743 (f) "Pharmacy" means any pharmacy that is subject to
1744 licensure or regulation by the department under chapter 465 and
1745 that dispenses or delivers a controlled substance to an
1746 individual or address in this state.

1747 (g) "Prescriber" means a prescribing physician, prescribing
1748 practitioner, or other prescribing health care practitioner.

1749 (h) "Active investigation" means an investigation that is
1750 being conducted with a reasonable, good faith belief that it
1751 could lead to the filing of administrative, civil, or criminal
1752 proceedings, or that is ongoing and continuing and for which
1753 there is a reasonable, good faith anticipation of securing an



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1754 arrest or prosecution in the foreseeable future.

1755 (i) "Law enforcement agency" means the Department of Law
1756 Enforcement, a Florida sheriff's department, a Florida police
1757 department, or a law enforcement agency of the Federal
1758 Government which enforces the laws of this state or the United
1759 States relating to controlled substances, and which its agents
1760 and officers are empowered by law to conduct criminal
1761 investigations and make arrests.

1762 (j) "Program manager" means an employee of or a person
1763 contracted by the Department of Health who is designated to
1764 ensure the integrity of the prescription drug monitoring program
1765 in accordance with the requirements established in paragraphs
1766 (2) (a) and (b).

1767 (2) (a) ~~By December 1, 2010,~~ The department shall design and
1768 establish a comprehensive electronic database system that has
1769 controlled substance prescriptions provided to it and that
1770 provides prescription information to a patient's health care
1771 practitioner and pharmacist who inform the department that they
1772 wish the patient advisory report provided to them. Otherwise,
1773 the patient advisory report will not be sent to the
1774 practitioner, pharmacy, or pharmacist. The system shall be
1775 designed to provide information regarding dispensed
1776 prescriptions of controlled substances and shall not infringe
1777 upon the legitimate prescribing or dispensing of a controlled
1778 substance by a prescriber or dispenser acting in good faith and
1779 in the course of professional practice. The system shall be
1780 consistent with standards of the American Society for Automation
1781 in Pharmacy (ASAP). The electronic system shall also comply with
1782 the Health Insurance Portability and Accountability Act (HIPAA)



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1783 as it pertains to protected health information (PHI), electronic
1784 protected health information (EPHI), and all other relevant
1785 state and federal privacy and security laws and regulations. The
1786 department shall establish policies and procedures as
1787 appropriate regarding the reporting, accessing the database,
1788 evaluation, management, development, implementation, operation,
1789 storage, and security of information within the system. The
1790 reporting of prescribed controlled substances shall include a
1791 dispensing transaction with a dispenser pursuant to chapter 465
1792 or through a dispensing transaction to an individual or address
1793 in this state with a pharmacy that is not located in this state
1794 but that is otherwise subject to the jurisdiction of this state
1795 as to that dispensing transaction. The reporting of patient
1796 advisory reports refers only to reports to patients, pharmacies,
1797 and practitioners. Separate reports that contain patient
1798 prescription history information and that are not patient
1799 advisory reports are provided to persons and entities as
1800 authorized in paragraphs (7)(b) and (c) and s. 893.0551.

1801 (b) The department, when the direct support organization
1802 receives at least \$20,000 in nonstate moneys or the state
1803 receives at least \$20,000 in federal grants for the prescription
1804 drug monitoring program, ~~and in consultation with the Office of~~
1805 ~~Drug Control~~, shall adopt rules as necessary concerning the
1806 reporting, accessing the database, evaluation, management,
1807 development, implementation, operation, security, and storage of
1808 information within the system, including rules for when patient
1809 advisory reports are provided to pharmacies and prescribers. The
1810 patient advisory report shall be provided in accordance with s.
1811 893.13(7)(a)8. The department shall work with the professional



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1812 health care licensure boards, such as the Board of Medicine, the
1813 Board of Osteopathic Medicine, and the Board of Pharmacy; other
1814 appropriate organizations, such as the Florida Pharmacy
1815 Association, ~~the Office of Drug Control~~, the Florida Medical
1816 Association, the Florida Retail Federation, and the Florida
1817 Osteopathic Medical Association, including those relating to
1818 pain management; and the Attorney General, the Department of Law
1819 Enforcement, and the Agency for Health Care Administration to
1820 develop rules appropriate for the prescription drug monitoring
1821 program.

1822 (c) All dispensers and prescribers subject to these
1823 reporting requirements shall be notified by the department of
1824 the implementation date for such reporting requirements.

1825 (d) The program manager shall work with professional health
1826 care licensure boards and the stakeholders listed in paragraph
1827 (b) to develop rules appropriate for identifying indicators of
1828 controlled substance abuse.

1829 (3) The pharmacy dispensing the controlled substance and
1830 each prescriber who directly dispenses a controlled substance
1831 shall submit to the electronic system, by a procedure and in a
1832 format established by the department and consistent with an
1833 ASAP-approved format, the following information for inclusion in
1834 the database:

1835 (a) The name of the prescribing practitioner, the
1836 practitioner's federal Drug Enforcement Administration
1837 registration number, the practitioner's National Provider
1838 Identification (NPI) or other appropriate identifier, and the
1839 date of the prescription.

1840 (b) The date the prescription was filled and the method of



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1841 payment, such as cash by an individual, insurance coverage
1842 through a third party, or Medicaid payment. This paragraph does
1843 not authorize the department to include individual credit card
1844 numbers or other account numbers in the database.

1845 (c) The full name, address, and date of birth of the person
1846 for whom the prescription was written.

1847 (d) The name, national drug code, quantity, and strength of
1848 the controlled substance dispensed.

1849 (e) The full name, federal Drug Enforcement Administration
1850 registration number, and address of the pharmacy or other
1851 location from which the controlled substance was dispensed. If
1852 the controlled substance was dispensed by a practitioner other
1853 than a pharmacist, the practitioner's full name, federal Drug
1854 Enforcement Administration registration number, and address.

1855 (f) The name of the pharmacy or practitioner, other than a
1856 pharmacist, dispensing the controlled substance and the
1857 practitioner's National Provider Identification (NPI).

1858 (g) Other appropriate identifying information as determined
1859 by department rule.

1860 (4) Each time a controlled substance is dispensed to an
1861 individual, the controlled substance shall be reported to the
1862 department through the system as soon thereafter as possible,
1863 but not more than 7 ~~15~~ days after the date the controlled
1864 substance is dispensed unless an extension is approved by the
1865 department for cause as determined by rule. A dispenser must
1866 meet the reporting requirements of this section by providing the
1867 required information concerning each controlled substance that
1868 it dispensed in a department-approved, secure methodology and
1869 format. Such approved formats may include, but are not limited



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1870 to, submission via the Internet, on a disc, or by use of regular
1871 mail.

1872 (5) When the following acts of dispensing or administering
1873 occur, the following are exempt from reporting under this
1874 section for that specific act of dispensing or administration:

1875 (a) A health care practitioner when administering a
1876 controlled substance directly to a patient if the amount of the
1877 controlled substance is adequate to treat the patient during
1878 that particular treatment session.

1879 (b) A pharmacist or health care practitioner when
1880 administering a controlled substance to a patient or resident
1881 receiving care as a patient at a hospital, nursing home,
1882 ambulatory surgical center, hospice, or intermediate care
1883 facility for the developmentally disabled which is licensed in
1884 this state.

1885 (c) A practitioner when administering or dispensing a
1886 controlled substance in the health care system of the Department
1887 of Corrections.

1888 (d) A practitioner when administering a controlled
1889 substance in the emergency room of a licensed hospital.

1890 (e) A health care practitioner when administering or
1891 dispensing a controlled substance to a person under the age of
1892 16.

1893 (f) A pharmacist or a dispensing practitioner when
1894 dispensing a one-time, 72-hour emergency resupply of a
1895 controlled substance to a patient.

1896 (6) The department may establish when to suspend and when
1897 to resume reporting information during a state-declared or
1898 nationally declared disaster.



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1899 (7) (a) A practitioner or pharmacist who dispenses a
1900 controlled substance must submit the information required by
1901 this section in an electronic or other method in an ASAP format
1902 approved by rule of the department unless otherwise provided in
1903 this section. The cost to the dispenser in submitting the
1904 information required by this section may not be material or
1905 extraordinary. Costs not considered to be material or
1906 extraordinary include, but are not limited to, regular postage,
1907 electronic media, regular electronic mail, and facsimile
1908 charges.

1909 (b) A pharmacy, prescriber, or dispenser shall have access
1910 to information in the prescription drug monitoring program's
1911 database which relates to a patient of that pharmacy,
1912 prescriber, or dispenser in a manner established by the
1913 department as needed for the purpose of reviewing the patient's
1914 controlled substance prescription history. Other access to the
1915 program's database shall be limited to the program's manager and
1916 to the designated program and support staff, who may act only at
1917 the direction of the program manager or, in the absence of the
1918 program manager, as authorized. Access by the program manager or
1919 such designated staff is for prescription drug program
1920 management only or for management of the program's database and
1921 its system in support of the requirements of this section and in
1922 furtherance of the prescription drug monitoring program.
1923 Confidential and exempt information in the database shall be
1924 released only as provided in paragraph (c) and s. 893.0551. The
1925 program manager, designated program and support staff who act at
1926 the direction of or in the absence of the program manager, and
1927 any individual who has similar access regarding the management



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1928 of the database from the prescription drug monitoring program
1929 shall submit fingerprints to the department for background
1930 screening. The department shall follow the procedure established
1931 by the Department of Law Enforcement to request a statewide
1932 criminal history record check and to request that the Department
1933 of Law Enforcement forward the fingerprints to the Federal
1934 Bureau of Investigation for a national criminal history record
1935 check.

1936 (c) The following entities shall not be allowed direct
1937 access to information in the prescription drug monitoring
1938 program database but may request from the program manager and,
1939 when authorized by the program manager, the program manager's
1940 program and support staff, information that is confidential and
1941 exempt under s. 893.0551. Prior to release, the request shall be
1942 verified as authentic and authorized with the requesting
1943 organization by the program manager, the program manager's
1944 program and support staff, or as determined in rules by the
1945 department as being authentic and as having been authorized by
1946 the requesting entity:

1947 1. The department or its relevant health care regulatory
1948 boards responsible for the licensure, regulation, or discipline
1949 of practitioners, pharmacists, or other persons who are
1950 authorized to prescribe, administer, or dispense controlled
1951 substances and who are involved in a specific controlled
1952 substance investigation involving a designated person for one or
1953 more prescribed controlled substances.

1954 2. The Attorney General for Medicaid fraud cases involving
1955 prescribed controlled substances.

1956 3. A law enforcement agency during active investigations



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1957 regarding potential criminal activity, fraud, or theft regarding
1958 prescribed controlled substances.

1959 4. A patient or the legal guardian or designated health
1960 care surrogate of an incapacitated patient as described in s.
1961 893.0551 who, for the purpose of verifying the accuracy of the
1962 database information, submits a written and notarized request
1963 that includes the patient's full name, address, and date of
1964 birth, and includes the same information if the legal guardian
1965 or health care surrogate submits the request. The request shall
1966 be validated by the department to verify the identity of the
1967 patient and the legal guardian or health care surrogate, if the
1968 patient's legal guardian or health care surrogate is the
1969 requestor. Such verification is also required for any request to
1970 change a patient's prescription history or other information
1971 related to his or her information in the electronic database.

1972
1973 Information in the database for the electronic prescription drug
1974 monitoring system is not discoverable or admissible in any civil
1975 or administrative action, except in an investigation and
1976 disciplinary proceeding by the department or the appropriate
1977 regulatory board.

1978 (d) The following entities shall not be allowed direct
1979 access to information in the prescription drug monitoring
1980 program database but may request from the program manager and,
1981 when authorized by the program manager, the program manager's
1982 program and support staff, information that contains no
1983 identifying information of any patient, physician, health care
1984 practitioner, prescriber, or dispenser and that is not
1985 confidential and exempt:



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1986 1. Department staff for the purpose of calculating
1987 performance measures pursuant to subsection (8).

1988 2. The Program Implementation and Oversight Task Force for
1989 its reporting to the Governor, the President of the Senate, and
1990 the Speaker of the House of Representatives regarding the
1991 prescription drug monitoring program. This subparagraph expires
1992 July 1, 2012.

1993 (e) All transmissions of data required by this section must
1994 comply with relevant state and federal privacy and security laws
1995 and regulations. However, any authorized agency or person under
1996 s. 893.0551 receiving such information as allowed by s. 893.0551
1997 may maintain the information received for up to 24 months before
1998 purging it from his or her records or maintain it for longer
1999 than 24 months if the information is pertinent to ongoing health
2000 care or an active law enforcement investigation or prosecution.

2001 (f) The program manager, upon determining a pattern
2002 consistent with the rules established under paragraph (2)(d) and
2003 having cause to believe a violation of s. 893.13(7)(a)8.,
2004 (8)(a), or (8)(b) has occurred, may provide relevant information
2005 to the applicable law enforcement agency.

2006 (8) To assist in fulfilling program responsibilities,
2007 performance measures shall be reported annually to the Governor,
2008 the President of the Senate, and the Speaker of the House of
2009 Representatives by the department each December 1, beginning in
2010 2011. Data that does not contain patient, physician, health care
2011 practitioner, prescriber, or dispenser identifying information
2012 may be requested during the year by department employees so that
2013 the department may undertake public health care and safety
2014 initiatives that take advantage of observed trends. Performance



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2015 measures may include, but are not limited to, efforts to achieve
2016 the following outcomes:

2017 (a) Reduction of the rate of inappropriate use of
2018 prescription drugs through department education and safety
2019 efforts.

2020 (b) Reduction of the quantity of pharmaceutical controlled
2021 substances obtained by individuals attempting to engage in fraud
2022 and deceit.

2023 (c) Increased coordination among partners participating in
2024 the prescription drug monitoring program.

2025 (d) Involvement of stakeholders in achieving improved
2026 patient health care and safety and reduction of prescription
2027 drug abuse and prescription drug diversion.

2028 (9) Any person who willfully and knowingly fails to report
2029 the dispensing of a controlled substance as required by this
2030 section commits a misdemeanor of the first degree, punishable as
2031 provided in s. 775.082 or s. 775.083.

2032 (10) All costs incurred by the department in administering
2033 the prescription drug monitoring program shall be funded through
2034 federal grants or private funding applied for or received by the
2035 state. The department may not commit funds for the monitoring
2036 program without ensuring funding is available. The prescription
2037 drug monitoring program and the implementation thereof are
2038 contingent upon receipt of the nonstate funding. The department
2039 and state government shall cooperate with the direct-support
2040 organization established pursuant to subsection (11) in seeking
2041 federal grant funds, other nonstate grant funds, gifts,
2042 donations, or other private moneys for the department so long as
2043 the costs of doing so are not considered material. Nonmaterial



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2044 costs for this purpose include, but are not limited to, the
2045 costs of mailing and personnel assigned to research or apply for
2046 a grant. Notwithstanding the exemptions to competitive-
2047 solicitation requirements under s. 287.057(3)(f), the department
2048 shall comply with the competitive-solicitation requirements
2049 under s. 287.057 for the procurement of any goods or services
2050 required by this section. Funds provided, directly or
2051 indirectly, by prescription drug manufacturers may not be used
2052 to implement the program.

2053 (11) ~~The Office of Drug Control, in coordination with the~~
2054 ~~department,~~ may establish a direct-support organization that has
2055 a board consisting of at least five members to provide
2056 assistance, funding, and promotional support for the activities
2057 authorized for the prescription drug monitoring program.

2058 (a) As used in this subsection, the term "direct-support
2059 organization" means an organization that is:

2060 1. A Florida corporation not for profit incorporated under
2061 chapter 617, exempted from filing fees, and approved by the
2062 Department of State.

2063 2. Organized and operated to conduct programs and
2064 activities; raise funds; request and receive grants, gifts, and
2065 bequests of money; acquire, receive, hold, and invest, in its
2066 own name, securities, funds, objects of value, or other
2067 property, either real or personal; and make expenditures or
2068 provide funding to or for the direct or indirect benefit of the
2069 department in the furtherance of the prescription drug
2070 monitoring program.

2071 (b) The direct-support organization is not considered a
2072 lobbying firm within the meaning of s. 11.045.



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2073 (c) The State Surgeon General ~~director of the Office of~~
2074 ~~Drug Control~~ shall appoint a board of directors for the direct-
2075 support organization. ~~The director may designate employees of~~
2076 ~~the Office of Drug Control, state employees other than state~~
2077 ~~employees from the department, and any other nonstate employees~~
2078 ~~as appropriate, to serve on the board.~~ Members of the board
2079 shall serve at the pleasure of ~~the director of the~~ State Surgeon
2080 General ~~Office of Drug Control~~. The State Surgeon General
2081 ~~director~~ shall provide guidance to members of the board to
2082 ensure that moneys received by the direct-support organization
2083 are not received from inappropriate sources. Inappropriate
2084 sources include, but are not limited to, donors, grantors,
2085 persons, or organizations that may monetarily or substantively
2086 benefit from the purchase of goods or services by the department
2087 in furtherance of the prescription drug monitoring program.

2088 (d) The direct-support organization shall operate under
2089 written contract with the department ~~Office of Drug Control~~. The
2090 contract must, at a minimum, provide for:

2091 1. Approval of the articles of incorporation and bylaws of
2092 the direct-support organization by the department ~~Office of Drug~~
2093 ~~Control~~.

2094 2. Submission of an annual budget for the approval of the
2095 department ~~Office of Drug Control~~.

2096 3. Certification by the department ~~Office of Drug Control~~
2097 in consultation with the department that the direct-support
2098 organization is complying with the terms of the contract in a
2099 manner consistent with and in furtherance of the goals and
2100 purposes of the prescription drug monitoring program and in the
2101 best interests of the state. Such certification must be made



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2102 annually and reported in the official minutes of a meeting of
2103 the direct-support organization.

2104 4. The reversion, without penalty, to ~~the Office of Drug~~
2105 ~~Control, or to~~ the state if ~~the Office of Drug Control ceases to~~
2106 ~~exist,~~ of all moneys and property held in trust by the direct-
2107 support organization for the benefit of the prescription drug
2108 monitoring program if the direct-support organization ceases to
2109 exist or if the contract is terminated.

2110 5. The fiscal year of the direct-support organization,
2111 which must begin July 1 of each year and end June 30 of the
2112 following year.

2113 6. The disclosure of the material provisions of the
2114 contract to donors of gifts, contributions, or bequests,
2115 including such disclosure on all promotional and fundraising
2116 publications, and an explanation to such donors of the
2117 distinction between the department ~~Office of Drug Control~~ and
2118 the direct-support organization.

2119 7. The direct-support organization's collecting, expending,
2120 and providing of funds to the department for the development,
2121 implementation, and operation of the prescription drug
2122 monitoring program as described in this section and s. 2,
2123 chapter 2009-198, Laws of Florida, as long as the task force is
2124 authorized. The direct-support organization may collect and
2125 expend funds to be used for the functions of the direct-support
2126 organization's board of directors, as necessary and approved by
2127 the department ~~director of the Office of Drug Control~~. In
2128 addition, the direct-support organization may collect and
2129 provide funding to the department in furtherance of the
2130 prescription drug monitoring program by:



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2131 a. Establishing and administering the prescription drug
2132 monitoring program's electronic database, including hardware and
2133 software.

2134 b. Conducting studies on the efficiency and effectiveness
2135 of the program to include feasibility studies as described in
2136 subsection (13).

2137 c. Providing funds for future enhancements of the program
2138 within the intent of this section.

2139 d. Providing user training of the prescription drug
2140 monitoring program, including distribution of materials to
2141 promote public awareness and education and conducting workshops
2142 or other meetings, for health care practitioners, pharmacists,
2143 and others as appropriate.

2144 e. Providing funds for travel expenses.

2145 f. Providing funds for administrative costs, including
2146 personnel, audits, facilities, and equipment.

2147 g. Fulfilling all other requirements necessary to implement
2148 and operate the program as outlined in this section.

2149 (e) The activities of the direct-support organization must
2150 be consistent with the goals and mission of the department
2151 ~~Office of Drug Control~~, as determined by the ~~office in~~
2152 ~~consultation with the~~ department, and in the best interests of
2153 the state. The direct-support organization must obtain a written
2154 approval from the department director ~~of the Office of Drug~~
2155 ~~Control~~ for any activities in support of the prescription drug
2156 monitoring program before undertaking those activities.

2157 (f) The ~~Office of Drug Control~~, in consultation with the
2158 department, may permit, without charge, appropriate use of
2159 administrative services, property, and facilities of ~~the Office~~



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2160 ~~of Drug Control~~ and the department by the direct-support
2161 organization, subject to this section. The use must be directly
2162 in keeping with the approved purposes of the direct-support
2163 organization and may not be made at times or places that would
2164 unreasonably interfere with opportunities for the public to use
2165 such facilities for established purposes. Any moneys received
2166 from rentals of facilities and properties managed by the ~~Office~~
2167 ~~of Drug Control~~ and the department may be held ~~by the Office of~~
2168 ~~Drug Control~~ or in a separate depository account in the name of
2169 the direct-support organization and subject to the provisions of
2170 the letter of agreement with the department ~~Office of Drug~~
2171 ~~Control~~. The letter of agreement must provide that any funds
2172 held in the separate depository account in the name of the
2173 direct-support organization must revert to the department ~~Office~~
2174 ~~of Drug Control~~ if the direct-support organization is no longer
2175 approved by the department ~~Office of Drug Control~~ to operate in
2176 the best interests of the state.

2177 (g) ~~The Office of Drug Control, in consultation with the~~
2178 ~~department,~~ may adopt rules under s. 120.54 to govern the use of
2179 administrative services, property, or facilities of the
2180 department or office by the direct-support organization.

2181 (h) The department ~~Office of Drug Control~~ may not permit
2182 the use of any administrative services, property, or facilities
2183 of the state by a direct-support organization if that
2184 organization does not provide equal membership and employment
2185 opportunities to all persons regardless of race, color,
2186 religion, gender, age, or national origin.

2187 (i) The direct-support organization shall provide for an
2188 independent annual financial audit in accordance with s.



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2189 215.981. Copies of the audit shall be provided to the department
2190 ~~Office of Drug Control~~ and the Office of Policy and Budget in
2191 the Executive Office of the Governor.

2192 (j) The direct-support organization may not exercise any
2193 power under s. 617.0302(12) or (16).

2194 (12) A prescriber or dispenser may have access to the
2195 information under this section which relates to a patient of
2196 that prescriber or dispenser as needed for the purpose of
2197 reviewing the patient's controlled drug prescription history. A
2198 prescriber or dispenser acting in good faith is immune from any
2199 civil, criminal, or administrative liability that might
2200 otherwise be incurred or imposed for receiving or using
2201 information from the prescription drug monitoring program. This
2202 subsection does not create a private cause of action, and a
2203 person may not recover damages against a prescriber or dispenser
2204 authorized to access information under this subsection for
2205 accessing or failing to access such information.

2206 (13) To the extent that funding is provided for such
2207 purpose through federal or private grants or gifts and other
2208 types of available moneys, the department, ~~in collaboration with~~
2209 ~~the Office of Drug Control,~~ shall study the feasibility of
2210 enhancing the prescription drug monitoring program for the
2211 purposes of public health initiatives and statistical reporting
2212 that respects the privacy of the patient, the prescriber, and
2213 the dispenser. Such a study shall be conducted in order to
2214 further improve the quality of health care services and safety
2215 by improving the prescribing and dispensing practices for
2216 prescription drugs, taking advantage of advances in technology,
2217 reducing duplicative prescriptions and the overprescribing of



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2218 prescription drugs, and reducing drug abuse. The requirements of
2219 the National All Schedules Prescription Electronic Reporting
2220 (NASPER) Act are authorized in order to apply for federal NASPER
2221 funding. In addition, the direct-support organization shall
2222 provide funding for the department, ~~in collaboration with the~~
2223 ~~Office of Drug Control,~~ to conduct training for health care
2224 practitioners and other appropriate persons in using the
2225 monitoring program to support the program enhancements.

2226 (14) A pharmacist, pharmacy, or dispensing health care
2227 practitioner or his or her agent, before releasing a controlled
2228 substance to any person not known to such dispenser, shall
2229 require the person purchasing, receiving, or otherwise acquiring
2230 the controlled substance to present valid photographic
2231 identification or other verification of his or her identity to
2232 the dispenser. If the person does not have proper
2233 identification, the dispenser may verify the validity of the
2234 prescription and the identity of the patient with the prescriber
2235 or his or her authorized agent. Verification of health plan
2236 eligibility through a real-time inquiry or adjudication system
2237 will be considered to be proper identification. This subsection
2238 does not apply in an institutional setting or to a long-term
2239 care facility, including, but not limited to, an assisted living
2240 facility or a hospital to which patients are admitted. As used
2241 in this subsection, the term "proper identification" means an
2242 identification that is issued by a state or the Federal
2243 Government containing the person's photograph, printed name, and
2244 signature or a document considered acceptable under 8 C.F.R. s.
2245 274a.2(b)(1)(v)(A) and (B).

2246 (15) The Agency for Health Care Administration shall



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2247 continue the promotion of electronic prescribing by health care
2248 practitioners, health care facilities, and pharmacies under s.
2249 408.0611.

2250 (16) ~~By October 1, 2010,~~ The department shall adopt rules
2251 pursuant to ss. 120.536(1) and 120.54 to administer the
2252 provisions of this section, which shall include as necessary the
2253 reporting, accessing, evaluation, management, development,
2254 implementation, operation, and storage of information within the
2255 monitoring program's system.

2256 Section 24. Section 893.065, Florida Statutes, is amended
2257 to read:

2258 893.065 Counterfeit-resistant prescription blanks for
2259 controlled substances listed in Schedule II, Schedule III, or
2260 Schedule IV.—The Department of Health shall develop and adopt by
2261 rule the form and content for a counterfeit-resistant
2262 prescription blank which must ~~may~~ be used by practitioners for
2263 the purpose of prescribing a controlled substance listed in
2264 Schedule II, Schedule III, ~~or~~ Schedule IV, or Schedule V
2265 pursuant to s. 456.42. The Department of Health may require the
2266 prescription blanks to be printed on distinctive, watermarked
2267 paper and to bear the preprinted name, address, and category of
2268 professional licensure of the practitioner and that
2269 practitioner's federal registry number for controlled
2270 substances. The prescription blanks may not be transferred.

2271 Section 25. Subsections (4) and (5) of section 893.07,
2272 Florida Statutes, are amended to read:

2273 893.07 Records.—

2274 (4) Every inventory or record required by this chapter,
2275 including prescription records, shall be maintained:



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2276 (a) Separately from all other records of the registrant, or
2277 (b) Alternatively, in the case of Schedule III, IV, or V
2278 controlled substances, in such form that information required by
2279 this chapter is readily retrievable from the ordinary business
2280 records of the registrant.

2281
2282 In either case, the records described in this subsection shall
2283 be kept and made available for a period of at least 2 years for
2284 inspection and copying by law enforcement officers whose duty it
2285 is to enforce the laws of this state relating to controlled
2286 substances. Law enforcement officers are not required to obtain
2287 a subpoena, court order, or search warrant in order to obtain
2288 access to or copies of such records.

2289 (5) Each person described in subsection (1) shall:

2290 (a) Maintain a record which shall contain a detailed list
2291 of controlled substances lost, destroyed, or stolen, if any; the
2292 kind and quantity of such controlled substances; and the date of
2293 the discovering of such loss, destruction, or theft.

2294 (b) In the event of the discovery of the theft or
2295 significant loss of controlled substances, report such theft or
2296 significant loss to the sheriff of that county within 24 hours
2297 after discovery. A person who fails to report a theft or
2298 significant loss of a substance listed in s. 893.03(3), (4), or
2299 (5) within 24 hours after discovery as required in this
2300 paragraph commits a misdemeanor of the second degree, punishable
2301 as provided in s. 775.082 or s. 775.083. A person who fails to
2302 report a theft or significant loss of a substance listed in s.
2303 893.03(2) within 24 hours after discovery as required in this
2304 paragraph commits a misdemeanor of the first degree, punishable



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2305 as provided in s. 775.082 or s. 775.083.

2306 Section 26. Subsection (7) of section 893.13, Florida
2307 Statutes, is amended to read:

2308 893.13 Prohibited acts; penalties.—

2309 (7) (a) A ~~It is unlawful for any person may not:~~

2310 1. ~~To~~ Distribute or dispense a controlled substance in
2311 violation of this chapter.

2312 2. ~~To~~ Refuse or fail to make, keep, or furnish any record,
2313 notification, order form, statement, invoice, or information
2314 required under this chapter.

2315 3. ~~To~~ Refuse ~~an~~ entry into any premises for any inspection
2316 or ~~to~~ refuse to allow any inspection authorized by this chapter.

2317 4. ~~To~~ Distribute a controlled substance named or described
2318 in s. 893.03(1) or (2) except pursuant to an order form as
2319 required by s. 893.06.

2320 5. ~~To~~ Keep or maintain any store, shop, warehouse,
2321 dwelling, building, vehicle, boat, aircraft, or other structure
2322 or place which is resorted to by persons using controlled
2323 substances in violation of this chapter for the purpose of using
2324 these substances, or which is used for keeping or selling them
2325 in violation of this chapter.

2326 6. ~~To~~ Use to his or her own personal advantage, or ~~to~~
2327 reveal, any information obtained in enforcement of this chapter
2328 except in a prosecution or administrative hearing for a
2329 violation of this chapter.

2330 7. ~~To~~ Possess a prescription form which has not been
2331 completed and signed by the practitioner whose name appears
2332 printed thereon, unless the person is that practitioner, is an
2333 agent or employee of that practitioner, is a pharmacist, or is a



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2334 supplier of prescription forms who is authorized by that
2335 practitioner to possess those forms.

2336 8. ~~To~~ Withhold information from a practitioner from whom
2337 the person seeks to obtain a controlled substance or a
2338 prescription for a controlled substance that the person making
2339 the request has received a controlled substance or a
2340 prescription for a controlled substance of like therapeutic use
2341 from another practitioner within the previous 30 days.

2342 9. ~~To~~ Acquire or obtain, or attempt to acquire or obtain,
2343 possession of a controlled substance by misrepresentation,
2344 fraud, forgery, deception, or subterfuge.

2345 10. ~~To~~ Affix any false or forged label to a package or
2346 receptacle containing a controlled substance.

2347 11. ~~To~~ Furnish false or fraudulent material information in,
2348 or omit any material information from, any report or other
2349 document required to be kept or filed under this chapter or any
2350 record required to be kept by this chapter.

2351 12. ~~To~~ Store anhydrous ammonia in a container that is not
2352 approved by the United States Department of Transportation to
2353 hold anhydrous ammonia or is not constructed in accordance with
2354 sound engineering, agricultural, or commercial practices.

2355 13. With the intent to obtain a controlled substance or
2356 combination of controlled substances that are not medically
2357 necessary for the person or an amount of a controlled substance
2358 or substances that are not medically necessary for the person,
2359 obtain or attempt to obtain from a practitioner a controlled
2360 substance or a prescription for a controlled substance by
2361 misrepresentation, fraud, forgery, deception, subterfuge, or
2362 concealment of a material fact. For purposes of this



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2363 subparagraph, a material fact includes whether the person has an
2364 existing prescription for a controlled substance issued for the
2365 same period of time by another practitioner or as described in
2366 subparagraph 8.

2367 (b) A health care practitioner, with the intent to provide
2368 a controlled substance or combination of controlled substances
2369 that are not medically necessary to his or her patient or an
2370 amount of controlled substances that are not medically necessary
2371 for his or her patient, may not provide a controlled substance
2372 or a prescription for a controlled substance by
2373 misrepresentation, fraud, forgery, deception, subterfuge, or
2374 concealment of a material fact. For purposes of this paragraph,
2375 a material fact includes whether the patient has an existing
2376 prescription for a controlled substance issued for the same
2377 period of time by another practitioner or as described in
2378 subparagraph (a)8.

2379 (c)~~(b)~~ Any person who violates the provisions of
2380 subparagraphs (a)1.-7. commits a misdemeanor of the first
2381 degree, punishable as provided in s. 775.082 or s. 775.083;
2382 except that, upon a second or subsequent violation, the person
2383 commits a felony of the third degree, punishable as provided in
2384 s. 775.082, s. 775.083, or s. 775.084.

2385 (d)~~(c)~~ Any person who violates the provisions of
2386 subparagraphs (a)8.-12. commits a felony of the third degree,
2387 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2388 (e) A person or health care practitioner who violates the
2389 provisions of paragraph (b) or subparagraph (a)13. commits a
2390 felony of the third degree, punishable as provided in s.
2391 775.082, s. 775.083, or s. 775.084, if any controlled substance



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2392 that is the subject of the offense is listed in Schedule II,
2393 Schedule III, or Schedule IV.

2394 Section 27. Present subsections (3) through (10) of section
2395 893.138, Florida Statutes, are redesignated as subsections (4)
2396 through (11), respectively, and a new subsection (3) is added to
2397 that section, to read:

2398 893.138 Local administrative action to abate drug-related,
2399 prostitution-related, or stolen-property-related public
2400 nuisances and criminal gang activity.—

2401 (3) Any pain-management clinic, as described in s. 458.3265
2402 or s. 459.0137, which has been used on more than two occasions
2403 within a 6-month period as the site of a violation of:

2404 (a) Section 784.011, s. 784.021, s. 784.03, or s. 784.045,
2405 relating to assault and battery;

2406 (b) Section 810.02, relating to burglary;

2407 (c) Section 812.014, relating to dealing in theft;

2408 (d) Section 812.131, relating to robbery by sudden
2409 snatching; or

2410 (e) Section 893.13, relating to the unlawful distribution
2411 of controlled substances,

2412
2413 may be declared to be a public nuisance, and such nuisance may
2414 be abated pursuant to the procedures provided in this section.

2415 Section 28. (1) DISPOSITION OF CONTROLLED SUBSTANCES.—

2416 (a) Within 10 days after the effective date of this act,
2417 each physician licensed under chapter 458, chapter 459, chapter
2418 461, or chapter 466, Florida Statutes, unless he or she meets
2419 one of the exceptions for physician who dispenses under s.
2420 465.0276, Florida Statutes, shall ensure that the undispensed



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2421 inventory of controlled substances listed in Schedule II or
2422 Schedule III as provided in s. 893.03, Florida Statutes,
2423 purchased under the physician's Drug Enforcement Administration
2424 number for dispensing is:

2425 1. Returned in compliance with the laws and rules adopted
2426 under chapter 499, Florida Statutes, to the wholesale
2427 distributor, as defined in s. 499.003, Florida Statutes, which
2428 distributed the controlled substances to the physician; or

2429 2. Turned in to local law enforcement agencies and
2430 abandoned.

2431 (b) Wholesale distributors shall buy back the undispensed
2432 inventory of controlled substances listed in Schedule II or
2433 Schedule III as provided in s. 893.03, Florida Statutes, which
2434 are in the manufacturer's original packing, unopened, and in
2435 date, in accordance with the established policies of the
2436 wholesale distributor or the contractual terms between the
2437 wholesale distributor and the physician concerning returns.

2438 (2) PUBLIC HEALTH EMERGENCY.—

2439 (a) The Legislature finds that:

2440 1. Prescription drug overdose has been declared a public
2441 health epidemic by the United States Centers for Disease Control
2442 and Prevention.

2443 2. Prescription drug abuse results in an average of seven
2444 deaths in this state each day.

2445 3. Physicians in this state purchased more than 85 percent
2446 of the oxycodone purchased by all practitioners in the United
2447 States in 2006.

2448 4. Physicians in this state purchased more than 93 percent
2449 of the methadone purchased by all practitioners in the United



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2450 States in 2006.

2451 5. Some physicians in this state dispense medically
2452 unjustifiable amounts of controlled substances to addicts and to
2453 people who intend to illegally sell the drugs.

2454 6. Physicians in this state who have purchased large
2455 quantities of controlled substances may have significant
2456 inventory 30 days after the effective date of this act.

2457 7. Thirty days after the effective date of this act, the
2458 only legal method for a dispensing practitioner to sell or
2459 otherwise transfer controlled substances listed in Schedule II
2460 or Schedule III as provided in s. 893.03, Florida Statutes,
2461 purchased for dispensing, is through the abandonment procedures
2462 of subsection (1) or as authorized under s. 465.0276, Florida
2463 Statutes.

2464 8. It is likely that the same physicians who purchase and
2465 dispense medically unjustifiable amounts of drugs will not
2466 legally dispose of the remaining inventory.

2467 9. The actions of such dispensing practitioners may result
2468 in substantial injury to the public health.

2469 (b) Immediately upon the effective date of this act, the
2470 State Health Officer shall declare a public health emergency
2471 pursuant to s. 381.00315, Florida Statutes. Pursuant to that
2472 declaration, the Department of Health, the Attorney General, the
2473 Department of Law Enforcement, and local law enforcement
2474 agencies shall take the following actions:

2475 1. Within 2 days after the effective date of this act, in
2476 consultation with wholesale distributors as defined in s.
2477 499.003, Florida Statutes, the Department of Health shall
2478 identify dispensing practitioners who purchased more than an



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2479 average of 2,000 unit doses of controlled substances listed in
2480 Schedule II or Schedule III as provided in s. 893.03, Florida
2481 Statutes, per month in the previous 6 months, and shall identify
2482 the dispensing practitioners in that group who pose the greatest
2483 threat to the public health based on an assessment of:

- 2484 a. The risk of noncompliance with subsection (1).
2485 b. The purchase amounts.
2486 c. The manner of medical practice.
2487 d. Any other factor set by the State Health Officer.
2488

2489 The Attorney General shall consult and coordinate with federal
2490 law enforcement agencies. The Department of Law Enforcement
2491 shall coordinate the efforts of local law enforcement agencies.

2492 2. On the 3rd day after the effective date of this act, the
2493 Department of Law Enforcement or local law enforcement agencies
2494 shall enter the business premises of the dispensing
2495 practitioners identified as posing the greatest threat to public
2496 health and quarantine any inventory of controlled substances
2497 listed in Schedule II or Schedule III as provided in s. 893.03,
2498 Florida Statutes, of such dispensing practitioners on site.

2499 3. The Department of Law Enforcement or local law
2500 enforcement agencies shall ensure the security of such inventory
2501 24 hours a day until the inventory is seized as contraband or
2502 deemed to be lawfully possessed for dispensing by the physician
2503 in accordance with s. 465.0276, Florida Statutes.

2504 4. On the 31st day after the effective date of this act,
2505 any remaining inventory of controlled substances listed in
2506 Schedule II or Schedule III as provided in s. 893.03, Florida
2507 Statutes, purchased for dispensing by practitioners is deemed



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2508 contraband under s. 893.12, Florida Statutes. The Department of
2509 Law Enforcement or local law enforcement agencies shall seize
2510 the inventory and comply with the provisions of s. 893.12,
2511 Florida Statutes, to destroy it.

2512 (c) In order to implement this subsection, the sum of \$3
2513 million of nonrecurring funds from the General Revenue Fund is
2514 appropriated to the Department of Law Enforcement for the 2010-
2515 2011 fiscal year. The Department of Law Enforcement shall expend
2516 the appropriation by reimbursing local law enforcement agencies
2517 for the overtime-hour costs associated with securing the
2518 quarantined controlled substance inventory as provided in
2519 paragraph (b) and activities related to investigation and
2520 prosecution of crimes related to prescribed controlled
2521 substances. If requests for reimbursement exceed the amount
2522 appropriated, the reimbursements shall be prorated by the hours
2523 of overtime per requesting agency at a maximum of one law
2524 enforcement officer per quarantine site.

2525 (3) REPEAL.—This section expires January 1, 2013.

2526 Section 29. The Department of Health shall establish a
2527 practitioner profile for dentists licensed under chapter 466,
2528 Florida Statutes, for a practitioner's designation as a
2529 controlled substance prescribing practitioner as provided in s.
2530 456.44, Florida Statutes.

2531 Section 30. If any provision of this act or its application
2532 to any person or circumstance is held invalid, the invalidity
2533 does not affect other provisions or applications of the act
2534 which can be given effect without the invalid provision or
2535 application, and to this end the provisions of this act are
2536 severable.



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2537 Section 31. This act shall take effect July 1, 2011.

2538

2539 ===== T I T L E A M E N D M E N T =====

2540 And the title is amended as follows:

2541 Delete everything before the enacting clause

2542 and insert:

2543 A bill to be entitled

2544 An act relating to prescription drugs; amending s.

2545 456.072, F.S.; making failure to comply with the

2546 requirements of s. 456.44, F.S., grounds for

2547 disciplinary action; providing mandatory

2548 administrative penalties for certain violations

2549 related to prescribing; amending s. 456.42, F.S.;

2550 requiring prescriptions for controlled substances to

2551 be written on a counterfeit-resistant pad produced by

2552 an approved vendor or electronically prescribed;

2553 providing conditions for being an approved vendor;

2554 creating s. 456.44, F.S.; providing definitions;

2555 requiring certain physicians to designate themselves

2556 as controlled substance prescribing practitioners on

2557 their practitioner profiles; providing an effective

2558 date; requiring registered physicians to meet certain

2559 standards of practice; requiring a physical

2560 examination; requiring a written protocol; requiring

2561 an assessment of risk for aberrant behavior; requiring

2562 a treatment plan; requiring specified informed

2563 consent; requiring consultation and referral in

2564 certain circumstances; requiring medical records

2565 meeting certain criteria; providing an exemption for



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2566 physicians meeting certain criteria; amending s.
2567 458.3265, F.S., relating to regulation of pain-
2568 management clinics and medical doctors; redefining the
2569 term "pain-management clinic"; providing definitions;
2570 providing an exemption from registration for clinics
2571 owned and operated by physicians or medical
2572 specialists meeting certain criteria; revising
2573 responsibilities of physicians in pain-management
2574 clinics; allowing physician assistants and advanced
2575 registered nurse practitioners to perform physical
2576 examinations; requiring physicians in pain-management
2577 clinics to ensure compliance with certain
2578 requirements; imposing facility and physical
2579 operations requirements; imposing infection control
2580 requirements; imposing health and safety requirements;
2581 imposing quality assurance requirements; imposing data
2582 collection and reporting requirements; revising
2583 rulemaking authority; conforming provisions to changes
2584 made by the act; providing for future expiration of
2585 provisions; amending s. 458.327, F.S.; providing that
2586 dispensing certain controlled substances in violation
2587 of specified provisions is a third-degree felony;
2588 providing penalties; amending s. 458.331, F.S.;
2589 providing that dispensing certain controlled
2590 substances in violation of specified provisions is
2591 grounds for disciplinary action; providing penalties;
2592 amending s. 459.0137, F.S., relating to regulation of
2593 pain-management clinics and osteopathic physicians;
2594 providing definitions; providing an exemption from



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2595 registration for clinics owned and operated by
2596 physicians meeting certain criteria; revising
2597 responsibilities of osteopathic physicians in pain-
2598 management clinics; allowing physician assistants and
2599 advanced registered nurse practitioners to perform
2600 physical examinations; requiring osteopathic
2601 physicians in pain-management clinics to ensure
2602 compliance with certain requirements; imposing
2603 facility and physical operations requirements;
2604 imposing infection control requirements; imposing
2605 health and safety requirements; imposing quality
2606 assurance requirements; imposing data collection and
2607 reporting requirements; revising rulemaking authority;
2608 conforming provisions to changes made by the act;
2609 providing for future expiration of provisions;
2610 amending s. 459.013, F.S.; providing that dispensing
2611 certain controlled substances in violation of
2612 specified provisions is a third-degree felony;
2613 providing penalties; amending s. 459.015, F.S.;
2614 providing that dispensing certain controlled
2615 substances in violation of specified provisions is
2616 grounds for disciplinary action; providing penalties;
2617 amending s. 465.015, F.S.; requiring a pharmacist to
2618 report to the sheriff within a specified period any
2619 instance in which a person fraudulently obtained or
2620 attempted to fraudulently obtain a controlled
2621 substance; providing criminal penalties; providing
2622 suggested criteria for the reports; amending s.
2623 465.016, F.S.; providing additional grounds for denial



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2624 of or disciplinary action against a pharmacist
2625 license; amending s. 465.018, F.S.; providing grounds
2626 for permit denial or discipline; requiring applicants
2627 to pay or make arrangements to pay amounts owed to the
2628 Department of Health; requiring an inspection;
2629 requiring permittees to maintain certain records;
2630 requiring a community pharmacy to be permitted under
2631 ch. 465, F.S., on or after a specified date in order
2632 to dispense Schedule II or Schedule III controlled
2633 substances; amending s. 465.022, F.S.; requiring the
2634 Department of Health to adopt rules related to
2635 procedures for dispensing controlled substances;
2636 providing requirements for the issuance of a pharmacy
2637 permit; requiring disclosure of financial interests;
2638 requiring submission of policies and procedures and
2639 providing for grounds for permit denial based on such
2640 policies and procedures; authorizing the Department of
2641 Health to phase in the policies and procedures
2642 requirement over an 18-month period beginning July 1,
2643 2011; requiring the Department of Health to deny a
2644 permit to applicants under certain circumstances;
2645 requiring permittees to provide notice of certain
2646 management changes; requiring prescription department
2647 managers to meet certain criteria; imposing duties on
2648 prescription department managers; limiting the number
2649 of locations a prescription department manager may
2650 manage; requiring the board to adopt rules related to
2651 recordkeeping; providing that permits are not
2652 transferable; amending s. 465.0276, F.S.; deleting a



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2653 provision establishing a 72-hour supply limit on
2654 dispensing certain controlled substances; prohibiting
2655 registered dispensing practitioners from dispensing
2656 certain controlled substances; revising the list of
2657 exceptions that allow registered dispensing
2658 practitioners to dispense certain controlled
2659 substances; amending s. 499.0051, F.S.; providing
2660 criminal penalties for violations of certain
2661 provisions of s. 499.0121, F.S.; amending s. 499.012,
2662 F.S.; requiring wholesale distributor permit
2663 applicants to submit documentation of credentialing
2664 policies; amending s. 499.0121, F.S.; providing
2665 reporting requirements regarding certain controlled
2666 substances for prescription drug wholesale
2667 distributors, out-of-state prescription drug wholesale
2668 distributors, retail pharmacy drug wholesale
2669 distributors, manufacturers, or repackagers that
2670 engage in the wholesale distribution of controlled
2671 substances to a retail pharmacy; requiring the
2672 Department of Health to share the reported data with
2673 law enforcement agencies; requiring the Department of
2674 Law Enforcement to make investigations based on the
2675 reported data; providing credentialing requirements
2676 for distribution of controlled substances to certain
2677 entities by wholesale distributors; requiring
2678 distributors to identify suspicious transactions;
2679 requiring distributors to determine the reasonableness
2680 of orders for controlled substances over certain
2681 amounts; requiring distributors to maintain documents



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2682 that support the report submitted to the Department of
2683 Health; requiring the department to assess data;
2684 requiring the department to report certain data to the
2685 Governor, President of the Senate, and Speaker of the
2686 House of Representatives by certain dates; prohibiting
2687 distribution to entities with certain criminal
2688 backgrounds; amending s. 499.05, F.S.; authorizing
2689 rulemaking concerning specified controlled substance
2690 wholesale distributor reporting requirements and
2691 credentialing requirements; amending s. 499.067, F.S.;
2692 authorizing the Department of Health to take
2693 disciplinary action against wholesale distributors
2694 failing to comply with specified credentialing or
2695 reporting requirements; amending s. 810.02, F.S.;
2696 authorizing separate judgments and sentences for
2697 burglary with the intent to commit theft of a
2698 controlled substance under specified provisions and
2699 for any applicable possession of controlled substance
2700 offense under specified provisions in certain
2701 circumstances; amending s. 812.014, F.S.; authorizing
2702 separate judgments and sentences for theft of a
2703 controlled substance under specified provisions and
2704 for any applicable possession of controlled substance
2705 offense under specified provisions in certain
2706 circumstances; amending s. 893.055, F.S., relating to
2707 the prescription drug monitoring program; deleting
2708 obsolete dates; deleting references to the Office of
2709 Drug Control; requiring reports to the prescription
2710 drug monitoring system to be made in 7 days rather



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2711 than 15 days; prohibiting the use of certain funds to
2712 implement the program; requiring criminal background
2713 screening for those persons who have direct access to
2714 the prescription drug monitoring program's database;
2715 requiring the State Surgeon General to appoint a board
2716 of directors for the direct-support organization;
2717 conforming provisions to changes made by the act;
2718 amending s. 893.065, F.S.; conforming provisions to
2719 changes made by the act; amending s. 893.07, F.S.;
2720 providing that law enforcement officers are not
2721 required to obtain a subpoena, court order, or search
2722 warrant in order to obtain access to or copies of
2723 specified controlled substance inventory records;
2724 requiring reporting of the discovery of the theft or
2725 loss of controlled substances to the sheriff within a
2726 specified period; providing criminal penalties;
2727 amending s. 893.13, F.S.; prohibiting a person from
2728 obtaining or attempting to obtain from a practitioner
2729 a controlled substance or a prescription for a
2730 controlled substance by misrepresentation, fraud,
2731 forgery, deception, subterfuge, or concealment of a
2732 material fact; prohibiting a health care provider from
2733 providing a controlled substance or a prescription for
2734 a controlled substance by misrepresentation, fraud,
2735 forgery, deception, subterfuge, or concealment of a
2736 material fact; prohibiting a person from adulterating
2737 a controlled substance for certain use without
2738 authorization by a prescribing physician; providing
2739 penalties; amending s. 893.138, F.S.; providing



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2740 circumstances in which a pain-management clinic may be
2741 declared a public nuisance; providing for the
2742 disposition of certain controlled substance inventory
2743 held by specified licensed physicians; providing
2744 certain requirements for a physician returning
2745 inventory to a distributor; requiring wholesale
2746 distributors to buy back certain undispensed inventory
2747 of controlled substances; providing for a declaration
2748 of a public health emergency; requiring certain
2749 actions relating to dispensing practitioners
2750 identified as posing the greatest threat to public
2751 health; providing an appropriation; providing for
2752 future expiration of program provisions; requiring the
2753 Department of Health to establish a practitioner
2754 profile for dentists; providing for severability;
2755 providing an effective date.