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CS/CS/HB 7095, Engrossed 3

2011 Legislature

1                                   A bill to be entitled  
 2       An act relating to prescription drugs; amending s.  
 3       456.072, F.S.; making failure to comply with the  
 4       requirements of s. 456.44, F.S., grounds for disciplinary  
 5       action; providing mandatory administrative penalties for  
 6       certain violations related to prescribing; amending s.  
 7       456.42, F.S.; requiring prescriptions for controlled  
 8       substances to be written on a counterfeit-resistant pad  
 9       produced by an approved vendor or electronically  
 10      prescribed; providing conditions for being an approved  
 11      vendor; creating s. 456.44, F.S.; providing definitions;  
 12      requiring certain physicians to designate themselves as  
 13      controlled substance prescribing practitioners on their  
 14      practitioner profiles; providing an effective date;  
 15      requiring registered physicians to meet certain standards  
 16      of practice; requiring a physical examination; requiring a  
 17      written protocol; requiring an assessment of risk for  
 18      aberrant behavior; requiring a treatment plan; requiring  
 19      specified informed consent; requiring consultation and  
 20      referral in certain circumstances; requiring medical  
 21      records meeting certain criteria; providing an exemption  
 22      for physicians meeting certain criteria; amending s.  
 23      458.3265, F.S., relating to regulation of pain-management  
 24      clinics and medical doctors; redefining the term "pain-  
 25      management clinic"; providing definitions; providing an  
 26      exemption from registration for clinics owned and operated  
 27      by physicians or medical specialists meeting certain  
 28      criteria; revising responsibilities of physicians in pain-

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29 management clinics; allowing physician assistants and  
30 advanced registered nurse practitioners to perform  
31 physical examinations; requiring physicians in pain-  
32 management clinics to ensure compliance with certain  
33 requirements; imposing facility and physical operations  
34 requirements; imposing infection control requirements;  
35 imposing health and safety requirements; imposing quality  
36 assurance requirements; imposing data collection and  
37 reporting requirements; revising rulemaking authority;  
38 conforming provisions to changes made by the act;  
39 providing for future expiration of provisions; amending s.  
40 458.327, F.S.; providing that dispensing certain  
41 controlled substances in violation of specified provisions  
42 is a third-degree felony; providing penalties; amending s.  
43 458.331, F.S.; providing that dispensing certain  
44 controlled substances in violation of specified provisions  
45 is grounds for disciplinary action; providing penalties;  
46 amending s. 459.0137, F.S., relating to regulation of  
47 pain-management clinics and osteopathic physicians;  
48 providing definitions; providing an exemption from  
49 registration for clinics owned and operated by physicians  
50 meeting certain criteria; revising responsibilities of  
51 osteopathic physicians in pain-management clinics;  
52 allowing physician assistants and advanced registered  
53 nurse practitioners to perform physical examinations;  
54 requiring osteopathic physicians in pain-management  
55 clinics to ensure compliance with certain requirements;  
56 imposing facility and physical operations requirements;

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57 | imposing infection control requirements; imposing health  
58 | and safety requirements; imposing quality assurance  
59 | requirements; imposing data collection and reporting  
60 | requirements; revising rulemaking authority; conforming  
61 | provisions to changes made by the act; providing for  
62 | future expiration of provisions; amending s. 459.013,  
63 | F.S.; providing that dispensing certain controlled  
64 | substances in violation of specified provisions is a  
65 | third-degree felony; providing penalties; amending s.  
66 | 459.015, F.S.; providing that dispensing certain  
67 | controlled substances in violation of specified provisions  
68 | is grounds for disciplinary action; providing penalties;  
69 | amending s. 465.015, F.S.; requiring a pharmacist to  
70 | report to the sheriff within a specified period any  
71 | instance in which a person fraudulently obtained or  
72 | attempted to fraudulently obtain a controlled substance;  
73 | providing criminal penalties; providing suggested criteria  
74 | for the reports; amending s. 465.016, F.S.; providing  
75 | additional grounds for denial of or disciplinary action  
76 | against a pharmacist license; amending s. 465.018, F.S.;  
77 | providing grounds for permit denial or discipline;  
78 | requiring applicants to pay or make arrangements to pay  
79 | amounts owed to the Department of Health; requiring an  
80 | inspection; requiring permittees to maintain certain  
81 | records; requiring a community pharmacy to be permitted  
82 | under ch. 465, F.S., on or after a specified date in order  
83 | to dispense Schedule II or Schedule III controlled  
84 | substances; amending s. 465.022, F.S.; requiring the

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85 Department of Health to adopt rules related to procedures  
86 for dispensing controlled substances; providing  
87 requirements for the issuance of a pharmacy permit;  
88 requiring disclosure of financial interests; requiring  
89 submission of policies and procedures and providing for  
90 grounds for permit denial based on such policies and  
91 procedures; authorizing the Department of Health to phase  
92 in the policies and procedures requirement over an 18-  
93 month period beginning July 1, 2011; requiring the  
94 Department of Health to deny a permit to applicants under  
95 certain circumstances; requiring permittees to provide  
96 notice of certain management changes; requiring  
97 prescription department managers to meet certain criteria;  
98 imposing duties on prescription department managers;  
99 limiting the number of locations a prescription department  
100 manager may manage; requiring the board to adopt rules  
101 related to recordkeeping; providing that permits are not  
102 transferable; amending s. 465.0276, F.S.; deleting a  
103 provision establishing a 72-hour supply limit on  
104 dispensing certain controlled substances; prohibiting  
105 registered dispensing practitioners from dispensing  
106 certain controlled substances; revising the list of  
107 exceptions that allow registered dispensing practitioners  
108 to dispense certain controlled substances; amending s.  
109 499.0051, F.S.; providing criminal penalties for  
110 violations of certain provisions of s. 499.0121, F.S.;  
111 amending s. 499.012, F.S.; requiring wholesale distributor  
112 permit applicants to submit documentation of credentialing

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113 policies; amending s. 499.0121, F.S.; providing reporting  
114 requirements regarding certain controlled substances for  
115 prescription drug wholesale distributors, out-of-state  
116 prescription drug wholesale distributors, retail pharmacy  
117 drug wholesale distributors, manufacturers, or repackagers  
118 that engage in the wholesale distribution of controlled  
119 substances to a retail pharmacy; requiring the Department  
120 of Health to share the reported data with law enforcement  
121 agencies; requiring the Department of Law Enforcement to  
122 make investigations based on the reported data; providing  
123 credentialing requirements for distribution of controlled  
124 substances to certain entities by wholesale distributors;  
125 requiring distributors to identify suspicious  
126 transactions; requiring distributors to determine the  
127 reasonableness of orders for controlled substances over  
128 certain amounts; requiring distributors to maintain  
129 documents that support the report submitted to the  
130 Department of Health; requiring the department to assess  
131 data; requiring the department to report certain data to  
132 the Governor, President of the Senate, and Speaker of the  
133 House of Representatives by certain dates; prohibiting  
134 distribution to entities with certain criminal  
135 backgrounds; amending s. 499.05, F.S.; authorizing  
136 rulemaking concerning specified controlled substance  
137 wholesale distributor reporting requirements and  
138 credentialing requirements; amending s. 499.067, F.S.;  
139 authorizing the Department of Health to take disciplinary  
140 action against wholesale distributors failing to comply

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141 with specified credentialing or reporting requirements;  
142 amending s. 810.02, F.S.; authorizing separate judgments  
143 and sentences for burglary with the intent to commit theft  
144 of a controlled substance under specified provisions and  
145 for any applicable possession of controlled substance  
146 offense under specified provisions in certain  
147 circumstances; amending s. 812.014, F.S.; authorizing  
148 separate judgments and sentences for theft of a controlled  
149 substance under specified provisions and for any  
150 applicable possession of controlled substance offense  
151 under specified provisions in certain circumstances;  
152 amending s. 893.055, F.S., relating to the prescription  
153 drug monitoring program; deleting obsolete dates; deleting  
154 references to the Office of Drug Control; requiring  
155 reports to the prescription drug monitoring system to be  
156 made in 7 days rather than 15 days; prohibiting the use of  
157 certain funds to implement the program; requiring criminal  
158 background screening for those persons who have direct  
159 access to the prescription drug monitoring program's  
160 database; requiring the State Surgeon General to appoint a  
161 board of directors for the direct-support organization;  
162 conforming provisions to changes made by the act; amending  
163 s. 893.065, F.S.; conforming provisions to changes made by  
164 the act; amending s. 893.07, F.S.; providing that law  
165 enforcement officers are not required to obtain a  
166 subpoena, court order, or search warrant in order to  
167 obtain access to or copies of specified controlled  
168 substance inventory records; requiring reporting of the

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169 |       discovery of the theft or loss of controlled substances to  
170 |       the sheriff within a specified period; providing criminal  
171 |       penalties; amending s. 893.13, F.S.; prohibiting a person  
172 |       from obtaining or attempting to obtain from a practitioner  
173 |       a controlled substance or a prescription for a controlled  
174 |       substance by misrepresentation, fraud, forgery, deception,  
175 |       subterfuge, or concealment of a material fact; prohibiting  
176 |       a health care provider from providing a controlled  
177 |       substance or a prescription for a controlled substance by  
178 |       misrepresentation, fraud, forgery, deception, subterfuge,  
179 |       or concealment of a material fact; prohibiting a person  
180 |       from adulterating a controlled substance for certain use  
181 |       without authorization by a prescribing physician;  
182 |       providing penalties; amending s. 893.138, F.S.; providing  
183 |       circumstances in which a pain-management clinic may be  
184 |       declared a public nuisance; providing for the disposition  
185 |       of certain controlled substance inventory held by  
186 |       specified licensed physicians; providing certain  
187 |       requirements for a physician returning inventory to a  
188 |       distributor; requiring wholesale distributors to buy back  
189 |       certain undispensed inventory of controlled substances;  
190 |       providing for a declaration of a public health emergency;  
191 |       requiring certain actions relating to dispensing  
192 |       practitioners identified as posing the greatest threat to  
193 |       public health; providing an appropriation; providing for  
194 |       future expiration of program provisions; requiring the  
195 |       Department of Health to establish a practitioner profile  
196 |       for dentists; providing for severability; providing an

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197 effective date.

198

199 Be It Enacted by the Legislature of the State of Florida:

200

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

205 456.072 Grounds for discipline; penalties; enforcement.—

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

209 (mm) Failure to comply with controlled substance  
 210 prescribing requirements of s. 456.44.

211 (7) Notwithstanding subsection (2), upon a finding that a  
 212 physician has prescribed or dispensed a controlled substance, or  
 213 caused a controlled substance to be prescribed or dispensed, in  
 214 a manner that violates the standard of practice set forth in s.  
 215 458.331(1)(q) or (t), s. 459.015(1)(t) or (x), s. 461.013(1)(o)  
 216 or (s), or s. 466.028(1)(p) or (x), the physician shall be  
 217 suspended for a period of not less than 6 months and pay a fine  
 218 of not less than \$10,000 per count. Repeated violations shall  
 219 result in increased penalties.

220 Section 2. Section 456.42, Florida Statutes, is amended to  
 221 read:

222 456.42 Written prescriptions for medicinal drugs.—

223 (1) A written prescription for a medicinal drug issued by  
 224 a health care practitioner licensed by law to prescribe such



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225 drug must be legibly printed or typed so as to be capable of  
 226 being understood by the pharmacist filling the prescription;  
 227 must contain the name of the prescribing practitioner, the name  
 228 and strength of the drug prescribed, the quantity of the drug  
 229 prescribed, and the directions for use of the drug; must be  
 230 dated; and must be signed by the prescribing practitioner on the  
 231 day when issued. ~~A written prescription for a controlled~~  
 232 ~~substance listed in chapter 893 must have the quantity of the~~  
 233 ~~drug prescribed in both textual and numerical formats and must~~  
 234 ~~be dated with the abbreviated month written out on the face of~~  
 235 ~~the prescription.~~ However, a prescription that is electronically  
 236 generated and transmitted must contain the name of the  
 237 prescribing practitioner, the name and strength of the drug  
 238 prescribed, the quantity of the drug prescribed in numerical  
 239 format, and the directions for use of the drug and must be dated  
 240 and signed by the prescribing practitioner only on the day  
 241 issued, which signature may be in an electronic format as  
 242 defined in s. 668.003(4).

243 (2) A written prescription for a controlled substance  
 244 listed in chapter 893 must have the quantity of the drug  
 245 prescribed in both textual and numerical formats, must be dated  
 246 with the abbreviated month written out on the face of the  
 247 prescription, and must be either written on a standardized  
 248 counterfeit-proof prescription pad produced by a vendor approved  
 249 by the department or electronically prescribed as that term is  
 250 used in s. 408.0611. As a condition of being an approved vendor,  
 251 a prescription pad vendor must submit a monthly report to the  
 252 department which, at a minimum, documents the number of

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253 prescription pads sold and identifies the purchasers. The  
 254 department may, by rule, require the reporting of additional  
 255 information.

256 Section 3. Section 456.44, Florida Statutes, is created to  
 257 read:

258 456.44 Controlled substance prescribing.-

259 (1) DEFINITIONS.-

260 (a) "Addiction medicine specialist" means a board-  
 261 certified psychiatrist with a subspecialty certification in  
 262 addiction medicine or who is eligible for such subspecialty  
 263 certification in addiction medicine, an addiction medicine  
 264 physician certified or eligible for certification by the  
 265 American Society of Addiction Medicine, or an osteopathic  
 266 physician who holds a certificate of added qualification in  
 267 Addiction Medicine through the American Osteopathic Association.

268 (b) "Adverse incident" means any incident set forth in s.  
 269 458.351(4)(a)-(e) or s. 459.026(4)(a)-(e).

270 (c) "Board-certified pain management physician" means a  
 271 physician who possesses board certification in pain medicine by  
 272 the American Board of Pain Medicine, board certification by the  
 273 American Board of Interventional Pain Physicians, or board  
 274 certification or subcertification in pain management by a  
 275 specialty board recognized by the American Association of  
 276 Physician Specialists or an osteopathic physician who holds a  
 277 certificate in Pain Management by the American Osteopathic  
 278 Association.

279 (d) "Chronic nonmalignant pain" means pain unrelated to  
 280 cancer or rheumatoid arthritis which persists beyond the usual

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281 course of disease or the injury that is the cause of the pain or  
 282 more than 90 days after surgery.

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

285 (2) REGISTRATION.—Effective January 1, 2012, a physician  
 286 licensed under chapter 458, chapter 459, chapter 461, or chapter  
 287 466 who prescribes any controlled substance, as defined in s.  
 288 893.03, for the treatment of chronic nonmalignant pain, must:

289 (a) Designate himself or herself as a controlled substance  
 290 prescribing practitioner on the physician's practitioner  
 291 profile.

292 (b) Comply with the requirements of this section and  
 293 applicable board rules.

294 (3) STANDARDS OF PRACTICE.—The standards of practice in  
 295 this section do not supersede the level of care, skill, and  
 296 treatment recognized in general law related to healthcare  
 297 licensure.

298 (a) A complete medical history and a physical examination  
 299 must be conducted before beginning any treatment and must be  
 300 documented in the medical record. The exact components of the  
 301 physical examination shall be left to the judgment of the  
 302 clinician who is expected to perform a physical examination  
 303 proportionate to the diagnosis that justifies a treatment. The  
 304 medical record must, at a minimum, document the nature and  
 305 intensity of the pain, current and past treatments for pain,  
 306 underlying or coexisting diseases or conditions, the effect of  
 307 the pain on physical and psychological function, a review of  
 308 previous medical records, previous diagnostic studies, and

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309 history of alcohol and substance abuse. The medical record shall  
310 also document the presence of one or more recognized medical  
311 indications for the use of a controlled substance. Each  
312 registrant must develop a written plan for assessing each  
313 patient's risk of aberrant drug-related behavior, which may  
314 include patient drug testing. Registrants must assess each  
315 patient's risk for aberrant drug-related behavior and monitor  
316 that risk on an ongoing basis in accordance with the plan.

317 (b) Each registrant must develop a written individualized  
318 treatment plan for each patient. The treatment plan shall state  
319 objectives that will be used to determine treatment success,  
320 such as pain relief and improved physical and psychosocial  
321 function, and shall indicate if any further diagnostic  
322 evaluations or other treatments are planned. After treatment  
323 begins, the physician shall adjust drug therapy to the  
324 individual medical needs of each patient. Other treatment  
325 modalities, including a rehabilitation program, shall be  
326 considered depending on the etiology of the pain and the extent  
327 to which the pain is associated with physical and psychosocial  
328 impairment. The interdisciplinary nature of the treatment plan  
329 shall be documented.

330 (c) The physician shall discuss the risks and benefits of  
331 the use of controlled substances, including the risks of abuse  
332 and addiction, as well as physical dependence and its  
333 consequences, with the patient, persons designated by the  
334 patient, or the patient's surrogate or guardian if the patient  
335 is incompetent. The physician shall use a written controlled  
336 substance agreement between the physician and the patient

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337 outlining the patient's responsibilities, including, but not  
338 limited to:

339 1. Number and frequency of controlled substance  
340 prescriptions and refills.

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

343 3. An agreement that controlled substances for the  
344 treatment of chronic nonmalignant pain shall be prescribed by a  
345 single treating physician unless otherwise authorized by the  
346 treating physician and documented in the medical record.

347 (d) The patient shall be seen by the physician at regular  
348 intervals, not to exceed 3 months, to assess the efficacy of  
349 treatment, ensure that controlled substance therapy remains  
350 indicated, evaluate the patient's progress toward treatment  
351 objectives, consider adverse drug effects, and review the  
352 etiology of the pain. Continuation or modification of therapy  
353 shall depend on the physician's evaluation of the patient's  
354 progress. If treatment goals are not being achieved, despite  
355 medication adjustments, the physician shall reevaluate the  
356 appropriateness of continued treatment. The physician shall  
357 monitor patient compliance in medication usage, related  
358 treatment plans, controlled substance agreements, and  
359 indications of substance abuse or diversion at a minimum of 3-  
360 month intervals.

361 (e) The physician shall refer the patient as necessary for  
362 additional evaluation and treatment in order to achieve  
363 treatment objectives. Special attention shall be given to those  
364 patients who are at risk for misusing their medications and

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365 those whose living arrangements pose a risk for medication  
 366 misuse or diversion. The management of pain in patients with a  
 367 history of substance abuse or with a comorbid psychiatric  
 368 disorder requires extra care, monitoring, and documentation and  
 369 requires consultation with or referral to an addictionologist or  
 370 physiatrist.

371 (f) A physician registered under this section must  
 372 maintain accurate, current, and complete records that are  
 373 accessible and readily available for review and comply with the  
 374 requirements of this section, the applicable practice act, and  
 375 applicable board rules. The medical records must include, but  
 376 are not limited to:

- 377 1. The complete medical history and a physical  
 378 examination, including history of drug abuse or dependence.
- 379 2. Diagnostic, therapeutic, and laboratory results.
- 380 3. Evaluations and consultations.
- 381 4. Treatment objectives.
- 382 5. Discussion of risks and benefits.
- 383 6. Treatments.
- 384 7. Medications, including date, type, dosage, and quantity  
 385 prescribed.
- 386 8. Instructions and agreements.
- 387 9. Periodic reviews.
- 388 10. Results of any drug testing.
- 389 11. A photocopy of the patient's government-issued photo  
 390 identification.
- 391 12. If a written prescription for a controlled substance  
 392 is given to the patient, a duplicate of the prescription.

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393           13. The physician's full name presented in a legible  
 394 manner.

395           (g) Patients with signs or symptoms of substance abuse  
 396 shall be immediately referred to a board-certified pain  
 397 management physician, an addiction medicine specialist, or a  
 398 mental health addiction facility as it pertains to drug abuse or  
 399 addiction unless the physician is board-certified or board-  
 400 eligible in pain management. Throughout the period of time  
 401 before receiving the consultant's report, a prescribing  
 402 physician shall clearly and completely document medical  
 403 justification for continued treatment with controlled substances  
 404 and those steps taken to ensure medically appropriate use of  
 405 controlled substances by the patient. Upon receipt of the  
 406 consultant's written report, the prescribing physician shall  
 407 incorporate the consultant's recommendations for continuing,  
 408 modifying, or discontinuing controlled substance therapy. The  
 409 resulting changes in treatment shall be specifically documented  
 410 in the patient's medical record. Evidence or behavioral  
 411 indications of diversion shall be followed by discontinuation of  
 412 controlled substance therapy and the patient shall be discharged  
 413 and all results of testing and actions taken by the physician  
 414 shall be documented in the patient's medical record.

415  
 416 This subsection does not apply to a board-certified  
 417 anesthesiologist, physiatrist, or neurologist, or to a board-  
 418 certified physician who has surgical privileges at a hospital or  
 419 ambulatory surgery center and primarily provides surgical  
 420 services. This subsection does not apply to a board-certified

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421 medical specialist who has also completed a fellowship in pain  
 422 medicine approved by the Accreditation Council for Graduate  
 423 Medical Education or the American Osteopathic Association, or  
 424 who is board certified in pain medicine by a board approved by  
 425 the American Board of Medical Specialties or the American  
 426 Osteopathic Association and performs interventional pain  
 427 procedures of the type routinely billed using surgical codes.

428 Section 4. Section 458.3265, Florida Statutes, is amended  
 429 to read:

430 458.3265 Pain-management clinics.—

431 (1) REGISTRATION.—

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

433 a. "Chronic nonmalignant pain" means pain unrelated to  
 434 cancer or rheumatoid arthritis which persists beyond the usual  
 435 course of disease or the injury that is the cause of the pain or  
 436 more than 90 days after surgery.

437 b. "Pain-management clinic" or "clinic" means any publicly  
 438 or privately owned facility:

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

441 (II) Where in any month a majority of patients are  
 442 prescribed opioids, benzodiazepines, barbiturates, or  
 443 carisoprodol for the treatment of chronic nonmalignant pain. All  
 444 ~~privately owned pain-management clinics, facilities, or offices,~~  
 445 ~~hereinafter referred to as "clinics," which advertise in any~~  
 446 ~~medium for any type of pain-management services, or employ a~~  
 447 ~~physician who is primarily engaged in the treatment of pain by~~  
 448 ~~prescribing or dispensing controlled substance medications,~~



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449           2. Each pain-management clinic must register with the  
 450 department unless:  
 451           ~~a.1.~~ That clinic is licensed as a facility pursuant to  
 452 chapter 395;  
 453           ~~b.2.~~ The majority of the physicians who provide services  
 454 in the clinic primarily provide surgical services;  
 455           ~~c.3.~~ The clinic is owned by a publicly held corporation  
 456 whose shares are traded on a national exchange or on the over-  
 457 the-counter market and whose total assets at the end of the  
 458 corporation's most recent fiscal quarter exceeded \$50 million;  
 459           ~~d.4.~~ The clinic is affiliated with an accredited medical  
 460 school at which training is provided for medical students,  
 461 residents, or fellows;  
 462           ~~e.5.~~ The clinic does not prescribe ~~or dispense~~ controlled  
 463 substances for the treatment of pain; ~~or~~  
 464           ~~f.6.~~ The clinic is owned by a corporate entity exempt from  
 465 federal taxation under 26 U.S.C. s. 501(c)(3); ~~or~~  
 466           g. The clinic is wholly owned and operated by one or more  
 467 board-certified anesthesiologists, physiatrists, or  
 468 neurologists; or  
 469           h. The clinic is wholly owned and operated by one or more  
 470 board-certified medical specialists who have also completed  
 471 fellowships in pain medicine approved by the Accreditation  
 472 Council for Graduate Medical Education, or who are also board-  
 473 certified in pain medicine by a board approved by the American  
 474 Board of Medical Specialties and perform interventional pain  
 475 procedures of the type routinely billed using surgical codes.  
 476           (b) Each clinic location shall be registered separately

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477 | regardless of whether the clinic is operated under the same  
478 | business name or management as another clinic.

479 |       (c) As a part of registration, a clinic must designate a  
480 | physician who is responsible for complying with all requirements  
481 | related to registration and operation of the clinic in  
482 | compliance with this section. Within 10 days after termination  
483 | of a designated physician, the clinic must notify the department  
484 | of the identity of another designated physician for that clinic.  
485 | The designated physician shall have a full, active, and  
486 | unencumbered license under this chapter or chapter 459 and shall  
487 | practice at the clinic location for which the physician has  
488 | assumed responsibility. Failing to have a licensed designated  
489 | physician practicing at the location of the registered clinic  
490 | may be the basis for a summary suspension of the clinic  
491 | registration certificate as described in s. 456.073(8) for a  
492 | license or s. 120.60(6).

493 |       (d) The department shall deny registration to any clinic  
494 | that is not fully owned by a physician licensed under this  
495 | chapter or chapter 459 or a group of physicians, each of whom is  
496 | licensed under this chapter or chapter 459; or that is not a  
497 | health care clinic licensed under part X of chapter 400.

498 |       (e) The department shall deny registration to any pain-  
499 | management clinic owned by or with any contractual or employment  
500 | relationship with a physician:

501 |           1. Whose Drug Enforcement Administration number has ever  
502 | been revoked.

503 |           2. Whose application for a license to prescribe, dispense,  
504 | or administer a controlled substance has been denied by any

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505 jurisdiction.

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

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

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

528 (h) If the registration of a pain-management clinic is  
529 revoked or suspended, the designated physician of the pain-  
530 management clinic, the owner or lessor of the pain-management  
531 clinic property, the manager, and the proprietor shall cease to  
532 operate the facility as a pain-management clinic as of the

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533 effective date of the suspension or revocation.

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

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

547 (k) If the clinic's registration is revoked, any person  
 548 named in the registration documents of the pain-management  
 549 clinic, including persons owning or operating the pain-  
 550 management clinic, may not, as an individual or as a part of a  
 551 group, apply to operate a pain-management clinic for 5 years  
 552 after the date the registration is revoked.

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

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

558 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities  
 559 apply to any physician who provides professional services in a  
 560 pain-management clinic that is required to be registered in

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561 subsection (1).

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

564 ~~1. The pain-management clinic is not registered with the~~  
565 ~~department as required by this section.~~

566 ~~2. Effective July 1, 2012, the physician has not~~  
567 ~~successfully completed a pain-medicine fellowship that is~~  
568 ~~accredited by the Accreditation Council for Graduate Medical~~  
569 ~~Education or a pain-medicine residency that is accredited by the~~  
570 ~~Accreditation Council for Graduate Medical Education or, prior~~  
571 ~~to July 1, 2012, does not comply with rules adopted by the~~  
572 ~~board.~~

573  
574 Any physician who qualifies to practice medicine in a pain-  
575 management clinic pursuant to rules adopted by the Board of  
576 Medicine as of July 1, 2012, may continue to practice medicine  
577 in a pain-management clinic as long as the physician continues  
578 to meet the qualifications set forth in the board rules. A  
579 physician who violates this paragraph is subject to disciplinary  
580 action by his or her appropriate medical regulatory board.

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

585 (c) A physician, a physician assistant, or an advanced  
586 registered nurse practitioner must perform a physical  
587 examination of a patient on the same day that the physician he  
588 ~~or she dispenses or prescribes~~ a controlled substance to a

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589 patient at a pain-management clinic. If the physician prescribes  
590 ~~or dispenses~~ more than a 72-hour dose of controlled substances  
591 for the treatment of chronic nonmalignant pain, the physician  
592 must document in the patient's record the reason for prescribing  
593 ~~or dispensing~~ that quantity.

594 (d) A physician authorized to prescribe controlled  
595 substances who practices at a pain-management clinic is  
596 responsible for maintaining the control and security of his or  
597 her prescription blanks and any other method used for  
598 prescribing controlled substance pain medication. The physician  
599 shall comply with the requirements for counterfeit-resistant  
600 prescription blanks in s. 893.065 and the rules adopted pursuant  
601 to that section. The physician shall notify, in writing, the  
602 department within 24 hours following any theft or loss of a  
603 prescription blank or breach of any other method for prescribing  
604 pain medication.

605 (e) The designated physician of a pain-management clinic  
606 shall notify the applicable board in writing of the date of  
607 termination of employment within 10 days after terminating his  
608 or her employment with a pain-management clinic that is required  
609 to be registered under subsection (1). Each physician practicing  
610 in a pain-management clinic shall advise the Board of Medicine,  
611 in writing, within 10 calendar days after beginning or ending  
612 his or her practice at a pain-management clinic.

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

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

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- 617 at a publicly accessible fixed location and must:
- 618 a. Display a sign that can be viewed by the public that
- 619 contains the clinic name, hours of operations, and a street
- 620 address.
- 621 b. Have a publicly listed telephone number and a dedicated
- 622 phone number to send and receive faxes with a fax machine that
- 623 shall be operational 24 hours per day.
- 624 c. Have emergency lighting and communications.
- 625 d. Have a reception and waiting area.
- 626 e. Provide a restroom.
- 627 f. Have an administrative area, including room for storage
- 628 of medical records, supplies, and equipment.
- 629 g. Have private patient examination rooms.
- 630 h. Have treatment rooms, if treatment is being provided to
- 631 the patients.
- 632 i. Display a printed sign located in a conspicuous place
- 633 in the waiting room viewable by the public with the name and
- 634 contact information of the clinic's designated physician and the
- 635 names of all physicians practicing in the clinic.
- 636 j. If the clinic stores and dispenses prescription drugs,
- 637 comply with ss. 499.0121 and 893.07.
- 638 2. This section does not excuse a physician from providing
- 639 any treatment or performing any medical duty without the proper
- 640 equipment and materials as required by the standard of care.
- 641 This section does not supersede the level of care, skill, and
- 642 treatment recognized in general law related to healthcare
- 643 licensure.
- 644 (g) Each physician practicing in a pain-management clinic

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645 is responsible for ensuring compliance with the following  
 646 infection control requirements.

647 1. The clinic shall maintain equipment and supplies to  
 648 support infection prevention and control activities.

649 2. The clinic shall identify infection risks based on the  
 650 following:

651 a. Geographic location, community, and population served.  
 652 b. The care, treatment, and services it provides.  
 653 c. An analysis of its infection surveillance and control  
 654 data.

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

657 a. Prioritized risks.  
 658 b. Limiting unprotected exposure to pathogens.  
 659 c. Limiting the transmission of infections associated with  
 660 procedures performed in the clinic.

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

663 (h) Each physician practicing in a pain-management clinic  
 664 is responsible for ensuring compliance with the following health  
 665 and safety requirements:

666 1. The clinic, including its grounds, buildings,  
 667 furniture, appliances, and equipment shall be structurally  
 668 sound, in good repair, clean, and free from health and safety  
 669 hazards.

670 2. The clinic shall have evacuation procedures in the  
 671 event of an emergency, which shall include provisions for the  
 672 evacuation of disabled patients and employees.



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673           3. The clinic shall have a written facility-specific  
 674 disaster plan setting forth actions that will be taken in the  
 675 event of clinic closure due to unforeseen disasters and shall  
 676 include provisions for the protection of medical records and any  
 677 controlled substances.

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

682           (i) The designated physician is responsible for ensuring  
 683 compliance with the following quality assurance requirements.  
 684 Each pain-management clinic shall have an ongoing quality  
 685 assurance program that objectively and systematically monitors  
 686 and evaluates the quality and appropriateness of patient care,  
 687 evaluates methods to improve patient care, identifies and  
 688 corrects deficiencies within the facility, alerts the designated  
 689 physician to identify and resolve recurring problems, and  
 690 provides for opportunities to improve the facility's performance  
 691 and to enhance and improve the quality of care provided to the  
 692 public. The designated physician shall establish a quality  
 693 assurance program that includes the following components:

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

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

697           3. The development of measures to correct, reduce,  
 698 minimize, or eliminate the risk of adverse incidents to  
 699 patients.

700           4. The documentation of these functions and periodic

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701 review no less than quarterly of such information by the  
 702 designated physician.

703 (j) The designated physician is responsible for ensuring  
 704 compliance with the following data collection and reporting  
 705 requirements:

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

709 2. The designated physician shall also report to the Board  
 710 of Medicine, in writing, on a quarterly basis the following  
 711 data:

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

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

716 c. The number of patients discharged due to drug  
 717 diversion.

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

723 (3) INSPECTION.—

724 (a) The department shall inspect the pain-management  
 725 clinic annually, including a review of the patient records, to  
 726 ensure that it complies with this section and the rules of the  
 727 Board of Medicine adopted pursuant to subsection (4) unless the  
 728 clinic is accredited by a nationally recognized accrediting

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729 agency approved by the Board of Medicine.

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

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

738 (4) RULEMAKING.—

739 (a) The department shall adopt rules necessary to  
 740 administer the registration and inspection of pain-management  
 741 clinics which establish the specific requirements, procedures,  
 742 forms, and fees.

743 ~~(b) The department shall adopt a rule defining what~~  
 744 ~~constitutes practice by a designated physician at the clinic~~  
 745 ~~location for which the physician has assumed responsibility, as~~  
 746 ~~set forth in subsection (1). When adopting the rule, the~~  
 747 ~~department shall consider the number of clinic employees, the~~  
 748 ~~location of the pain-management clinic, the clinic's hours of~~  
 749 ~~operation, and the amount of controlled substances being~~  
 750 ~~prescribed, dispensed, or administered at the pain-management~~  
 751 ~~clinic.~~

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

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

- 763            1. ~~Facility operations;~~
- 764            2. ~~Physical operations;~~
- 765            3. ~~Infection control requirements;~~
- 766            4. ~~Health and safety requirements;~~
- 767            5. ~~Quality assurance requirements;~~
- 768            6. ~~Patient records;~~
- 769            7. ~~training requirements for all facility health care~~  
 770            ~~practitioners who are not regulated by another board.~~
- 771            8. ~~Inspections; and~~
- 772            9. ~~Data collection and reporting requirements.~~

773  
 774            ~~A physician is primarily engaged in the treatment of pain by~~  
 775            ~~prescribing or dispensing controlled substance medications when~~  
 776            ~~the majority of the patients seen are prescribed or dispensed~~  
 777            ~~controlled substance medications for the treatment of chronic~~  
 778            ~~nonmalignant pain. Chronic nonmalignant pain is pain unrelated~~  
 779            ~~to cancer which persists beyond the usual course of the disease~~  
 780            ~~or the injury that is the cause of the pain or more than 90 days~~  
 781            ~~after surgery.~~

782            (5) PENALTIES; ENFORCEMENT.—

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

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785 requirements of this section; chapter 499, the Florida Drug and  
 786 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and  
 787 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug  
 788 Abuse Prevention and Control Act; chapter 893, the Florida  
 789 Comprehensive Drug Abuse Prevention and Control Act; or the  
 790 rules of the department. In determining whether a penalty is to  
 791 be imposed, and in fixing the amount of the fine, the department  
 792 shall consider the following factors:

793 1. The gravity of the violation, including the probability  
 794 that death or serious physical or emotional harm to a patient  
 795 has resulted, or could have resulted, from the pain-management  
 796 clinic's actions or the actions of the physician, the severity  
 797 of the action or potential harm, and the extent to which the  
 798 provisions of the applicable laws or rules were violated.

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

801 3. Whether there were any previous violations at the pain-  
 802 management clinic.

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

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

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

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

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

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

821 Section 5. Paragraph (f) is added to subsection (1) of  
 822 section 458.327, Florida Statutes, to read:

823 458.327 Penalty for violations.—

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

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

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

831 458.331 Grounds for disciplinary action; action by the  
 832 board and department.—

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

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

837 Section 7. Section 459.0137, Florida Statutes, is amended  
 838 to read:

839 459.0137 Pain-management clinics.—

840 (1) REGISTRATION.—

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

842           a. "Chronic nonmalignant pain" means pain unrelated to

843 cancer or rheumatoid arthritis which persists beyond the usual

844 course of disease or the injury that is the cause of the pain or

845 more than 90 days after surgery.

846           b. "Pain-management clinic" or "clinic" means any publicly

847 or privately owned facility:

848           (I) That advertises in any medium for any type of pain-

849 management services; or

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

851 prescribed opioids, benzodiazepines, barbiturates, or

852 carisoprodol for the treatment of chronic nonmalignant pain. All

853 ~~privately owned pain-management clinics, facilities, or offices,~~

854 ~~hereinafter referred to as "clinics," which advertise in any~~

855 ~~medium for any type of pain-management services, or employ an~~

856 ~~osteopathic physician who is primarily engaged in the treatment~~

857 ~~of pain by prescribing or dispensing controlled substance~~

858 ~~medications,~~

859           2. Each pain-management clinic must register with the

860 department unless:

861           a.1. That clinic is licensed as a facility pursuant to

862 chapter 395;

863           b.2. The majority of the physicians who provide services

864 in the clinic primarily provide surgical services;

865           c.3. The clinic is owned by a publicly held corporation

866 whose shares are traded on a national exchange or on the over-

867 the-counter market and whose total assets at the end of the

868 corporation's most recent fiscal quarter exceeded \$50 million;

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869 d.4. The clinic is affiliated with an accredited medical  
870 school at which training is provided for medical students,  
871 residents, or fellows;

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

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

876 g. The clinic is wholly owned and operated by one or more  
877 board-certified anesthesiologists, physiatrists, or  
878 neurologists; or

879 h. The clinic is wholly owned and operated by one or more  
880 board-certified medical specialists who have also completed  
881 fellowships in pain medicine approved by the Accreditation  
882 Council for Graduate Medical Education or the American  
883 Osteopathic Association, or who are also board-certified in pain  
884 medicine by a board approved by the American Board of Medical  
885 Specialties or the American Osteopathic Association and perform  
886 interventional pain procedures of the type routinely billed  
887 using surgical codes.

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

891 (c) As a part of registration, a clinic must designate an  
892 osteopathic physician who is responsible for complying with all  
893 requirements related to registration and operation of the clinic  
894 in compliance with this section. Within 10 days after  
895 termination of a designated osteopathic physician, the clinic  
896 must notify the department of the identity of another designated



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897 physician for that clinic. The designated physician shall have a  
898 full, active, and unencumbered license under chapter 458 or this  
899 chapter and shall practice at the clinic location for which the  
900 physician has assumed responsibility. Failing to have a licensed  
901 designated osteopathic physician practicing at the location of  
902 the registered clinic may be the basis for a summary suspension  
903 of the clinic registration certificate as described in s.  
904 456.073(8) for a license or s. 120.60(6).

905 (d) The department shall deny registration to any clinic  
906 that is not fully owned by a physician licensed under chapter  
907 458 or this chapter or a group of physicians, each of whom is  
908 licensed under chapter 458 or this chapter; or that is not a  
909 health care clinic licensed under part X of chapter 400.

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

913 1. Whose Drug Enforcement Administration number has ever  
914 been revoked.

915 2. Whose application for a license to prescribe, dispense,  
916 or administer a controlled substance has been denied by any  
917 jurisdiction.

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

924 (f) If the department finds that a pain-management clinic

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925 does not meet the requirement of paragraph (d) or is owned,  
926 directly or indirectly, by a person meeting any criteria listed  
927 in paragraph (e), the department shall revoke the certificate of  
928 registration previously issued by the department. As determined  
929 by rule, the department may grant an exemption to denying a  
930 registration or revoking a previously issued registration if  
931 more than 10 years have elapsed since adjudication. As used in  
932 this subsection, the term "convicted" includes an adjudication  
933 of guilt following a plea of guilty or nolo contendere or the  
934 forfeiture of a bond when charged with a crime.

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

940 (h) If the registration of a pain-management clinic is  
941 revoked or suspended, the designated physician of the pain-  
942 management clinic, the owner or lessor of the pain-management  
943 clinic property, the manager, and the proprietor shall cease to  
944 operate the facility as a pain-management clinic as of the  
945 effective date of the suspension or revocation.

946 (i) If a pain-management clinic registration is revoked or  
947 suspended, the designated physician of the pain-management  
948 clinic, the owner or lessor of the clinic property, the manager,  
949 or the proprietor is responsible for removing all signs and  
950 symbols identifying the premises as a pain-management clinic.

951 (j) Upon the effective date of the suspension or  
952 revocation, the designated physician of the pain-management

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953 clinic shall advise the department of the disposition of the  
 954 medicinal drugs located on the premises. The disposition is  
 955 subject to the supervision and approval of the department.  
 956 Medicinal drugs that are purchased or held by a pain-management  
 957 clinic that is not registered may be deemed adulterated pursuant  
 958 to s. 499.006.

959 (k) If the clinic's registration is revoked, any person  
 960 named in the registration documents of the pain-management  
 961 clinic, including persons owning or operating the pain-  
 962 management clinic, may not, as an individual or as a part of a  
 963 group, make application for a permit to operate a pain-  
 964 management clinic for 5 years after the date the registration is  
 965 revoked.

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

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

971 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities  
 972 apply to any osteopathic physician who provides professional  
 973 services in a pain-management clinic that is required to be  
 974 registered in subsection (1).

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

977 ~~1. the pain-management clinic is not registered with the~~  
 978 ~~department as required by this section.~~ 1.

979 ~~2. Effective July 1, 2012, the physician has not~~  
 980 ~~successfully completed a pain-medicine fellowship that is~~

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981 ~~accredited by the Accreditation Council for Graduate Medical~~  
 982 ~~Education or the American Osteopathic Association or a pain-~~  
 983 ~~medicine residency that is accredited by the Accreditation~~  
 984 ~~Council for Graduate Medical Education or the American~~  
 985 ~~Osteopathic Association or, prior to July 1, 2012, does not~~  
 986 ~~comply with rules adopted by the board.~~

987  
 988 Any physician who qualifies to practice medicine in a pain-  
 989 management clinic pursuant to rules adopted by the Board of  
 990 Osteopathic Medicine as of July 1, 2012, may continue to  
 991 practice medicine in a pain-management clinic as long as the  
 992 physician continues to meet the qualifications set forth in the  
 993 board rules. An osteopathic physician who violates this  
 994 paragraph is subject to disciplinary action by his or her  
 995 appropriate medical regulatory board.

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

1000 (c) An osteopathic physician, a physician assistant, or an  
 1001 advanced registered nurse practitioner must perform a physical  
 1002 examination of a patient on the same day that the physician ~~he~~  
 1003 ~~or she dispenses or~~ prescribes a controlled substance to a  
 1004 patient at a pain-management clinic. If the osteopathic  
 1005 physician prescribes ~~or dispenses~~ more than a 72-hour dose of  
 1006 controlled substances for the treatment of chronic nonmalignant  
 1007 pain, the osteopathic physician must document in the patient's  
 1008 record the reason for prescribing ~~or dispensing~~ that quantity.

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1009 (d) An osteopathic physician authorized to prescribe  
 1010 controlled substances who practices at a pain-management clinic  
 1011 is responsible for maintaining the control and security of his  
 1012 or her prescription blanks and any other method used for  
 1013 prescribing controlled substance pain medication. The  
 1014 osteopathic physician shall comply with the requirements for  
 1015 counterfeit-resistant prescription blanks in s. 893.065 and the  
 1016 rules adopted pursuant to that section. The osteopathic  
 1017 physician shall notify, in writing, the department within 24  
 1018 hours following any theft or loss of a prescription blank or  
 1019 breach of any other method for prescribing pain medication.

1020 (e) The designated osteopathic physician of a pain-  
 1021 management clinic shall notify the applicable board in writing  
 1022 of the date of termination of employment within 10 days after  
 1023 terminating his or her employment with a pain-management clinic  
 1024 that is required to be registered under subsection (1). Each  
 1025 osteopathic physician practicing in a pain-management clinic  
 1026 shall advise the Board of Osteopathic Medicine in writing within  
 1027 10 calendar days after beginning or ending his or her practice  
 1028 at a pain-management clinic.

1029 (f) Each osteopathic physician practicing in a pain-  
 1030 management clinic is responsible for ensuring compliance with  
 1031 the following facility and physical operations requirements:

1032 1. A pain-management clinic shall be located and operated  
 1033 at a publicly accessible fixed location and must:

1034 a. Display a sign that can be viewed by the public that  
 1035 contains the clinic name, hours of operations, and a street  
 1036 address.

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1037 b. Have a publicly listed telephone number and a dedicated  
 1038 phone number to send and receive faxes with a fax machine that  
 1039 shall be operational 24 hours per day.

1040 c. Have emergency lighting and communications.

1041 d. Have a reception and waiting area.

1042 e. Provide a restroom.

1043 f. Have an administrative area including room for storage  
 1044 of medical records, supplies and equipment.

1045 g. Have private patient examination rooms.

1046 h. Have treatment rooms, if treatment is being provided to  
 1047 the patient.

1048 i. Display a printed sign located in a conspicuous place  
 1049 in the waiting room viewable by the public with the name and  
 1050 contact information of the clinic-designated physician and the  
 1051 names of all physicians practicing in the clinic.

1052 j. If the clinic stores and dispenses prescription drug,  
 1053 comply with ss. 499.0121 and 893.07.

1054 2. This section does not excuse an osteopathic physician  
 1055 from providing any treatment or performing any medical duty  
 1056 without the proper equipment and materials as required by the  
 1057 standard of care. This section does not supersede the level of  
 1058 care, skill, and treatment recognized in general law related to  
 1059 healthcare licensure.

1060 (g) Each osteopathic physician practicing in a pain-  
 1061 management clinic is responsible for ensuring compliance with  
 1062 the following infection control requirements.

1063 1. The clinic shall maintain equipment and supplies to  
 1064 support infection prevention and control activities.

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1065 2. The clinic shall identify infection risks based on the  
 1066 following:

1067 a. Geographic location, community, and population served.

1068 b. The care, treatment and services it provides.

1069 c. An analysis of its infection surveillance and control  
 1070 data.

1071 3. The clinic shall maintain written infection prevention  
 1072 policies and procedures that address the following:

1073 a. Prioritized risks.

1074 b. Limiting unprotected exposure to pathogen.

1075 c. Limiting the transmission of infections associated with  
 1076 procedures performed in the clinic.

1077 d. Limiting the transmission of infections associated with  
 1078 the clinic's use of medical equipment, devices, and supplies.

1079 (h) Each osteopathic physician practicing in a pain-  
 1080 management clinic is responsible for ensuring compliance with  
 1081 the following health and safety requirements.

1082 1. The clinic, including its grounds, buildings,  
 1083 furniture, appliances, and equipment shall be structurally  
 1084 sound, in good repair, clean, and free from health and safety  
 1085 hazards.

1086 2. The clinic shall have evacuation procedures in the  
 1087 event of an emergency which shall include provisions for the  
 1088 evacuation of disabled patients and employees.

1089 3. The clinic shall have a written facility-specific  
 1090 disaster plan which sets forth actions that will be taken in the  
 1091 event of clinic closure due to unforeseen disasters and shall  
 1092 include provisions for the protection of medical records and any

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1093 controlled substances.

1094 4. Each clinic shall have at least one employee on the  
 1095 premises during patient care hours who is certified in Basic  
 1096 Life Support and is trained in reacting to accidents and medical  
 1097 emergencies until emergency medical personnel arrive.

1098 (i) The designated physician is responsible for ensuring  
 1099 compliance with the following quality assurance requirements.  
 1100 Each pain-management clinic shall have an ongoing quality  
 1101 assurance program that objectively and systematically monitors  
 1102 and evaluates the quality and appropriateness of patient care,  
 1103 evaluates methods to improve patient care, identifies and  
 1104 corrects deficiencies within the facility, alerts the designated  
 1105 physician to identify and resolve recurring problems, and  
 1106 provides for opportunities to improve the facility's performance  
 1107 and to enhance and improve the quality of care provided to the  
 1108 public. The designated physician shall establish a quality  
 1109 assurance program that includes the following components:

1110 1. The identification, investigation, and analysis of the  
 1111 frequency and causes of adverse incidents to patients.

1112 2. The identification of trends or patterns of incidents.

1113 3. The development of measures to correct, reduce,  
 1114 minimize, or eliminate the risk of adverse incidents to  
 1115 patients.

1116 4. The documentation of these functions and periodic  
 1117 review no less than quarterly of such information by the  
 1118 designated physician.

1119 (j) The designated physician is responsible for ensuring  
 1120 compliance with the following data collection and reporting



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1121 requirements:

1122 1. The designated physician for each pain-management

1123 clinic shall report all adverse incidents to the department as

1124 set forth in s. 459.026.

1125 2. The designated physician shall also report to the Board

1126 of Osteopathic Medicine, in writing, on a quarterly basis, the

1127 following data:

1128 a. Number of new and repeat patients seen and treated at

1129 the clinic who are prescribed controlled substance medications

1130 for the treatment of chronic, nonmalignant pain.

1131 b. The number of patients discharged due to drug abuse.

1132 c. The number of patients discharged due to drug

1133 diversion.

1134 d. The number of patients treated at the pain clinic whose

1135 domicile is located somewhere other than in this state. A

1136 patient's domicile is the patient's fixed or permanent home to

1137 which he or she intends to return even though he or she may

1138 temporarily reside elsewhere.

1139 (3) INSPECTION.—

1140 (a) The department shall inspect the pain-management

1141 clinic annually, including a review of the patient records, to

1142 ensure that it complies with this section and the rules of the

1143 Board of Osteopathic Medicine adopted pursuant to subsection (4)

1144 unless the clinic is accredited by a nationally recognized

1145 accrediting agency approved by the Board of Osteopathic

1146 Medicine.

1147 (b) During an onsite inspection, the department shall make

1148 a reasonable attempt to discuss each violation with the owner or

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1149 designated physician of the pain-management clinic before  
 1150 issuing a formal written notification.

1151 (c) Any action taken to correct a violation shall be  
 1152 documented in writing by the owner or designated physician of  
 1153 the pain-management clinic and verified by followup visits by  
 1154 departmental personnel.

1155 (4) RULEMAKING.—

1156 (a) The department shall adopt rules necessary to  
 1157 administer the registration and inspection of pain-management  
 1158 clinics which establish the specific requirements, procedures,  
 1159 forms, and fees.

1160 ~~(b) The department shall adopt a rule defining what~~  
 1161 ~~constitutes practice by a designated osteopathic physician at~~  
 1162 ~~the clinic location for which the physician has assumed~~  
 1163 ~~responsibility, as set forth in subsection (1). When adopting~~  
 1164 ~~the rule, the department shall consider the number of clinic~~  
 1165 ~~employees, the location of the pain-management clinic, the~~  
 1166 ~~clinic's hours of operation, and the amount of controlled~~  
 1167 ~~substances being prescribed, dispensed, or administered at the~~  
 1168 ~~pain-management clinic.~~

1169 ~~(c) The Board of Osteopathic Medicine shall adopt a rule~~  
 1170 ~~establishing the maximum number of prescriptions for Schedule II~~  
 1171 ~~or Schedule III controlled substances or the controlled~~  
 1172 ~~substance Alprazolam which may be written at any one registered~~  
 1173 ~~pain-management clinic during any 24-hour period.~~

1174 (b) ~~(d)~~ The Board of Osteopathic Medicine shall adopt rules  
 1175 setting forth standards of practice for osteopathic physicians  
 1176 practicing in privately owned pain-management clinics that

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1177 ~~primarily engage in the treatment of pain by prescribing or~~  
 1178 ~~dispensing controlled substance medications. Such rules shall~~  
 1179 ~~address, but need not be limited to:~~

- 1180 ~~1. Facility operations;~~
- 1181 ~~2. Physical operations;~~
- 1182 ~~3. Infection control requirements;~~
- 1183 ~~4. Health and safety requirements;~~
- 1184 ~~5. Quality assurance requirements;~~
- 1185 ~~6. Patient records;~~
- 1186 ~~7. training requirements for all facility health care~~  
 1187 ~~practitioners who are not regulated by another board.~~
- 1188 ~~8. Inspections; and~~
- 1189 ~~9. Data collection and reporting requirements.~~

1190  
 1191 ~~An osteopathic physician is primarily engaged in the treatment~~  
 1192 ~~of pain by prescribing or dispensing controlled substance~~  
 1193 ~~medications when the majority of the patients seen are~~  
 1194 ~~prescribed or dispensed controlled substance medications for the~~  
 1195 ~~treatment of chronic nonmalignant pain. Chronic nonmalignant~~  
 1196 ~~pain is pain unrelated to cancer which persists beyond the usual~~  
 1197 ~~course of the disease or the injury that is the cause of the~~  
 1198 ~~pain or more than 90 days after surgery.~~

1199 (5) PENALTIES; ENFORCEMENT.—

1200 (a) The department may impose an administrative fine on  
 1201 the clinic of up to \$5,000 per violation for violating the  
 1202 requirements of this section; chapter 499, the Florida Drug and  
 1203 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and  
 1204 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug

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1205 Abuse Prevention and Control Act; chapter 893, the Florida  
 1206 Comprehensive Drug Abuse Prevention and Control Act; or the  
 1207 rules of the department. In determining whether a penalty is to  
 1208 be imposed, and in fixing the amount of the fine, the department  
 1209 shall consider the following factors:

1210       1. The gravity of the violation, including the probability  
 1211 that death or serious physical or emotional harm to a patient  
 1212 has resulted, or could have resulted, from the pain-management  
 1213 clinic's actions or the actions of the osteopathic physician,  
 1214 the severity of the action or potential harm, and the extent to  
 1215 which the provisions of the applicable laws or rules were  
 1216 violated.

1217       2. What actions, if any, the owner or designated  
 1218 osteopathic physician took to correct the violations.

1219       3. Whether there were any previous violations at the pain-  
 1220 management clinic.

1221       4. The financial benefits that the pain-management clinic  
 1222 derived from committing or continuing to commit the violation.

1223       (b) Each day a violation continues after the date fixed  
 1224 for termination of the violation as ordered by the department  
 1225 constitutes an additional, separate, and distinct violation.

1226       (c) The department may impose a fine and, in the case of  
 1227 an owner-operated pain-management clinic, revoke or deny a pain-  
 1228 management clinic's registration, if the clinic's designated  
 1229 osteopathic physician knowingly and intentionally misrepresents  
 1230 actions taken to correct a violation.

1231       (d) An owner or designated osteopathic physician of a  
 1232 pain-management clinic who concurrently operates an unregistered

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1233 pain-management clinic is subject to an administrative fine of  
 1234 \$5,000 per day.

1235 (e) If the owner of a pain-management clinic that requires  
 1236 registration fails to apply to register the clinic upon a change  
 1237 of ownership and operates the clinic under the new ownership,  
 1238 the owner is subject to a fine of \$5,000.

1239 (6) EXPIRATION.—This section expires January 1, 2016.

1240 Section 8. Paragraph (f) is added to subsection (1) of  
 1241 section 459.013, Florida Statutes, to read:

1242 459.013 Penalty for violations.—

1243 (1) Each of the following acts constitutes a felony of the  
 1244 third degree, punishable as provided in s. 775.082, s. 775.083,  
 1245 or s. 775.084:

1246 (f) Dispensing a controlled substance listed in Schedule  
 1247 II or Schedule III in violation of s. 465.0276.

1248 Section 9. Paragraph (tt) is added to subsection (1) of  
 1249 section 459.015, Florida Statutes, to read:

1250 459.015 Grounds for disciplinary action; action by the  
 1251 board and department.—

1252 (1) The following acts constitute grounds for denial of a  
 1253 license or disciplinary action, as specified in s. 456.072(2):

1254 (tt) Dispensing a controlled substance listed in Schedule  
 1255 II or Schedule III in violation of s. 465.0276.

1256 Section 10. Subsections (3) and (4) of section 465.015,  
 1257 Florida Statutes, are renumbered as subsections (4) and (5),  
 1258 respectively, a new subsection (3) is added to that section, and  
 1259 present subsection (4) of that section is amended, to read:

1260 465.015 Violations and penalties.—

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1261           (3) It is unlawful for any pharmacist to knowingly fail to  
 1262 report to the sheriff or other chief law enforcement agency of  
 1263 the county where the pharmacy is located within 24 hours after  
 1264 learning of any instance in which a person obtained or attempted  
 1265 to obtain a controlled substance, as defined in s. 893.02, or at  
 1266 the close of business on the next business day, whichever is  
 1267 later, that the pharmacist knew or believed was obtained or  
 1268 attempted to be obtained through fraudulent methods or  
 1269 representations from the pharmacy at which the pharmacist  
 1270 practiced pharmacy. Any pharmacist who knowingly fails to make  
 1271 such a report within 24 hours after learning of the fraud or  
 1272 attempted fraud or at the close of business on the next business  
 1273 day, whichever is later, commits a misdemeanor of the first  
 1274 degree, punishable as provided in s. 775.082 or s. 775.083. A  
 1275 sufficient report of the fraudulent obtaining of controlled  
 1276 substances under this subsection must contain, at a minimum, a  
 1277 copy of the prescription used or presented and a narrative,  
 1278 including all information available to the pharmacist concerning  
 1279 the transaction, such as the name and telephone number of the  
 1280 prescribing physician; the name, description, and any personal  
 1281 identification information pertaining to the person who  
 1282 presented the prescription; and all other material information,  
 1283 such as photographic or video surveillance of the transaction.

1284           (5)~~(4)~~ Any person who violates any provision of subsection  
 1285 (1) or subsection (4) ~~(3)~~ commits a misdemeanor of the first  
 1286 degree, punishable as provided in s. 775.082 or s. 775.083. Any  
 1287 person who violates any provision of subsection (2) commits a  
 1288 felony of the third degree, punishable as provided in s.

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1289 775.082, s. 775.083, or s. 775.084. In any warrant, information,  
 1290 or indictment, it shall not be necessary to negative any  
 1291 exceptions, and the burden of any exception shall be upon the  
 1292 defendant.

1293 Section 11. Paragraph (t) is added to subsection (1) of  
 1294 section 465.016, Florida Statutes, to read:

1295 465.016 Disciplinary actions.—

1296 (1) The following acts constitute grounds for denial of a  
 1297 license or disciplinary action, as specified in s. 456.072(2):

1298 (t) Committing an error or omission during the performance  
 1299 of a specific function of prescription drug processing, which  
 1300 includes, for purposes of this paragraph:

- 1301 1. Receiving, interpreting, or clarifying a prescription.
- 1302 2. Entering prescription data into the pharmacy's record.
- 1303 3. Verifying or validating a prescription.
- 1304 4. Performing pharmaceutical calculations.
- 1305 5. Performing prospective drug review as defined by the  
 1306 board.
- 1307 6. Obtaining refill and substitution authorizations.
- 1308 7. Interpreting or acting on clinical data.
- 1309 8. Performing therapeutic interventions.
- 1310 9. Providing drug information concerning a patient's  
 1311 prescription.
- 1312 10. Providing patient counseling.

1313 Section 12. Section 465.018, Florida Statutes, is amended  
 1314 to read:

1315 465.018 Community pharmacies; permits.—

1316 (1) Any person desiring a permit to operate a community

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1317 pharmacy shall apply to the department.

1318 (2) If the board office certifies that the application  
 1319 complies with the laws of the state and the rules of the board  
 1320 governing pharmacies, the department shall issue the permit. No  
 1321 permit shall be issued unless a licensed pharmacist is  
 1322 designated as the prescription department manager ~~responsible~~  
 1323 ~~for maintaining all drug records, providing for the security of~~  
 1324 ~~the prescription department, and following such other rules as~~  
 1325 ~~relate to the practice of the profession of pharmacy. The~~  
 1326 ~~permittee and the newly designated prescription department~~  
 1327 ~~manager shall notify the department within 10 days of any change~~  
 1328 ~~in prescription department manager.~~

1329 (3) The board may suspend or revoke the permit of, or may  
 1330 refuse to issue a permit to:

1331 (a) Any person who has been disciplined or who has  
 1332 abandoned a permit or allowed a permit to become void after  
 1333 written notice that disciplinary proceedings had been or would  
 1334 be brought against the permit;

1335 (b) Any person who is an officer, director, or person  
 1336 interested directly or indirectly in a person or business entity  
 1337 that has had a permit disciplined or abandoned or become void  
 1338 after written notice that disciplinary proceedings had been or  
 1339 would be brought against the permit; or

1340 (c) Any person who is or has been an officer of a business  
 1341 entity, or who was interested directly or indirectly in a  
 1342 business entity, the permit of which has been disciplined or  
 1343 abandoned or become null and void after written notice that  
 1344 disciplinary proceedings had been or would be brought against



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1345 the permit.

1346 (4) In addition to any other remedies provided by law, the  
 1347 board may deny the application or suspend or revoke the license,  
 1348 registration, or certificate of any entity regulated or licensed  
 1349 by it if the applicant, licensee, registrant, or licenseholder,  
 1350 or, in the case of a corporation, partnership, or other business  
 1351 entity, if any officer, director, agent, or managing employee of  
 1352 that business entity or any affiliated person, partner, or  
 1353 shareholder having an ownership interest equal to 5 percent or  
 1354 greater in that business entity, has failed to pay all  
 1355 outstanding fines, liens, or overpayments assessed by final  
 1356 order of the department, unless a repayment plan is approved by  
 1357 the department, or has failed to comply with any repayment plan.

1358 (5) In reviewing any application requesting a change of  
 1359 ownership or a change of licensee or registrant, the transferor  
 1360 shall, before board approval of the change, repay or make  
 1361 arrangements to repay any amounts owed to the department. If the  
 1362 transferor fails to repay or make arrangements to repay the  
 1363 amounts owed to the department, the license or registration may  
 1364 not be issued to the transferee until repayment or until  
 1365 arrangements for repayment are made.

1366 (6) Passing an onsite inspection is a prerequisite to the  
 1367 issuance of an initial permit or a permit for a change of  
 1368 location. The department must make the inspection within 90 days  
 1369 before issuance of the permit.

1370 (7) Community pharmacies that dispense controlled  
 1371 substances must maintain a record of all controlled substance  
 1372 dispensing consistent with the requirements of s. 893.07 and

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1373 must make the record available to the department and law  
 1374 enforcement agencies upon request.

1375 Section 13. In order to dispense controlled substances  
 1376 listed in Schedule II or Schedule III, as provided in s. 893.03,  
 1377 Florida Statutes, on or after July 1, 2012, a community pharmacy  
 1378 permittee must be permitted pursuant to chapter 465, Florida  
 1379 Statutes, as amended by this act and any rules adopted  
 1380 thereunder.

1381 Section 14. Section 465.022, Florida Statutes, is amended  
 1382 to read:

1383 465.022 Pharmacies; general requirements; fees.—

1384 (1) The board shall adopt rules pursuant to ss. 120.536(1)  
 1385 and 120.54 to implement the provisions of this chapter. Such  
 1386 rules shall include, but shall not be limited to, rules relating  
 1387 to:

1388 (a) General drug safety measures.

1389 (b) Minimum standards for the physical facilities of  
 1390 pharmacies.

1391 (c) Safe storage of floor-stock drugs.

1392 (d) Functions of a pharmacist in an institutional  
 1393 pharmacy, consistent with the size and scope of the pharmacy.

1394 (e) Procedures for the safe storage and handling of  
 1395 radioactive drugs.

1396 (f) Procedures for the distribution and disposition of  
 1397 medicinal drugs distributed pursuant to s. 499.028.

1398 (g) Procedures for transfer of prescription files and  
 1399 medicinal drugs upon the change of ownership or closing of a  
 1400 pharmacy.

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1401 (h) Minimum equipment which a pharmacy shall at all times  
 1402 possess to fill prescriptions properly.

1403 (i) Procedures for the dispensing of controlled substances  
 1404 to minimize dispensing based on fraudulent representations or  
 1405 invalid practitioner-patient relationships.

1406 (2) A pharmacy permit may ~~shall~~ be issued only to a  
 1407 natural person who is at least 18 years of age, to a partnership  
 1408 comprised of at least one natural person and all of whose  
 1409 partners are all at least 18 years of age, to a governmental  
 1410 agency, or to a business entity that is properly registered with  
 1411 the Secretary of State, if required by law, and has been issued  
 1412 a federal employer tax identification number ~~corporation that is~~  
 1413 ~~registered pursuant to chapter 607 or chapter 617 whose~~  
 1414 ~~officers, directors, and shareholders are at least 18 years of~~  
 1415 ~~age. Permits issued to business entities may be issued only to~~  
 1416 entities whose affiliated persons, members, partners, officers,  
 1417 directors, and agents, including persons required to be  
 1418 fingerprinted under subsection (3), are not less than 18 years  
 1419 of age.

1420 (3) Any person or business entity, ~~partnership, or~~  
 1421 ~~corporation~~ before engaging in the operation of a pharmacy,  
 1422 shall file with the board a sworn application on forms provided  
 1423 by the department. For purposes of this section, any person  
 1424 required to provide fingerprints under this subsection is an  
 1425 affiliated person within the meaning of s. 465.023(1).

1426 (a) An application for a pharmacy permit must include a  
 1427 set of fingerprints from each person having an ownership  
 1428 interest of 5 percent or greater and from any person who,

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1429 directly or indirectly, manages, oversees, or controls the  
1430 operation of the applicant, including officers and members of  
1431 the board of directors of an applicant that is a corporation.  
1432 The applicant must provide payment in the application for the  
1433 cost of state and national criminal history records checks.

1434 1. For corporations having more than \$100 million of  
1435 business taxable assets in this state, in lieu of these  
1436 fingerprint requirements, the department shall require the  
1437 prescription department manager or consultant pharmacist of  
1438 record who will be directly involved in the management and  
1439 operation of the pharmacy to submit a set of fingerprints.

1440 2. A representative of a corporation described in  
1441 subparagraph 1. satisfies the requirement to submit a set of his  
1442 or her fingerprints if the fingerprints are on file with the  
1443 department or the Agency for Health Care Administration, meet  
1444 the fingerprint specifications for submission by the Department  
1445 of Law Enforcement, and are available to the department.

1446 (b) The department shall annually submit the fingerprints  
1447 provided by the applicant to the Department of Law Enforcement  
1448 for a state criminal history records check. The Department of  
1449 Law Enforcement shall annually forward the fingerprints to the  
1450 Federal Bureau of Investigation for a national criminal history  
1451 records check. The department shall report the results of annual  
1452 criminal history records checks to wholesale distributors  
1453 permitted under chapter 499 for the purposes of s. 499.0121(15).

1454 (c) In addition to those documents required by the  
1455 department or board, each applicant having any financial or  
1456 ownership interest greater than 5 percent in the subject of the

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1457 application must submit a signed affidavit disclosing any  
 1458 financial or ownership interest greater than 5 percent in any  
 1459 pharmacy permitted in the past 5 years, which pharmacy has  
 1460 closed voluntarily or involuntarily, has filed a voluntary  
 1461 relinquishment of its permit, has had its permit suspended or  
 1462 revoked, or has had an injunction issued against it by a  
 1463 regulatory agency. The affidavit must disclose the reason such  
 1464 entity was closed, whether voluntary or involuntary.

1465 (4) An application for a pharmacy permit must include the  
 1466 applicant's written policies and procedures for preventing  
 1467 controlled substance dispensing based on fraudulent  
 1468 representations or invalid practitioner-patient relationships.  
 1469 The board must review the policies and procedures and may deny a  
 1470 permit if the policies and procedures are insufficient to  
 1471 reasonably prevent such dispensing. The department may phase in  
 1472 the submission and review of policies and procedures over one  
 1473 18-month period beginning July 1, 2011.

1474 (5)-(4) The department or board shall deny an application  
 1475 for a pharmacy permit if the applicant or an affiliated person,  
 1476 partner, officer, director, or prescription department manager  
 1477 or consultant pharmacist of record of the applicant ~~has~~:

1478 (a) ~~Has~~ obtained a permit by misrepresentation or fraud.~~†~~

1479 (b) ~~Has~~ attempted to procure, or has procured, a permit  
 1480 for any other person by making, or causing to be made, any false  
 1481 representation.~~†~~

1482 (c) ~~Has~~ been convicted of, or entered a plea of guilty or  
 1483 nolo contendere to, regardless of adjudication, a crime in any  
 1484 jurisdiction which relates to the practice of, or the ability to

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1485 practice, the profession of pharmacy.~~†~~

1486 (d) Has been convicted of, or entered a plea of guilty or  
 1487 nolo contendere to, regardless of adjudication, a crime in any  
 1488 jurisdiction which relates to health care fraud.~~†~~

1489 (e) Has been convicted of, or entered a plea of guilty or  
 1490 nolo contendere to, regardless of adjudication, a felony under  
 1491 chapter 409, chapter 817, or chapter 893, or a similar felony  
 1492 offense committed in another state or jurisdiction, since July  
 1493 1, 2009. Been terminated for cause, pursuant to the appeals  
 1494 procedures established by the state or Federal Government, from  
 1495 any state Medicaid program or the federal Medicare program,  
 1496 unless the applicant has been in good standing with a state  
 1497 Medicaid program or the federal Medicare program for the most  
 1498 recent 5 years and the termination occurred at least 20 years  
 1499 ago; or

1500 (f) Has been convicted of, or entered a plea of guilty or  
 1501 nolo contendere to, regardless of adjudication, a felony under  
 1502 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1,  
 1503 2009.

1504 (g) Has been terminated for cause from the Florida  
 1505 Medicaid program pursuant to s. 409.913, unless the applicant  
 1506 has been in good standing with the Florida Medicaid program for  
 1507 the most recent 5-year period.

1508 (h) Has been terminated for cause, pursuant to the appeals  
 1509 procedures established by the state, from any other state  
 1510 Medicaid program, unless the applicant has been in good standing  
 1511 with a state Medicaid program for the most recent 5-year period  
 1512 and the termination occurred at least 20 years before the date

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1513 of the application.

1514 (i) Is currently listed on the United States Department of  
 1515 Health and Human Services Office of Inspector General's List of  
 1516 Excluded Individuals and Entities.

1517 (j)~~(f)~~ Has dispensed any medicinal drug based upon a  
 1518 communication that purports to be a prescription as defined by  
 1519 s. 465.003(14) or s. 893.02 when the pharmacist knows or has  
 1520 reason to believe that the purported prescription is not based  
 1521 upon a valid practitioner-patient relationship that includes a  
 1522 documented patient evaluation, including history and a physical  
 1523 examination adequate to establish the diagnosis for which any  
 1524 drug is prescribed and any other requirement established by  
 1525 board rule under chapter 458, chapter 459, chapter 461, chapter  
 1526 463, chapter 464, or chapter 466.

1527  
 1528 For felonies in which the defendant entered a plea of guilty or  
 1529 nolo contendere in an agreement with the court to enter a  
 1530 pretrial intervention or drug diversion program, the department  
 1531 shall deny the application if upon final resolution of the case  
 1532 the licensee has failed to successfully complete the program.

1533 (6) The department or board may deny an application for a  
 1534 pharmacy permit if the applicant or an affiliated person,  
 1535 partner, officer, director, or prescription department manager  
 1536 or consultant pharmacist of record of the applicant has violated  
 1537 or failed to comply with any provision of this chapter; chapter  
 1538 499, the Florida Drug and Cosmetic Act; chapter 893; 21 U.S.C.  
 1539 ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C.  
 1540 ss. 821 et seq., the Comprehensive Drug Abuse Prevention and

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1541 Control Act; or any rules or regulations promulgated thereunder  
 1542 unless the violation or noncompliance is technical.

1543 (7)-(5) After the application has been filed with the board  
 1544 and the permit fee provided in this section has been received,  
 1545 the board shall cause the application to be fully investigated,  
 1546 both as to the qualifications of the applicant and the  
 1547 prescription department manager or consultant pharmacist  
 1548 designated to be in charge and as to the premises and location  
 1549 described in the application.

1550 (8)-(6) The Board of Pharmacy shall have the authority to  
 1551 determine whether a bona fide transfer of ownership is present  
 1552 and that the sale of a pharmacy is not being accomplished for  
 1553 the purpose of avoiding an administrative prosecution.

1554 (9)-(7) Upon the completion of the investigation of an  
 1555 application, the board shall approve or deny ~~disapprove~~ the  
 1556 application. If approved, the permit shall be issued by the  
 1557 department.

1558 (10)-(8) A permittee must notify the department, on a form  
 1559 approved by the board, within 10 days after any change in  
 1560 prescription department manager or consultant pharmacist of  
 1561 record. ~~Permits issued by the department are not transferable.~~

1562 (11) A permittee must notify the department of the  
 1563 identity of the prescription department manager within 10 days  
 1564 after employment. The prescription department manager must  
 1565 comply with the following requirements:

1566 (a) The prescription department manager of a permittee  
 1567 must obtain and maintain all drug records required by any state  
 1568 or federal law to be obtained by a pharmacy, including, but not



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1569 limited to, records required by or under this chapter, chapter  
 1570 499, or chapter 893. The prescription department manager must  
 1571 ensure the permittee's compliance with all rules adopted under  
 1572 those chapters as they relate to the practice of the profession  
 1573 of pharmacy and the sale of prescription drugs.

1574 (b) The prescription department manager must ensure the  
 1575 security of the prescription department. The prescription  
 1576 department manager must notify the board of any theft or  
 1577 significant loss of any controlled substances within 1 business  
 1578 day after discovery of the theft or loss.

1579 (c) A registered pharmacist may not serve as the  
 1580 prescription department manager in more than one location unless  
 1581 approved by the board.

1582 (12) The board shall adopt rules that require the keeping  
 1583 of such records of prescription drugs as are necessary for the  
 1584 protection of public health, safety, and welfare.

1585 (a) All required records documenting prescription drug  
 1586 distributions shall be readily available or immediately  
 1587 retrievable during an inspection by the department.

1588 (b) The records must be maintained for 4 years after the  
 1589 creation or receipt of the record, whichever is later.

1590 (13) Permits issued by the department are not  
 1591 transferable.

1592 (14)~~(9)~~ The board shall set the fees for the following:

- 1593 (a) Initial permit fee not to exceed \$250.
- 1594 (b) Biennial permit renewal not to exceed \$250.
- 1595 (c) Delinquent fee not to exceed \$100.
- 1596 (d) Change of location fee not to exceed \$100.

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1597 Section 15. Paragraph (b) of subsection (1) of section  
 1598 465.0276, Florida Statutes, is amended to read:

1599 465.0276 Dispensing practitioner.—

1600 (1)

1601 (b)1. A practitioner registered under this section may not  
 1602 dispense ~~more than a 72-hour supply of~~ a controlled substance  
 1603 listed in Schedule II ~~or~~, Schedule III as provided in, Schedule  
 1604 IV, ~~or Schedule V of s. 893.03 for any patient who pays for the~~  
 1605 medication by cash, check, or credit card in a clinic registered  
 1606 under s. 458.3265 or s. 459.0137. A practitioner who violates  
 1607 this paragraph commits a felony of the third degree, punishable  
 1608 as provided in s. 775.082, s. 775.083, or s. 775.084. This  
 1609 paragraph does not apply to:

1610 ~~1. A practitioner who dispenses medication to a workers'~~  
 1611 ~~compensation patient pursuant to chapter 440.~~

1612 ~~2. A practitioner who dispenses medication to an insured~~  
 1613 ~~patient who pays by cash, check, or credit card to cover any~~  
 1614 ~~applicable copayment or deductible.~~

1615 ~~1.3.~~ The dispensing of complimentary packages of medicinal  
 1616 drugs which are labeled as a drug sample or complimentary drug  
 1617 as defined in s. 499.028 to the practitioner's own patients in  
 1618 the regular course of her or his practice without the payment of  
 1619 a fee or remuneration of any kind, whether direct or indirect,  
 1620 as provided in subsection (5).

1621 2. The dispensing of controlled substances in the health  
 1622 care system of the Department of Corrections.

1623 3. The dispensing of a controlled substance listed in  
 1624 Schedule II or Schedule III in connection with the performance

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1625 of a surgical procedure. The amount dispensed pursuant to the  
 1626 subparagraph may not exceed a 14-day supply. This exception does  
 1627 not allow for the dispensing of a controlled substance listed in  
 1628 Schedule II or Schedule III more than 14 days after the  
 1629 performance of the surgical procedure. For purposes of this  
 1630 subparagraph, the term "surgical procedure" means any procedure  
 1631 in any setting which involves, or reasonably should involve:

1632 a. Perioperative medication and sedation that allows the  
 1633 patient to tolerate unpleasant procedures while maintaining  
 1634 adequate cardiorespiratory function and the ability to respond  
 1635 purposefully to verbal or tactile stimulation and makes intra-  
 1636 and post-operative monitoring necessary; or

1637 b. The use of general anesthesia or major conduction  
 1638 anesthesia and preoperative sedation.

1639 4. The dispensing of a controlled substance listed in  
 1640 Schedule II or Schedule III pursuant to an approved clinical  
 1641 trial. For purposes of this subparagraph, the term "approved  
 1642 clinical trial" means a clinical research study or clinical  
 1643 investigation that, in whole or in part, is state or federally  
 1644 funded or is conducted under an investigational new drug  
 1645 application that is reviewed by the United States Food and Drug  
 1646 Administration.

1647 5. The dispensing of methadone in a facility licensed  
 1648 under s. 397.427 where medication-assisted treatment for opiate  
 1649 addiction is provided.

1650 6. The dispensing of a controlled substance listed in  
 1651 Schedule II or Schedule III to a patient of a facility licensed  
 1652 under part IV of chapter 400.

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1653 Section 16. Subsections (16) and (17) are added to section  
 1654 499.0051, Florida Statutes, to read:

1655 499.0051 Criminal acts.—

1656 (16) FALSE REPORT.—Any person who submits a report  
 1657 required by s. 499.0121(14) knowing that such report contains a  
 1658 false statement commits a felony of the third degree, punishable  
 1659 as provided in s. 775.082, s. 775.083, or s. 775.084.

1660 (17) CONTROLLED SUBSTANCE DISTRIBUTION.—Any person who  
 1661 engages in the wholesale distribution of prescription drugs and  
 1662 who knowingly distributes controlled substances in violation of  
 1663 s. 499.0121(14) commits a felony of the third degree, punishable  
 1664 as provided in s. 775.082, s. 775.083, or s. 775.084. In  
 1665 addition to any other fine that may be imposed, a person  
 1666 convicted of such a violation may be sentenced to pay a fine  
 1667 that does not exceed three times the gross monetary value gained  
 1668 from such violation, plus court costs and the reasonable costs  
 1669 of investigation and prosecution.

1670 Section 17. Paragraph (o) is added to subsection (8) of  
 1671 section 499.012, Florida Statutes, to read:

1672 499.012 Permit application requirements.—

1673 (8) An application for a permit or to renew a permit for a  
 1674 prescription drug wholesale distributor or an out-of-state  
 1675 prescription drug wholesale distributor submitted to the  
 1676 department must include:

1677 (o) Documentation of the credentialing policies and  
 1678 procedures required by s. 499.0121(14).

1679 Section 18. Subsections (14) and (15) are added to section  
 1680 499.0121, Florida Statutes, to read:

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1681           499.0121 Storage and handling of prescription drugs;  
 1682 recordkeeping.—The department shall adopt rules to implement  
 1683 this section as necessary to protect the public health, safety,  
 1684 and welfare. Such rules shall include, but not be limited to,  
 1685 requirements for the storage and handling of prescription drugs  
 1686 and for the establishment and maintenance of prescription drug  
 1687 distribution records.

1688           (14) DISTRIBUTION REPORTING.—Each prescription drug  
 1689 wholesale distributor, out-of-state prescription drug wholesale  
 1690 distributor, retail pharmacy drug wholesale distributor,  
 1691 manufacturer, or repackager that engages in the wholesale  
 1692 distribution of controlled substances as defined in s. 893.02  
 1693 shall submit a report to the department of its receipts and  
 1694 distributions of controlled substances listed in Schedule II,  
 1695 Schedule III, Schedule IV, or Schedule V as provided in s.  
 1696 893.03. Wholesale distributor facilities located within this  
 1697 state shall report all transactions involving controlled  
 1698 substances, and wholesale distributor facilities located outside  
 1699 this state shall report all distributions to entities located in  
 1700 this state. If the prescription drug wholesale distributor, out-  
 1701 of-state prescription drug wholesale distributor, retail  
 1702 pharmacy drug wholesale distributor, manufacturer, or repackager  
 1703 does not have any controlled substance distributions for the  
 1704 month, a report shall be sent indicating that no distributions  
 1705 occurred in the period. The report shall be submitted monthly by  
 1706 the 20th of the next month, in the electronic format used for  
 1707 controlled substance reporting to the Automation of Reports and  
 1708 Consolidated Orders System division of the federal Drug

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1709 Enforcement Administration. Submission of electronic data must  
 1710 be made in a secured Internet environment that allows for manual  
 1711 or automated transmission. Upon successful transmission, an  
 1712 acknowledgement page must be displayed to confirm receipt. The  
 1713 report must contain the following information:

1714 (a) The federal Drug Enforcement Administration  
 1715 registration number of the wholesale distributing location.

1716 (b) The federal Drug Enforcement Administration  
 1717 registration number of the entity to which the drugs are  
 1718 distributed or from which the drugs are received.

1719 (c) The transaction code that indicates the type of  
 1720 transaction.

1721 (d) The National Drug Code identifier of the product and  
 1722 the quantity distributed or received.

1723 (e) The Drug Enforcement Administration Form 222 number or  
 1724 Controlled Substance Ordering System Identifier on all schedule  
 1725 II transactions.

1726 (f) The date of the transaction.

1727  
 1728 The department must share the reported data with the Department  
 1729 of Law Enforcement and local law enforcement agencies upon  
 1730 request and must monitor purchasing to identify purchasing  
 1731 levels that are inconsistent with the purchasing entity's  
 1732 clinical needs. The Department of Law Enforcement shall  
 1733 investigate purchases at levels that are inconsistent with the  
 1734 purchasing entity's clinical needs to determine whether  
 1735 violations of chapter 893 have occurred.

1736 (15) DUE DILIGENCE OF PURCHASERS.—

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1737        (a) Each prescription drug wholesale distributor, out-of-  
 1738 state prescription drug wholesale distributor, and retail  
 1739 pharmacy drug wholesale distributor must establish and maintain  
 1740 policies and procedures to credential physicians licensed under  
 1741 chapter 458, chapter 459, chapter 461, or chapter 466 and  
 1742 pharmacies that purchase or otherwise receive from the wholesale  
 1743 distributor controlled substances listed in Schedule II or  
 1744 Schedule III as provided in s. 893.03. The prescription drug  
 1745 wholesale distributor, out-of-state prescription drug wholesale  
 1746 distributor, or retail pharmacy drug wholesale distributor shall  
 1747 maintain records of such credentialing and make the records  
 1748 available to the department upon request. Such credentialing  
 1749 must, at a minimum, include:

1750            1. A determination of the clinical nature of the receiving  
 1751 entity, including any specialty practice area.

1752            2. A review of the receiving entity's history of Schedule  
 1753 II and Schedule III controlled substance purchasing from the  
 1754 wholesale distributor.

1755            3. A determination that the receiving entity's Schedule II  
 1756 and Schedule III controlled substance purchasing history, if  
 1757 any, is consistent with and reasonable for that entity's  
 1758 clinical business needs.

1759        (b) A wholesale distributor must take reasonable measures  
 1760 to identify its customers, understand the normal and expected  
 1761 transactions conducted by those customers, and identify those  
 1762 transactions that are suspicious in nature. A wholesale  
 1763 distributor must establish internal policies and procedures for  
 1764 identifying suspicious orders and preventing suspicious

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1765 transactions. A wholesale distributor must assess orders for  
1766 greater than 5,000 unit doses of any one controlled substance in  
1767 any one month to determine whether the purchase is reasonable.  
1768 In making such assessments, a wholesale distributor may consider  
1769 the purchasing entity's clinical business needs, location, and  
1770 population served, in addition to other factors established in  
1771 the distributor's policies and procedures. A wholesale  
1772 distributor must report to the department any regulated  
1773 transaction involving an extraordinary quantity of a listed  
1774 chemical, an uncommon method of payment or delivery, or any  
1775 other circumstance that the regulated person believes may  
1776 indicate that the listed chemical will be used in violation of  
1777 the law. The wholesale distributor shall maintain records that  
1778 document the report submitted to the department in compliance  
1779 with this paragraph.

1780 (c) A wholesale distributor may not distribute controlled  
1781 substances to an entity if any criminal history record check for  
1782 any person associated with that entity shows that the person has  
1783 been convicted of, or entered a plea of guilty or nolo  
1784 contendere to, regardless of adjudication, a crime in any  
1785 jurisdiction related to controlled substances, the practice of  
1786 pharmacy, or the dispensing of medicinal drugs.

1787 (d) The department shall assess national data from the  
1788 Automation of Reports and Consolidated Orders System of the  
1789 federal Drug Enforcement Administration, excluding Florida data,  
1790 and identify the national average of grams of hydrocodone,  
1791 morphine, oxycodone, and methadone distributed per pharmacy  
1792 registrant per month in the most recent year for which data is



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1793 available. The department shall report the average for each of  
 1794 these drugs to the Governor, the President of the Senate, and  
 1795 the Speaker of the House of Representatives by November 1, 2011.  
 1796 The department shall assess the data reported pursuant to  
 1797 subsection (14) and identify the statewide average of grams of  
 1798 each benzodiazapine distributed per community pharmacy per  
 1799 month. The department shall report the average for each  
 1800 benzodiazapine to the Governor, the President of the Senate, and  
 1801 the Speaker of the House of Representatives by November 1, 2011.

1802 Section 19. Paragraphs (o) and (p) are added to subsection  
 1803 (1) of section 499.05, Florida Statutes, to read:

1804 499.05 Rules.—

1805 (1) The department shall adopt rules to implement and  
 1806 enforce this part with respect to:

1807 (o) Wholesale distributor reporting requirements of s.  
 1808 499.0121(14).

1809 (p) Wholesale distributor credentialing and distribution  
 1810 requirements of s. 499.0121(15).

1811 Section 20. Subsections (8) and (9) are added to section  
 1812 499.067, Florida Statutes, to read:

1813 499.067 Denial, suspension, or revocation of permit,  
 1814 certification, or registration.—

1815 (8) The department may deny, suspend, or revoke a permit  
 1816 if it finds the permittee has not complied with the  
 1817 credentialing requirements of s. 499.0121(15).

1818 (9) The department may deny, suspend, or revoke a permit  
 1819 if it finds the permittee has not complied with the reporting  
 1820 requirements of, or knowingly made a false statement in a report

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1821 required by, s. 499.0121(14).

1822 Section 21. Paragraph (f) is added to subsection (3) of  
 1823 section 810.02, Florida Statutes, to read:

1824 810.02 Burglary.—

1825 (3) Burglary is a felony of the second degree, punishable  
 1826 as provided in s. 775.082, s. 775.083, or s. 775.084, if, in the  
 1827 course of committing the offense, the offender does not make an  
 1828 assault or battery and is not and does not become armed with a  
 1829 dangerous weapon or explosive, and the offender enters or  
 1830 remains in a:

1831 (f) Structure or conveyance when the offense intended to  
 1832 be committed therein is theft of a controlled substance as  
 1833 defined in s. 893.02. Notwithstanding any other law, separate  
 1834 judgments and sentences for burglary with the intent to commit  
 1835 theft of a controlled substance under this paragraph and for any  
 1836 applicable possession of controlled substance offense under s.  
 1837 893.13 or trafficking in controlled substance offense under s.  
 1838 893.135 may be imposed when all such offenses involve the same  
 1839 amount or amounts of a controlled substance.

1840  
 1841 However, if the burglary is committed within a county that is  
 1842 subject to a state of emergency declared by the Governor under  
 1843 chapter 252 after the declaration of emergency is made and the  
 1844 perpetration of the burglary is facilitated by conditions  
 1845 arising from the emergency, the burglary is a felony of the  
 1846 first degree, punishable as provided in s. 775.082, s. 775.083,  
 1847 or s. 775.084. As used in this subsection, the term "conditions  
 1848 arising from the emergency" means civil unrest, power outages,

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1849 | curfews, voluntary or mandatory evacuations, or a reduction in  
 1850 | the presence of or response time for first responders or  
 1851 | homeland security personnel. A person arrested for committing a  
 1852 | burglary within a county that is subject to such a state of  
 1853 | emergency may not be released until the person appears before a  
 1854 | committing magistrate at a first appearance hearing. For  
 1855 | purposes of sentencing under chapter 921, a felony offense that  
 1856 | is reclassified under this subsection is ranked one level above  
 1857 | the ranking under s. 921.0022 or s. 921.0023 of the offense  
 1858 | committed.

1859 |       Section 22. Paragraph (c) of subsection (2) of section  
 1860 | 812.014, Florida Statutes, is amended to read:

1861 |       812.014 Theft.—

1862 |       (2)

1863 |       (c) It is grand theft of the third degree and a felony of  
 1864 | the third degree, punishable as provided in s. 775.082, s.  
 1865 | 775.083, or s. 775.084, if the property stolen is:

- 1866 |       1. Valued at \$300 or more, but less than \$5,000.
- 1867 |       2. Valued at \$5,000 or more, but less than \$10,000.
- 1868 |       3. Valued at \$10,000 or more, but less than \$20,000.
- 1869 |       4. A will, codicil, or other testamentary instrument.
- 1870 |       5. A firearm.
- 1871 |       6. A motor vehicle, except as provided in paragraph (a).
- 1872 |       7. Any commercially farmed animal, including any animal of  
 1873 | the equine, bovine, or swine class, or other grazing animal, and  
 1874 | including aquaculture species raised at a certified aquaculture  
 1875 | facility. If the property stolen is aquaculture species raised  
 1876 | at a certified aquaculture facility, then a \$10,000 fine shall

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- 1877 | be imposed.
- 1878 |       8. Any fire extinguisher.
- 1879 |       9. Any amount of citrus fruit consisting of 2,000 or more
- 1880 | individual pieces of fruit.
- 1881 |       10. Taken from a designated construction site identified
- 1882 | by the posting of a sign as provided for in s. 810.09(2)(d).
- 1883 |       11. Any stop sign.
- 1884 |       12. Anhydrous ammonia.
- 1885 |       13. Any amount of a controlled substance as defined in s.
- 1886 | 893.02. Notwithstanding any other law, separate judgments and
- 1887 | sentences for theft of a controlled substance under this
- 1888 | subparagraph and for any applicable possession of controlled
- 1889 | substance offense under s. 893.13 or trafficking in controlled
- 1890 | substance offense under s. 893.135 may be imposed when all such
- 1891 | offenses involve the same amount or amounts of a controlled
- 1892 | substance.

1893 |

1894 | However, if the property is stolen within a county that is

1895 | subject to a state of emergency declared by the Governor under

1896 | chapter 252, the property is stolen after the declaration of

1897 | emergency is made, and the perpetration of the theft is

1898 | facilitated by conditions arising from the emergency, the

1899 | offender commits a felony of the second degree, punishable as

1900 | provided in s. 775.082, s. 775.083, or s. 775.084, if the

1901 | property is valued at \$5,000 or more, but less than \$10,000, as

1902 | provided under subparagraph 2., or if the property is valued at

1903 | \$10,000 or more, but less than \$20,000, as provided under

1904 | subparagraph 3. As used in this paragraph, the term "conditions

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1905 arising from the emergency" means civil unrest, power outages,  
 1906 curfews, voluntary or mandatory evacuations, or a reduction in  
 1907 the presence of or the response time for first responders or  
 1908 homeland security personnel. For purposes of sentencing under  
 1909 chapter 921, a felony offense that is reclassified under this  
 1910 paragraph is ranked one level above the ranking under s.  
 1911 921.0022 or s. 921.0023 of the offense committed.

1912 Section 23. Section 893.055, Florida Statutes, is amended  
 1913 to read:

1914 893.055 Prescription drug monitoring program.—

1915 (1) As used in this section, the term:

1916 (a) "Patient advisory report" or "advisory report" means  
 1917 information provided by the department in writing, or as  
 1918 determined by the department, to a prescriber, dispenser,  
 1919 pharmacy, or patient concerning the dispensing of controlled  
 1920 substances. All advisory reports are for informational purposes  
 1921 only and impose no obligations of any nature or any legal duty  
 1922 on a prescriber, dispenser, pharmacy, or patient. The patient  
 1923 advisory report shall be provided in accordance with s.

1924 893.13(7)(a)8. The advisory reports issued by the department are  
 1925 not subject to discovery or introduction into evidence in any  
 1926 civil or administrative action against a prescriber, dispenser,  
 1927 pharmacy, or patient arising out of matters that are the subject  
 1928 of the report; and a person who participates in preparing,  
 1929 reviewing, issuing, or any other activity related to an advisory  
 1930 report may not be permitted or required to testify in any such  
 1931 civil action as to any findings, recommendations, evaluations,  
 1932 opinions, or other actions taken in connection with preparing,

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1933 reviewing, or issuing such a report.

1934 (b) "Controlled substance" means a controlled substance

1935 listed in Schedule II, Schedule III, or Schedule IV in s.

1936 893.03.

1937 (c) "Dispenser" means a pharmacy, dispensing pharmacist,

1938 or dispensing health care practitioner.

1939 (d) "Health care practitioner" or "practitioner" means any

1940 practitioner who is subject to licensure or regulation by the

1941 department under chapter 458, chapter 459, chapter 461, chapter

1942 462, chapter 464, chapter 465, or chapter 466.

1943 (e) "Health care regulatory board" means any board for a

1944 practitioner or health care practitioner who is licensed or

1945 regulated by the department.

1946 (f) "Pharmacy" means any pharmacy that is subject to

1947 licensure or regulation by the department under chapter 465 and

1948 that dispenses or delivers a controlled substance to an

1949 individual or address in this state.

1950 (g) "Prescriber" means a prescribing physician,

1951 prescribing practitioner, or other prescribing health care

1952 practitioner.

1953 (h) "Active investigation" means an investigation that is

1954 being conducted with a reasonable, good faith belief that it

1955 could lead to the filing of administrative, civil, or criminal

1956 proceedings, or that is ongoing and continuing and for which

1957 there is a reasonable, good faith anticipation of securing an

1958 arrest or prosecution in the foreseeable future.

1959 (i) "Law enforcement agency" means the Department of Law

1960 Enforcement, a Florida sheriff's department, a Florida police

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1961 department, or a law enforcement agency of the Federal  
 1962 Government which enforces the laws of this state or the United  
 1963 States relating to controlled substances, and which its agents  
 1964 and officers are empowered by law to conduct criminal  
 1965 investigations and make arrests.

1966 (j) "Program manager" means an employee of or a person  
 1967 contracted by the Department of Health who is designated to  
 1968 ensure the integrity of the prescription drug monitoring program  
 1969 in accordance with the requirements established in paragraphs  
 1970 (2) (a) and (b).

1971 (2) (a) ~~By December 1, 2010,~~ The department shall design  
 1972 and establish a comprehensive electronic database system that  
 1973 has controlled substance prescriptions provided to it and that  
 1974 provides prescription information to a patient's health care  
 1975 practitioner and pharmacist who inform the department that they  
 1976 wish the patient advisory report provided to them. Otherwise,  
 1977 the patient advisory report will not be sent to the  
 1978 practitioner, pharmacy, or pharmacist. The system shall be  
 1979 designed to provide information regarding dispensed  
 1980 prescriptions of controlled substances and shall not infringe  
 1981 upon the legitimate prescribing or dispensing of a controlled  
 1982 substance by a prescriber or dispenser acting in good faith and  
 1983 in the course of professional practice. The system shall be  
 1984 consistent with standards of the American Society for Automation  
 1985 in Pharmacy (ASAP). The electronic system shall also comply with  
 1986 the Health Insurance Portability and Accountability Act (HIPAA)  
 1987 as it pertains to protected health information (PHI), electronic  
 1988 protected health information (EPHI), and all other relevant

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1989 state and federal privacy and security laws and regulations. The  
 1990 department shall establish policies and procedures as  
 1991 appropriate regarding the reporting, accessing the database,  
 1992 evaluation, management, development, implementation, operation,  
 1993 storage, and security of information within the system. The  
 1994 reporting of prescribed controlled substances shall include a  
 1995 dispensing transaction with a dispenser pursuant to chapter 465  
 1996 or through a dispensing transaction to an individual or address  
 1997 in this state with a pharmacy that is not located in this state  
 1998 but that is otherwise subject to the jurisdiction of this state  
 1999 as to that dispensing transaction. The reporting of patient  
 2000 advisory reports refers only to reports to patients, pharmacies,  
 2001 and practitioners. Separate reports that contain patient  
 2002 prescription history information and that are not patient  
 2003 advisory reports are provided to persons and entities as  
 2004 authorized in paragraphs (7) (b) and (c) and s. 893.0551.

2005 (b) The department, when the direct support organization  
 2006 receives at least \$20,000 in nonstate moneys or the state  
 2007 receives at least \$20,000 in federal grants for the prescription  
 2008 drug monitoring program, ~~and in consultation with the Office of~~  
 2009 ~~Drug Control,~~ shall adopt rules as necessary concerning the  
 2010 reporting, accessing the database, evaluation, management,  
 2011 development, implementation, operation, security, and storage of  
 2012 information within the system, including rules for when patient  
 2013 advisory reports are provided to pharmacies and prescribers. The  
 2014 patient advisory report shall be provided in accordance with s.  
 2015 893.13(7) (a)8. The department shall work with the professional  
 2016 health care licensure boards, such as the Board of Medicine, the



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2017 Board of Osteopathic Medicine, and the Board of Pharmacy; other  
 2018 appropriate organizations, such as the Florida Pharmacy  
 2019 Association, ~~the Office of Drug Control~~, the Florida Medical  
 2020 Association, the Florida Retail Federation, and the Florida  
 2021 Osteopathic Medical Association, including those relating to  
 2022 pain management; and the Attorney General, the Department of Law  
 2023 Enforcement, and the Agency for Health Care Administration to  
 2024 develop rules appropriate for the prescription drug monitoring  
 2025 program.

2026 (c) All dispensers and prescribers subject to these  
 2027 reporting requirements shall be notified by the department of  
 2028 the implementation date for such reporting requirements.

2029 (d) The program manager shall work with professional  
 2030 health care licensure boards and the stakeholders listed in  
 2031 paragraph (b) to develop rules appropriate for identifying  
 2032 indicators of controlled substance abuse.

2033 (3) The pharmacy dispensing the controlled substance and  
 2034 each prescriber who directly dispenses a controlled substance  
 2035 shall submit to the electronic system, by a procedure and in a  
 2036 format established by the department and consistent with an  
 2037 ASAP-approved format, the following information for inclusion in  
 2038 the database:

2039 (a) The name of the prescribing practitioner, the  
 2040 practitioner's federal Drug Enforcement Administration  
 2041 registration number, the practitioner's National Provider  
 2042 Identification (NPI) or other appropriate identifier, and the  
 2043 date of the prescription.

2044 (b) The date the prescription was filled and the method of

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2045 payment, such as cash by an individual, insurance coverage  
 2046 through a third party, or Medicaid payment. This paragraph does  
 2047 not authorize the department to include individual credit card  
 2048 numbers or other account numbers in the database.

2049 (c) The full name, address, and date of birth of the  
 2050 person for whom the prescription was written.

2051 (d) The name, national drug code, quantity, and strength  
 2052 of the controlled substance dispensed.

2053 (e) The full name, federal Drug Enforcement Administration  
 2054 registration number, and address of the pharmacy or other  
 2055 location from which the controlled substance was dispensed. If  
 2056 the controlled substance was dispensed by a practitioner other  
 2057 than a pharmacist, the practitioner's full name, federal Drug  
 2058 Enforcement Administration registration number, and address.

2059 (f) The name of the pharmacy or practitioner, other than a  
 2060 pharmacist, dispensing the controlled substance and the  
 2061 practitioner's National Provider Identification (NPI).

2062 (g) Other appropriate identifying information as  
 2063 determined by department rule.

2064 (4) Each time a controlled substance is dispensed to an  
 2065 individual, the controlled substance shall be reported to the  
 2066 department through the system as soon thereafter as possible,  
 2067 but not more than 7 ~~15~~ days after the date the controlled  
 2068 substance is dispensed unless an extension is approved by the  
 2069 department for cause as determined by rule. A dispenser must  
 2070 meet the reporting requirements of this section by providing the  
 2071 required information concerning each controlled substance that  
 2072 it dispensed in a department-approved, secure methodology and

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2073 | format. Such approved formats may include, but are not limited  
2074 | to, submission via the Internet, on a disc, or by use of regular  
2075 | mail.

2076 |         (5) When the following acts of dispensing or administering  
2077 | occur, the following are exempt from reporting under this  
2078 | section for that specific act of dispensing or administration:

2079 |             (a) A health care practitioner when administering a  
2080 | controlled substance directly to a patient if the amount of the  
2081 | controlled substance is adequate to treat the patient during  
2082 | that particular treatment session.

2083 |             (b) A pharmacist or health care practitioner when  
2084 | administering a controlled substance to a patient or resident  
2085 | receiving care as a patient at a hospital, nursing home,  
2086 | ambulatory surgical center, hospice, or intermediate care  
2087 | facility for the developmentally disabled which is licensed in  
2088 | this state.

2089 |             (c) A practitioner when administering or dispensing a  
2090 | controlled substance in the health care system of the Department  
2091 | of Corrections.

2092 |             (d) A practitioner when administering a controlled  
2093 | substance in the emergency room of a licensed hospital.

2094 |             (e) A health care practitioner when administering or  
2095 | dispensing a controlled substance to a person under the age of  
2096 | 16.

2097 |             (f) A pharmacist or a dispensing practitioner when  
2098 | dispensing a one-time, 72-hour emergency resupply of a  
2099 | controlled substance to a patient.

2100 |         (6) The department may establish when to suspend and when

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2101 to resume reporting information during a state-declared or  
2102 nationally declared disaster.

2103 (7) (a) A practitioner or pharmacist who dispenses a  
2104 controlled substance must submit the information required by  
2105 this section in an electronic or other method in an ASAP format  
2106 approved by rule of the department unless otherwise provided in  
2107 this section. The cost to the dispenser in submitting the  
2108 information required by this section may not be material or  
2109 extraordinary. Costs not considered to be material or  
2110 extraordinary include, but are not limited to, regular postage,  
2111 electronic media, regular electronic mail, and facsimile  
2112 charges.

2113 (b) A pharmacy, prescriber, or dispenser shall have access  
2114 to information in the prescription drug monitoring program's  
2115 database which relates to a patient of that pharmacy,  
2116 prescriber, or dispenser in a manner established by the  
2117 department as needed for the purpose of reviewing the patient's  
2118 controlled substance prescription history. Other access to the  
2119 program's database shall be limited to the program's manager and  
2120 to the designated program and support staff, who may act only at  
2121 the direction of the program manager or, in the absence of the  
2122 program manager, as authorized. Access by the program manager or  
2123 such designated staff is for prescription drug program  
2124 management only or for management of the program's database and  
2125 its system in support of the requirements of this section and in  
2126 furtherance of the prescription drug monitoring program.  
2127 Confidential and exempt information in the database shall be  
2128 released only as provided in paragraph (c) and s. 893.0551. The

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2129 program manager, designated program and support staff who act at  
 2130 the direction of or in the absence of the program manager, and  
 2131 any individual who has similar access regarding the management  
 2132 of the database from the prescription drug monitoring program  
 2133 shall submit fingerprints to the department for background  
 2134 screening. The department shall follow the procedure established  
 2135 by the Department of Law Enforcement to request a statewide  
 2136 criminal history record check and to request that the Department  
 2137 of Law Enforcement forward the fingerprints to the Federal  
 2138 Bureau of Investigation for a national criminal history record  
 2139 check.

2140 (c) The following entities shall not be allowed direct  
 2141 access to information in the prescription drug monitoring  
 2142 program database but may request from the program manager and,  
 2143 when authorized by the program manager, the program manager's  
 2144 program and support staff, information that is confidential and  
 2145 exempt under s. 893.0551. Prior to release, the request shall be  
 2146 verified as authentic and authorized with the requesting  
 2147 organization by the program manager, the program manager's  
 2148 program and support staff, or as determined in rules by the  
 2149 department as being authentic and as having been authorized by  
 2150 the requesting entity:

2151 1. The department or its relevant health care regulatory  
 2152 boards responsible for the licensure, regulation, or discipline  
 2153 of practitioners, pharmacists, or other persons who are  
 2154 authorized to prescribe, administer, or dispense controlled  
 2155 substances and who are involved in a specific controlled  
 2156 substance investigation involving a designated person for one or

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2157 | more prescribed controlled substances.

2158 |         2. The Attorney General for Medicaid fraud cases involving  
2159 | prescribed controlled substances.

2160 |         3. A law enforcement agency during active investigations  
2161 | regarding potential criminal activity, fraud, or theft regarding  
2162 | prescribed controlled substances.

2163 |         4. A patient or the legal guardian or designated health  
2164 | care surrogate of an incapacitated patient as described in s.  
2165 | 893.0551 who, for the purpose of verifying the accuracy of the  
2166 | database information, submits a written and notarized request  
2167 | that includes the patient's full name, address, and date of  
2168 | birth, and includes the same information if the legal guardian  
2169 | or health care surrogate submits the request. The request shall  
2170 | be validated by the department to verify the identity of the  
2171 | patient and the legal guardian or health care surrogate, if the  
2172 | patient's legal guardian or health care surrogate is the  
2173 | requestor. Such verification is also required for any request to  
2174 | change a patient's prescription history or other information  
2175 | related to his or her information in the electronic database.

2176 |  
2177 | Information in the database for the electronic prescription drug  
2178 | monitoring system is not discoverable or admissible in any civil  
2179 | or administrative action, except in an investigation and  
2180 | disciplinary proceeding by the department or the appropriate  
2181 | regulatory board.

2182 |         (d) The following entities shall not be allowed direct  
2183 | access to information in the prescription drug monitoring  
2184 | program database but may request from the program manager and,

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2185 when authorized by the program manager, the program manager's  
2186 program and support staff, information that contains no  
2187 identifying information of any patient, physician, health care  
2188 practitioner, prescriber, or dispenser and that is not  
2189 confidential and exempt:

2190 1. Department staff for the purpose of calculating  
2191 performance measures pursuant to subsection (8).

2192 2. The Program Implementation and Oversight Task Force for  
2193 its reporting to the Governor, the President of the Senate, and  
2194 the Speaker of the House of Representatives regarding the  
2195 prescription drug monitoring program. This subparagraph expires  
2196 July 1, 2012.

2197 (e) All transmissions of data required by this section  
2198 must comply with relevant state and federal privacy and security  
2199 laws and regulations. However, any authorized agency or person  
2200 under s. 893.0551 receiving such information as allowed by s.  
2201 893.0551 may maintain the information received for up to 24  
2202 months before purging it from his or her records or maintain it  
2203 for longer than 24 months if the information is pertinent to  
2204 ongoing health care or an active law enforcement investigation  
2205 or prosecution.

2206 (f) The program manager, upon determining a pattern  
2207 consistent with the rules established under paragraph (2) (d) and  
2208 having cause to believe a violation of s. 893.13(7) (a) 8.,  
2209 (8) (a), or (8) (b) has occurred, may provide relevant information  
2210 to the applicable law enforcement agency.

2211 (8) To assist in fulfilling program responsibilities,  
2212 performance measures shall be reported annually to the Governor,

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2213 the President of the Senate, and the Speaker of the House of  
 2214 Representatives by the department each December 1, beginning in  
 2215 2011. Data that does not contain patient, physician, health care  
 2216 practitioner, prescriber, or dispenser identifying information  
 2217 may be requested during the year by department employees so that  
 2218 the department may undertake public health care and safety  
 2219 initiatives that take advantage of observed trends. Performance  
 2220 measures may include, but are not limited to, efforts to achieve  
 2221 the following outcomes:

2222 (a) Reduction of the rate of inappropriate use of  
 2223 prescription drugs through department education and safety  
 2224 efforts.

2225 (b) Reduction of the quantity of pharmaceutical controlled  
 2226 substances obtained by individuals attempting to engage in fraud  
 2227 and deceit.

2228 (c) Increased coordination among partners participating in  
 2229 the prescription drug monitoring program.

2230 (d) Involvement of stakeholders in achieving improved  
 2231 patient health care and safety and reduction of prescription  
 2232 drug abuse and prescription drug diversion.

2233 (9) Any person who willfully and knowingly fails to report  
 2234 the dispensing of a controlled substance as required by this  
 2235 section commits a misdemeanor of the first degree, punishable as  
 2236 provided in s. 775.082 or s. 775.083.

2237 (10) All costs incurred by the department in administering  
 2238 the prescription drug monitoring program shall be funded through  
 2239 federal grants or private funding applied for or received by the  
 2240 state. The department may not commit funds for the monitoring



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2241 program without ensuring funding is available. The prescription  
 2242 drug monitoring program and the implementation thereof are  
 2243 contingent upon receipt of the nonstate funding. The department  
 2244 and state government shall cooperate with the direct-support  
 2245 organization established pursuant to subsection (11) in seeking  
 2246 federal grant funds, other nonstate grant funds, gifts,  
 2247 donations, or other private moneys for the department so long as  
 2248 the costs of doing so are not considered material. Nonmaterial  
 2249 costs for this purpose include, but are not limited to, the  
 2250 costs of mailing and personnel assigned to research or apply for  
 2251 a grant. Notwithstanding the exemptions to competitive-  
 2252 solicitation requirements under s. 287.057(3)(f), the department  
 2253 shall comply with the competitive-solicitation requirements  
 2254 under s. 287.057 for the procurement of any goods or services  
 2255 required by this section. Funds provided, directly or  
 2256 indirectly, by prescription drug manufacturers may not be used  
 2257 to implement the program.

2258 (11) ~~The Office of Drug Control, in coordination with the~~  
 2259 ~~department,~~ may establish a direct-support organization that has  
 2260 a board consisting of at least five members to provide  
 2261 assistance, funding, and promotional support for the activities  
 2262 authorized for the prescription drug monitoring program.

2263 (a) As used in this subsection, the term "direct-support  
 2264 organization" means an organization that is:

- 2265 1. A Florida corporation not for profit incorporated under  
 2266 chapter 617, exempted from filing fees, and approved by the  
 2267 Department of State.
- 2268 2. Organized and operated to conduct programs and

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2269 | activities; raise funds; request and receive grants, gifts, and  
 2270 | bequests of money; acquire, receive, hold, and invest, in its  
 2271 | own name, securities, funds, objects of value, or other  
 2272 | property, either real or personal; and make expenditures or  
 2273 | provide funding to or for the direct or indirect benefit of the  
 2274 | department in the furtherance of the prescription drug  
 2275 | monitoring program.

2276 | (b) The direct-support organization is not considered a  
 2277 | lobbying firm within the meaning of s. 11.045.

2278 | (c) The State Surgeon General ~~director of the Office of~~  
 2279 | ~~Drug Control~~ shall appoint a board of directors for the direct-  
 2280 | support organization. ~~The director may designate employees of~~  
 2281 | ~~the Office of Drug Control, state employees other than state~~  
 2282 | ~~employees from the department, and any other nonstate employees~~  
 2283 | ~~as appropriate, to serve on the board.~~ Members of the board  
 2284 | shall serve at the pleasure of ~~the director of the~~ State Surgeon  
 2285 | General ~~Office of Drug Control~~. The State Surgeon General  
 2286 | ~~director~~ shall provide guidance to members of the board to  
 2287 | ensure that moneys received by the direct-support organization  
 2288 | are not received from inappropriate sources. Inappropriate  
 2289 | sources include, but are not limited to, donors, grantors,  
 2290 | persons, or organizations that may monetarily or substantively  
 2291 | benefit from the purchase of goods or services by the department  
 2292 | in furtherance of the prescription drug monitoring program.

2293 | (d) The direct-support organization shall operate under  
 2294 | written contract with the department ~~Office of Drug Control~~. The  
 2295 | contract must, at a minimum, provide for:

2296 | 1. Approval of the articles of incorporation and bylaws of

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2297 | the direct-support organization by the department ~~Office of Drug~~  
 2298 | ~~Control~~.

2299 |         2. Submission of an annual budget for the approval of the  
 2300 | department ~~Office of Drug Control~~.

2301 |         3. Certification by the department ~~Office of Drug Control~~  
 2302 | in consultation with the department that the direct-support  
 2303 | organization is complying with the terms of the contract in a  
 2304 | manner consistent with and in furtherance of the goals and  
 2305 | purposes of the prescription drug monitoring program and in the  
 2306 | best interests of the state. Such certification must be made  
 2307 | annually and reported in the official minutes of a meeting of  
 2308 | the direct-support organization.

2309 |         4. The reversion, without penalty, to ~~the Office of Drug~~  
 2310 | ~~Control, or to the state if the Office of Drug Control ceases to~~  
 2311 | ~~exist~~, of all moneys and property held in trust by the direct-  
 2312 | support organization for the benefit of the prescription drug  
 2313 | monitoring program if the direct-support organization ceases to  
 2314 | exist or if the contract is terminated.

2315 |         5. The fiscal year of the direct-support organization,  
 2316 | which must begin July 1 of each year and end June 30 of the  
 2317 | following year.

2318 |         6. The disclosure of the material provisions of the  
 2319 | contract to donors of gifts, contributions, or bequests,  
 2320 | including such disclosure on all promotional and fundraising  
 2321 | publications, and an explanation to such donors of the  
 2322 | distinction between the department ~~Office of Drug Control~~ and  
 2323 | the direct-support organization.

2324 |         7. The direct-support organization's collecting,

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2325 expending, and providing of funds to the department for the  
 2326 development, implementation, and operation of the prescription  
 2327 drug monitoring program as described in this section and s. 2,  
 2328 chapter 2009-198, Laws of Florida, as long as the task force is  
 2329 authorized. The direct-support organization may collect and  
 2330 expend funds to be used for the functions of the direct-support  
 2331 organization's board of directors, as necessary and approved by  
 2332 the department ~~director of the Office of Drug Control~~. In  
 2333 addition, the direct-support organization may collect and  
 2334 provide funding to the department in furtherance of the  
 2335 prescription drug monitoring program by:

2336 a. Establishing and administering the prescription drug  
 2337 monitoring program's electronic database, including hardware and  
 2338 software.

2339 b. Conducting studies on the efficiency and effectiveness  
 2340 of the program to include feasibility studies as described in  
 2341 subsection (13).

2342 c. Providing funds for future enhancements of the program  
 2343 within the intent of this section.

2344 d. Providing user training of the prescription drug  
 2345 monitoring program, including distribution of materials to  
 2346 promote public awareness and education and conducting workshops  
 2347 or other meetings, for health care practitioners, pharmacists,  
 2348 and others as appropriate.

2349 e. Providing funds for travel expenses.

2350 f. Providing funds for administrative costs, including  
 2351 personnel, audits, facilities, and equipment.

2352 g. Fulfilling all other requirements necessary to

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2353 | implement and operate the program as outlined in this section.

2354 |         (e) The activities of the direct-support organization must  
 2355 | be consistent with the goals and mission of the department  
 2356 | ~~Office of Drug Control~~, as determined by the ~~office in~~  
 2357 | ~~consultation with the~~ department, and in the best interests of  
 2358 | the state. The direct-support organization must obtain a written  
 2359 | approval from the department ~~director of the Office of Drug~~  
 2360 | ~~Control~~ for any activities in support of the prescription drug  
 2361 | monitoring program before undertaking those activities.

2362 |         (f) The ~~Office of Drug Control, in consultation with the~~  
 2363 | ~~department,~~ may permit, without charge, appropriate use of  
 2364 | administrative services, property, and facilities of ~~the Office~~  
 2365 | ~~of Drug Control and~~ the department by the direct-support  
 2366 | organization, subject to this section. The use must be directly  
 2367 | in keeping with the approved purposes of the direct-support  
 2368 | organization and may not be made at times or places that would  
 2369 | unreasonably interfere with opportunities for the public to use  
 2370 | such facilities for established purposes. Any moneys received  
 2371 | from rentals of facilities and properties managed by the ~~Office~~  
 2372 | ~~of Drug Control and the~~ department may be held ~~by the Office of~~  
 2373 | ~~Drug Control or~~ in a separate depository account in the name of  
 2374 | the direct-support organization and subject to the provisions of  
 2375 | the letter of agreement with the department ~~Office of Drug~~  
 2376 | ~~Control~~. The letter of agreement must provide that any funds  
 2377 | held in the separate depository account in the name of the  
 2378 | direct-support organization must revert to the department ~~Office~~  
 2379 | ~~of Drug Control~~ if the direct-support organization is no longer  
 2380 | approved by the department ~~Office of Drug Control~~ to operate in

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2381 the best interests of the state.

2382 (g) ~~The Office of Drug Control, in consultation with the~~  
 2383 ~~department,~~ may adopt rules under s. 120.54 to govern the use of  
 2384 administrative services, property, or facilities of the  
 2385 department or office by the direct-support organization.

2386 (h) The department ~~Office of Drug Control~~ may not permit  
 2387 the use of any administrative services, property, or facilities  
 2388 of the state by a direct-support organization if that  
 2389 organization does not provide equal membership and employment  
 2390 opportunities to all persons regardless of race, color,  
 2391 religion, gender, age, or national origin.

2392 (i) The direct-support organization shall provide for an  
 2393 independent annual financial audit in accordance with s.  
 2394 215.981. Copies of the audit shall be provided to the department  
 2395 ~~Office of Drug Control~~ and the Office of Policy and Budget in  
 2396 the Executive Office of the Governor.

2397 (j) The direct-support organization may not exercise any  
 2398 power under s. 617.0302(12) or (16).

2399 (12) A prescriber or dispenser may have access to the  
 2400 information under this section which relates to a patient of  
 2401 that prescriber or dispenser as needed for the purpose of  
 2402 reviewing the patient's controlled drug prescription history. A  
 2403 prescriber or dispenser acting in good faith is immune from any  
 2404 civil, criminal, or administrative liability that might  
 2405 otherwise be incurred or imposed for receiving or using  
 2406 information from the prescription drug monitoring program. This  
 2407 subsection does not create a private cause of action, and a  
 2408 person may not recover damages against a prescriber or dispenser

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2409 | authorized to access information under this subsection for  
 2410 | accessing or failing to access such information.

2411 |       (13) To the extent that funding is provided for such  
 2412 | purpose through federal or private grants or gifts and other  
 2413 | types of available moneys, the department, ~~in collaboration with~~  
 2414 | ~~the Office of Drug Control,~~ shall study the feasibility of  
 2415 | enhancing the prescription drug monitoring program for the  
 2416 | purposes of public health initiatives and statistical reporting  
 2417 | that respects the privacy of the patient, the prescriber, and  
 2418 | the dispenser. Such a study shall be conducted in order to  
 2419 | further improve the quality of health care services and safety  
 2420 | by improving the prescribing and dispensing practices for  
 2421 | prescription drugs, taking advantage of advances in technology,  
 2422 | reducing duplicative prescriptions and the overprescribing of  
 2423 | prescription drugs, and reducing drug abuse. The requirements of  
 2424 | the National All Schedules Prescription Electronic Reporting  
 2425 | (NASPER) Act are authorized in order to apply for federal NASPER  
 2426 | funding. In addition, the direct-support organization shall  
 2427 | provide funding for the department, ~~in collaboration with the~~  
 2428 | ~~Office of Drug Control,~~ to conduct training for health care  
 2429 | practitioners and other appropriate persons in using the  
 2430 | monitoring program to support the program enhancements.

2431 |       (14) A pharmacist, pharmacy, or dispensing health care  
 2432 | practitioner or his or her agent, before releasing a controlled  
 2433 | substance to any person not known to such dispenser, shall  
 2434 | require the person purchasing, receiving, or otherwise acquiring  
 2435 | the controlled substance to present valid photographic  
 2436 | identification or other verification of his or her identity to

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2437 the dispenser. If the person does not have proper  
 2438 identification, the dispenser may verify the validity of the  
 2439 prescription and the identity of the patient with the prescriber  
 2440 or his or her authorized agent. Verification of health plan  
 2441 eligibility through a real-time inquiry or adjudication system  
 2442 will be considered to be proper identification. This subsection  
 2443 does not apply in an institutional setting or to a long-term  
 2444 care facility, including, but not limited to, an assisted living  
 2445 facility or a hospital to which patients are admitted. As used  
 2446 in this subsection, the term "proper identification" means an  
 2447 identification that is issued by a state or the Federal  
 2448 Government containing the person's photograph, printed name, and  
 2449 signature or a document considered acceptable under 8 C.F.R. s.  
 2450 274a.2(b)(1)(v)(A) and (B).

2451 (15) The Agency for Health Care Administration shall  
 2452 continue the promotion of electronic prescribing by health care  
 2453 practitioners, health care facilities, and pharmacies under s.  
 2454 408.0611.

2455 (16) ~~By October 1, 2010,~~ The department shall adopt rules  
 2456 pursuant to ss. 120.536(1) and 120.54 to administer the  
 2457 provisions of this section, which shall include as necessary the  
 2458 reporting, accessing, evaluation, management, development,  
 2459 implementation, operation, and storage of information within the  
 2460 monitoring program's system.

2461 Section 24. Section 893.065, Florida Statutes, is amended  
 2462 to read:

2463 893.065 Counterfeit-resistant prescription blanks for  
 2464 controlled substances listed in Schedule II, Schedule III, or



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2465 Schedule IV.—The Department of Health shall develop and adopt by  
 2466 rule the form and content for a counterfeit-resistant  
 2467 prescription blank which must ~~may~~ be used by practitioners for  
 2468 the purpose of prescribing a controlled substance listed in  
 2469 Schedule II, Schedule III, ~~or~~ Schedule IV, or Schedule V  
 2470 pursuant to s. 456.42. The Department of Health may require the  
 2471 prescription blanks to be printed on distinctive, watermarked  
 2472 paper and to bear the preprinted name, address, and category of  
 2473 professional licensure of the practitioner and that  
 2474 practitioner's federal registry number for controlled  
 2475 substances. The prescription blanks may not be transferred.

2476 Section 25. Subsections (4) and (5) of section 893.07,  
 2477 Florida Statutes, are amended to read:

2478 893.07 Records.—

2479 (4) Every inventory or record required by this chapter,  
 2480 including prescription records, shall be maintained:

2481 (a) Separately from all other records of the registrant,  
 2482 or

2483 (b) Alternatively, in the case of Schedule III, IV, or V  
 2484 controlled substances, in such form that information required by  
 2485 this chapter is readily retrievable from the ordinary business  
 2486 records of the registrant.

2487  
 2488 In either case, the records described in this subsection shall  
 2489 be kept and made available for a period of at least 2 years for  
 2490 inspection and copying by law enforcement officers whose duty it  
 2491 is to enforce the laws of this state relating to controlled  
 2492 substances. Law enforcement officers are not required to obtain

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2493 a subpoena, court order, or search warrant in order to obtain  
 2494 access to or copies of such records.

2495 (5) Each person described in subsection (1) shall:

2496 (a) Maintain a record which shall contain a detailed list  
 2497 of controlled substances lost, destroyed, or stolen, if any; the  
 2498 kind and quantity of such controlled substances; and the date of  
 2499 the discovering of such loss, destruction, or theft.

2500 (b) In the event of the discovery of the theft or  
 2501 significant loss of controlled substances, report such theft or  
 2502 significant loss to the sheriff of that county within 24 hours  
 2503 after discovery. A person who fails to report a theft or  
 2504 significant loss of a substance listed in s. 893.03(3), (4), or  
 2505 (5) within 24 hours after discovery as required in this  
 2506 paragraph commits a misdemeanor of the second degree, punishable  
 2507 as provided in s. 775.082 or s. 775.083. A person who fails to  
 2508 report a theft or significant loss of a substance listed in s.  
 2509 893.03(2) within 24 hours after discovery as required in this  
 2510 paragraph commits a misdemeanor of the first degree, punishable  
 2511 as provided in s. 775.082 or s. 775.083.

2512 Section 26. Subsection (7) of section 893.13, Florida  
 2513 Statutes, is amended to read:

2514 893.13 Prohibited acts; penalties.—

2515 (7) (a) A ~~It is unlawful for any person may not:~~

2516 1. ~~To~~ Distribute or dispense a controlled substance in  
 2517 violation of this chapter.

2518 2. ~~To~~ Refuse or fail to make, keep, or furnish any record,  
 2519 notification, order form, statement, invoice, or information  
 2520 required under this chapter.

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2521           3. ~~To~~ Refuse ~~an~~ entry into any premises for any inspection  
 2522 or ~~to~~ refuse to allow any inspection authorized by this chapter.

2523           4. ~~To~~ Distribute a controlled substance named or described  
 2524 in s. 893.03(1) or (2) except pursuant to an order form as  
 2525 required by s. 893.06.

2526           5. ~~To~~ Keep or maintain any store, shop, warehouse,  
 2527 dwelling, building, vehicle, boat, aircraft, or other structure  
 2528 or place which is resorted to by persons using controlled  
 2529 substances in violation of this chapter for the purpose of using  
 2530 these substances, or which is used for keeping or selling them  
 2531 in violation of this chapter.

2532           6. ~~To~~ Use to his or her own personal advantage, or ~~to~~  
 2533 reveal, any information obtained in enforcement of this chapter  
 2534 except in a prosecution or administrative hearing for a  
 2535 violation of this chapter.

2536           7. ~~To~~ Possess a prescription form which has not been  
 2537 completed and signed by the practitioner whose name appears  
 2538 printed thereon, unless the person is that practitioner, is an  
 2539 agent or employee of that practitioner, is a pharmacist, or is a  
 2540 supplier of prescription forms who is authorized by that  
 2541 practitioner to possess those forms.

2542           8. ~~To~~ Withhold information from a practitioner from whom  
 2543 the person seeks to obtain a controlled substance or a  
 2544 prescription for a controlled substance that the person making  
 2545 the request has received a controlled substance or a  
 2546 prescription for a controlled substance of like therapeutic use  
 2547 from another practitioner within the previous 30 days.

2548           9. ~~To~~ Acquire or obtain, or attempt to acquire or obtain,

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2549 possession of a controlled substance by misrepresentation,  
 2550 fraud, forgery, deception, or subterfuge.

2551 10. ~~10.~~ Affix any false or forged label to a package or  
 2552 receptacle containing a controlled substance.

2553 11. ~~11.~~ Furnish false or fraudulent material information  
 2554 in, or omit any material information from, any report or other  
 2555 document required to be kept or filed under this chapter or any  
 2556 record required to be kept by this chapter.

2557 12. ~~12.~~ Store anhydrous ammonia in a container that is not  
 2558 approved by the United States Department of Transportation to  
 2559 hold anhydrous ammonia or is not constructed in accordance with  
 2560 sound engineering, agricultural, or commercial practices.

2561 13. With the intent to obtain a controlled substance or  
 2562 combination of controlled substances that are not medically  
 2563 necessary for the person or an amount of a controlled substance  
 2564 or substances that are not medically necessary for the person,  
 2565 obtain or attempt to obtain from a practitioner a controlled  
 2566 substance or a prescription for a controlled substance by  
 2567 misrepresentation, fraud, forgery, deception, subterfuge, or  
 2568 concealment of a material fact. For purposes of this  
 2569 subparagraph, a material fact includes whether the person has an  
 2570 existing prescription for a controlled substance issued for the  
 2571 same period of time by another practitioner or as described in  
 2572 subparagraph 8.

2573 (b) A health care practitioner, with the intent to provide  
 2574 a controlled substance or combination of controlled substances  
 2575 that are not medically necessary to his or her patient or an  
 2576 amount of controlled substances that are not medically necessary

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2577 for his or her patient, may not provide a controlled substance  
 2578 or a prescription for a controlled substance by  
 2579 misrepresentation, fraud, forgery, deception, subterfuge, or  
 2580 concealment of a material fact. For purposes of this paragraph,  
 2581 a material fact includes whether the patient has an existing  
 2582 prescription for a controlled substance issued for the same  
 2583 period of time by another practitioner or as described in  
 2584 subparagraph (a)8.

2585 (c)~~(b)~~ Any person who violates the provisions of  
 2586 subparagraphs (a)1.-7. commits a misdemeanor of the first  
 2587 degree, punishable as provided in s. 775.082 or s. 775.083;  
 2588 except that, upon a second or subsequent violation, the person  
 2589 commits a felony of the third degree, punishable as provided in  
 2590 s. 775.082, s. 775.083, or s. 775.084.

2591 (d)~~(e)~~ Any person who violates the provisions of  
 2592 subparagraphs (a)8.-12. commits a felony of the third degree,  
 2593 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2594 (e) A person or health care practitioner who violates the  
 2595 provisions of paragraph (b) or subparagraph (a)13. commits a  
 2596 felony of the third degree, punishable as provided in s.  
 2597 775.082, s. 775.083, or s. 775.084, if any controlled substance  
 2598 that is the subject of the offense is listed in Schedule II,  
 2599 Schedule III, or Schedule IV.

2600 Section 27. Present subsections (3) through (10) of  
 2601 section 893.138, Florida Statutes, are redesignated as  
 2602 subsections (4) through (11), respectively, and a new subsection  
 2603 (3) is added to that section, to read:

2604 893.138 Local administrative action to abate drug-related,

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2605 prostitution-related, or stolen-property-related public  
 2606 nuisances and criminal gang activity.—

2607 (3) Any pain-management clinic, as described in s.  
 2608 458.3265 or s. 459.0137, which has been used on more than two  
 2609 occasions within a 6-month period as the site of a violation of:

2610 (a) Section 784.011, s. 784.021, s. 784.03, or s. 784.045,  
 2611 relating to assault and battery;

2612 (b) Section 810.02, relating to burglary;

2613 (c) Section 812.014, relating to dealing in theft;

2614 (d) Section 812.131, relating to robbery by sudden  
 2615 snatching; or

2616 (e) Section 893.13, relating to the unlawful distribution  
 2617 of controlled substances,

2618  
 2619 may be declared to be a public nuisance, and such nuisance may  
 2620 be abated pursuant to the procedures provided in this section.

2621 Section 28. (1) DISPOSITION OF CONTROLLED SUBSTANCES.—

2622 (a) Within 10 days after the effective date of this act,  
 2623 each physician licensed under chapter 458, chapter 459, chapter  
 2624 461, or chapter 466, Florida Statutes, unless he or she meets  
 2625 one of the exceptions for physician who dispenses under s.  
 2626 465.0276, Florida Statutes, shall ensure that the undispensed  
 2627 inventory of controlled substances listed in Schedule II or  
 2628 Schedule III as provided in s. 893.03, Florida Statutes,  
 2629 purchased under the physician's Drug Enforcement Administration  
 2630 number for dispensing is:

2631 1. Returned in compliance with the laws and rules adopted  
 2632 under chapter 499, Florida Statutes, to the wholesale

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2633 distributor, as defined in s. 499.003, Florida Statutes, which  
 2634 distributed the controlled substances to the physician; or

2635 2. Turned in to local law enforcement agencies and  
 2636 abandoned.

2637 (b) Wholesale distributors shall buy back the undispensed  
 2638 inventory of controlled substances listed in Schedule II or  
 2639 Schedule III as provided in s. 893.03, Florida Statutes, which  
 2640 are in the manufacturer's original packing, unopened, and in  
 2641 date, in accordance with the established policies of the  
 2642 wholesale distributor or the contractual terms between the  
 2643 wholesale distributor and the physician concerning returns.

2644 (2) PUBLIC HEALTH EMERGENCY.—

2645 (a) The Legislature finds that:

2646 1. Prescription drug overdose has been declared a public  
 2647 health epidemic by the United States Centers for Disease Control  
 2648 and Prevention.

2649 2. Prescription drug abuse results in an average of seven  
 2650 deaths in this state each day.

2651 3. Physicians in this state purchased more than 85 percent  
 2652 of the oxycodone purchased by all practitioners in the United  
 2653 States in 2006.

2654 4. Physicians in this state purchased more than 93 percent  
 2655 of the methadone purchased by all practitioners in the United  
 2656 States in 2006.

2657 5. Some physicians in this state dispense medically  
 2658 unjustifiable amounts of controlled substances to addicts and to  
 2659 people who intend to illegally sell the drugs.

2660 6. Physicians in this state who have purchased large

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2661 quantities of controlled substances may have significant  
2662 inventory 30 days after the effective date of this act.

2663 7. Thirty days after the effective date of this act, the  
2664 only legal method for a dispensing practitioner to sell or  
2665 otherwise transfer controlled substances listed in Schedule II  
2666 or Schedule III as provided in s. 893.03, Florida Statutes,  
2667 purchased for dispensing, is through the abandonment procedures  
2668 of subsection (1) or as authorized under s. 465.0276, Florida  
2669 Statutes.

2670 8. It is likely that the same physicians who purchase and  
2671 dispense medically unjustifiable amounts of drugs will not  
2672 legally dispose of the remaining inventory.

2673 9. The actions of such dispensing practitioners may result  
2674 in substantial injury to the public health.

2675 (b) Immediately upon the effective date of this act, the  
2676 State Health Officer shall declare a public health emergency  
2677 pursuant to s. 381.00315, Florida Statutes. Pursuant to that  
2678 declaration, the Department of Health, the Attorney General, the  
2679 Department of Law Enforcement, and local law enforcement  
2680 agencies shall take the following actions:

2681 1. Within 2 days after the effective date of this act, in  
2682 consultation with wholesale distributors as defined in s.  
2683 499.003, Florida Statutes, the Department of Health shall  
2684 identify dispensing practitioners who purchased more than an  
2685 average of 2,000 unit doses of controlled substances listed in  
2686 Schedule II or Schedule III as provided in s. 893.03, Florida  
2687 Statutes, per month in the previous 6 months, and shall identify  
2688 the dispensing practitioners in that group who pose the greatest



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2689 threat to the public health based on an assessment of:  
 2690 a. The risk of noncompliance with subsection (1).  
 2691 b. The purchase amounts.  
 2692 c. The manner of medical practice.  
 2693 d. Any other factor set by the State Health Officer.  
 2694  
 2695 The Attorney General shall consult and coordinate with federal  
 2696 law enforcement agencies. The Department of Law Enforcement  
 2697 shall coordinate the efforts of local law enforcement agencies.  
 2698 2. On the 3rd day after the effective date of this act,  
 2699 the Department of Law Enforcement or local law enforcement  
 2700 agencies shall enter the business premises of the dispensing  
 2701 practitioners identified as posing the greatest threat to public  
 2702 health and quarantine any inventory of controlled substances  
 2703 listed in Schedule II or Schedule III as provided in s. 893.03,  
 2704 Florida Statutes, of such dispensing practitioners on site.  
 2705 3. The Department of Law Enforcement or local law  
 2706 enforcement agencies shall ensure the security of such inventory  
 2707 24 hours a day until the inventory is seized as contraband or  
 2708 deemed to be lawfully possessed for dispensing by the physician  
 2709 in accordance with s. 465.0276, Florida Statutes.  
 2710 4. On the 31st day after the effective date of this act,  
 2711 any remaining inventory of controlled substances listed in  
 2712 Schedule II or Schedule III as provided in s. 893.03, Florida  
 2713 Statutes, purchased for dispensing by practitioners is deemed  
 2714 contraband under s. 893.12, Florida Statutes. The Department of  
 2715 Law Enforcement or local law enforcement agencies shall seize  
 2716 the inventory and comply with the provisions of s. 893.12,

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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2717 Florida Statutes, to destroy it.

2718 (c) In order to implement this subsection, the sum of \$3  
 2719 million of nonrecurring funds from the General Revenue Fund is  
 2720 appropriated to the Department of Law Enforcement for the 2010-  
 2721 2011 fiscal year. The Department of Law Enforcement shall expend  
 2722 the appropriation by reimbursing local law enforcement agencies  
 2723 for the overtime-hour costs associated with securing the  
 2724 quarantined controlled substance inventory as provided in  
 2725 paragraph (b) and activities related to investigation and  
 2726 prosecution of crimes related to prescribed controlled  
 2727 substances. If requests for reimbursement exceed the amount  
 2728 appropriated, the reimbursements shall be prorated by the hours  
 2729 of overtime per requesting agency at a maximum of one law  
 2730 enforcement officer per quarantine site.

2731 (3) REPEAL.—This section expires January 1, 2013.

2732 Section 29. The Department of Health shall establish a  
 2733 practitioner profile for dentists licensed under chapter 466,  
 2734 Florida Statutes, for a practitioner's designation as a  
 2735 controlled substance prescribing practitioner as provided in s.  
 2736 456.44, Florida Statutes.

2737 Section 30. If any provision of this act or its  
 2738 application to any person or circumstance is held invalid, the  
 2739 invalidity does not affect other provisions or applications of  
 2740 the act which can be given effect without the invalid provision  
 2741 or application, and to this end the provisions of this act are  
 2742 severable.

2743 Section 31. This act shall take effect July 1, 2011.