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LEGISLATIVE ACTION

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| Senate              | . | House               |
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| Floor: AD/3R        | . | Floor: C            |
| 05/06/2011 04:09 PM | . | 05/06/2011 08:10 PM |
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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.~~ ~~;~~ ~~or~~

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.

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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.