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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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discovery of the theft or loss of controlled substances to the sheriff within a specified period; providing criminal penalties; amending s. 893.13, F.S.; prohibiting a person from obtaining or attempting to obtain from a practitioner a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact; prohibiting a health care provider from providing a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact; prohibiting a person from adulterating a controlled substance for certain use without authorization by a prescribing physician; providing penalties; amending s. 893.138, F.S.; providing circumstances in which a pain-management clinic may be declared a public nuisance; providing for the disposition of certain controlled substance inventory held by specified licensed physicians; providing certain requirements for a physician returning inventory to a distributor; requiring wholesale distributors to buy back certain undispensed inventory of controlled substances; providing for a declaration of a public health emergency; requiring certain actions relating to dispensing practitioners identified as posing the greatest threat to public health; providing an appropriation; providing for future expiration of program provisions; requiring the Department of Health to establish a practitioner profile for dentists; providing for severability; providing an

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effective date.

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

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

456.072 Grounds for discipline; penalties; enforcement.—

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

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

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

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

456.42 Written prescriptions for medicinal drugs.—

(1) A written prescription for a medicinal drug issued by 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 physiatrist 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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those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addictionologist or psychiatrist.

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

1. The complete medical history and a physical examination, including history of drug abuse or dependence.
2. Diagnostic, therapeutic, and laboratory results.
3. Evaluations and consultations.
4. Treatment objectives.
5. Discussion of risks and benefits.
6. Treatments.
7. Medications, including date, type, dosage, and quantity prescribed.
8. Instructions and agreements.
9. Periodic reviews.
10. Results of any drug testing.
11. A photocopy of the patient's government-issued photo identification.
12. If a written prescription for a controlled substance 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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medical specialist who has also completed a fellowship in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who is board certified in pain medicine by a board approved by the American Board of Medical Specialties or the American Osteopathic Association and performs interventional pain procedures of the type routinely billed using surgical codes.

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

458.3265 Pain-management clinics.—

(1) REGISTRATION.—

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

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

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

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

(II) Where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain. All privately owned pain-management clinics, facilities, or offices, hereinafter referred to as "clinics," which advertise in any medium for any type of pain-management services, or employ a physician who is primarily engaged in the treatment of pain by 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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jurisdiction.

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

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

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

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

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effective date of the suspension or revocation.

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

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

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

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

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

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

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subsection (1).

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

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

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

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

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

(c) A physician, a physician assistant, or an advanced registered nurse practitioner must perform a physical examination of a patient on the same day that the physician ~~he 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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at a publicly accessible fixed location and must:

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

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

c. Have emergency lighting and communications.

d. Have a reception and waiting area.

e. Provide a restroom.

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

g. Have private patient examination rooms.

h. Have treatment rooms, if treatment is being provided to the patients.

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

j. If the clinic stores and dispenses prescription drugs, comply with ss. 499.0121 and 893.07.

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

(g) Each physician practicing in a pain-management clinic

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

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

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

a. Geographic location, community, and population served.

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

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

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

a. Prioritized risks.

b. Limiting unprotected exposure to pathogens.

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

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

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

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

2. The clinic shall have evacuation procedures in the event of an emergency, which shall include provisions for the 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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agency approved by the Board of Medicine.

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

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

(4) RULEMAKING.—

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

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

~~(c) The Board of Medicine shall adopt a rule establishing the maximum number of prescriptions for Schedule II or Schedule III controlled substances or the controlled substance Alprazolam which may be written at any one registered pain-management 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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requirements of this section; chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug Abuse Prevention and Control Act; chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act; or the rules of the department. In determining whether a penalty is to be imposed, and in fixing the amount of the fine, the department shall consider the following factors:

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

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

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

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

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

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

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

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

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

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

458.327 Penalty for violations.—

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

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

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

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

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

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

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

459.0137 Pain-management clinics.—

(1) REGISTRATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(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.~~; ~~or~~

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

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

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

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

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

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

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

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

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

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

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

c. Have emergency lighting and communications.

d. Have a reception and waiting area.

e. Provide a restroom.

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

g. Have private patient examination rooms.

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

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

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

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

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

1. The clinic shall maintain equipment and supplies to 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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requirements:

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

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

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

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

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

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

(3) INSPECTION.—

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

(b) During an onsite inspection, the department shall make 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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~~primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications. Such rules shall address, but need not be limited to:~~

~~1. Facility operations;~~

~~2. Physical operations;~~

~~3. Infection control requirements;~~

~~4. Health and safety requirements;~~

~~5. Quality assurance requirements;~~

~~6. Patient records;~~

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

~~8. Inspections; and~~

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

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

(5) PENALTIES; ENFORCEMENT.—

(a) The department may impose an administrative fine on the clinic of up to \$5,000 per violation for violating the requirements of this section; chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and 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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pain-management clinic is subject to an administrative fine of \$5,000 per day.

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

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

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

459.013 Penalty for violations.—

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

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

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

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

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

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

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

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

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

465.016 Disciplinary actions.—

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

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

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

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

465.018 Community pharmacies; permits.—

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

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pharmacy shall apply to the department.

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

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

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

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

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

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the permit.

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

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

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

(7) Community pharmacies that dispense controlled substances must maintain a record of all controlled substance 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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required by, s. 499.0121(14).

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

810.02 Burglary.—

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

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

However, if the burglary is committed within a county that is subject to a state of emergency declared by the Governor under chapter 252 after the declaration of emergency is made and the perpetration of the burglary is facilitated by conditions arising from the emergency, the burglary is a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. As used in this subsection, the term "conditions 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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arising from the emergency" means civil unrest, power outages, curfews, voluntary or mandatory evacuations, or a reduction in the presence of or the response time for first responders or homeland security personnel. For purposes of sentencing under chapter 921, a felony offense that is reclassified under this paragraph is ranked one level above the ranking under s. 921.0022 or s. 921.0023 of the offense committed.

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

893.055 Prescription drug monitoring program.—

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

(a) "Patient advisory report" or "advisory report" means information provided by the department in writing, or as determined by the department, to a prescriber, dispenser, pharmacy, or patient concerning the dispensing of controlled substances. All advisory reports are for informational purposes only and impose no obligations of any nature or any legal duty on a prescriber, dispenser, pharmacy, or patient. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)8. The advisory reports issued by the department are not subject to discovery or introduction into evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient arising out of matters that are the subject of the report; and a person who participates in preparing, reviewing, issuing, or any other activity related to an advisory report may not be permitted or required to testify in any such civil action as to any findings, recommendations, evaluations, 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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department, or a law enforcement agency of the Federal Government which enforces the laws of this state or the United States relating to controlled substances, and which its agents and officers are empowered by law to conduct criminal investigations and make arrests.

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

(2) (a) ~~By December 1, 2010,~~ The department shall design and establish a comprehensive electronic database system that has controlled substance prescriptions provided to it and that provides prescription information to a patient's health care practitioner and pharmacist who inform the department that they wish the patient advisory report provided to them. Otherwise, the patient advisory report will not be sent to the practitioner, pharmacy, or pharmacist. The system shall be designed to provide information regarding dispensed prescriptions of controlled substances and shall not infringe upon the legitimate prescribing or dispensing of a controlled substance by a prescriber or dispenser acting in good faith and in the course of professional practice. The system shall be consistent with standards of the American Society for Automation in Pharmacy (ASAP). The electronic system shall also comply with the Health Insurance Portability and Accountability Act (HIPAA) as it pertains to protected health information (PHI), electronic 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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Board of Osteopathic Medicine, and the Board of Pharmacy; other appropriate organizations, such as the Florida Pharmacy Association, ~~the Office of Drug Control~~, the Florida Medical Association, the Florida Retail Federation, and the Florida Osteopathic Medical Association, including those relating to pain management; and the Attorney General, the Department of Law Enforcement, and the Agency for Health Care Administration to develop rules appropriate for the prescription drug monitoring program.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(10) All costs incurred by the department in administering the prescription drug monitoring program shall be funded through federal grants or private funding applied for or received by the 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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activities; raise funds; request and receive grants, gifts, and bequests of money; acquire, receive, hold, and invest, in its own name, securities, funds, objects of value, or other property, either real or personal; and make expenditures or provide funding to or for the direct or indirect benefit of the department in the furtherance of the prescription drug monitoring program.

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

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

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

1. Approval of the articles of incorporation and bylaws of

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

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

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

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

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

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

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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the best interests of the state.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

893.07 Records.—

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

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

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

In either case, the records described in this subsection shall be kept and made available for a period of at least 2 years for inspection and copying by law enforcement officers whose duty it is to enforce the laws of this state relating to controlled 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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3. ~~To~~ Refuse ~~an~~ entry into any premises for any inspection or ~~to~~ refuse to allow any inspection authorized by this chapter.

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

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

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

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

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

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

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

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

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

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

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

(b) A health care practitioner, with the intent to provide
a controlled substance or combination of controlled substances
that are not medically necessary to his or her patient or an
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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prostitution-related, or stolen-property-related public nuisances and criminal gang activity.—

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

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

(b) Section 810.02, relating to burglary;

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

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

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

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

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

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

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

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

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

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

(2) PUBLIC HEALTH EMERGENCY.—

(a) The Legislature finds that:

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

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

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

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

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

6. Physicians in this state who have purchased large

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

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

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

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

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

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

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threat to the public health based on an assessment of:

a. The risk of noncompliance with subsection (1).

b. The purchase amounts.

c. The manner of medical practice.

d. Any other factor set by the State Health Officer.

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

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

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

4. On the 31st day after the effective date of this act, any remaining inventory of controlled substances listed in Schedule II or Schedule III as provided in s. 893.03, Florida Statutes, purchased for dispensing by practitioners is deemed contraband under s. 893.12, Florida Statutes. The Department of Law Enforcement or local law enforcement agencies shall seize the inventory and comply with the provisions of s. 893.12,

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Florida Statutes, to destroy it.

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

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

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

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

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