

1 A bill to be entitled
2 An act relating to controlled substances; 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 register with the
13 appropriate board to prescribe controlled substances for
14 the treatment of chronic, nonmalignant pain; providing an
15 effective date; requiring registered physicians to meet
16 certain standards of practice; requiring a physical
17 examination; requiring a written protocol; requiring an
18 assessment of risk for aberrant behavior; requiring a
19 treatment plan; requiring specified informed consent;
20 requiring consultation and referral in certain
21 circumstances; requiring medical records meeting certain
22 criteria; requiring a prescription log; providing an
23 exemption for physicians meeting certain criteria;
24 amending s. 458.3265, F.S., relating to regulation of
25 pain-management clinics and medical doctors; amending the
26 definition of a pain-management clinic; providing
27 definitions; providing an exemption from registration for
28 clinics owned and operated by physicians meeting certain

29 criteria; requiring physicians in pain-management clinics
30 to ensure compliance with certain requirements; imposing
31 facility and physical operations requirements; imposing
32 infection control requirements; imposing health and safety
33 requirements; imposing quality assurance requirements;
34 imposing data collection and reporting requirements;
35 amending rulemaking authority; conforming provisions to
36 changes made by the act; providing for future expiration
37 of provisions; amending s. 458.327, F.S.; providing that
38 dispensing certain controlled substances in violation of
39 specified provisions is a third-degree felony; providing
40 penalties; amending s. 458.331, F.S.; providing that
41 dispensing certain controlled substances in violation of
42 specified provisions is grounds for disciplinary action;
43 providing penalties; amending s. 459.0137, F.S., relating
44 to regulation of pain-management clinics and osteopathic
45 physicians; providing definitions; providing an exemption
46 from registration for clinics owned and operated by
47 physicians meeting certain criteria; requiring osteopathic
48 physicians in pain-management clinics to ensure compliance
49 with certain requirements; imposing facility and physical
50 operations requirements; imposing infection control
51 requirements; imposing health and safety requirements;
52 imposing quality assurance requirements; imposing data
53 collection and reporting requirements; amending rulemaking
54 authority; conforming provisions to changes made by the
55 act; providing for future expiration of provisions;
56 amending s. 459.013, F.S.; providing that dispensing

57 | certain controlled substances in violation of specified
58 | provisions is a third-degree felony; providing penalties;
59 | amending s. 459.015, F.S.; providing that dispensing
60 | certain controlled substances in violation of specified
61 | provisions is grounds for disciplinary action; providing
62 | penalties; amending s. 465.015, F.S.; requiring a
63 | pharmacist to report to the sheriff within a specified
64 | period any instance in which a person fraudulently
65 | obtained or attempted to fraudulently obtain a controlled
66 | substance; providing criminal penalties; providing
67 | requirements for reports; amending s. 465.016, F.S.;
68 | providing additional grounds for denial of or disciplinary
69 | action against a pharmacist license; amending s. 465.018,
70 | F.S.; providing grounds for permit denial or discipline;
71 | requiring applicants to pay or make arrangements to pay
72 | amounts owed to the Department of Health; requiring an
73 | inspection; limiting the community pharmacies that may
74 | dispense controlled substances; providing an effective
75 | date; providing exemptions; requiring permittees to
76 | maintain certain records; amending s. 465.022, F.S.;
77 | requiring the Department of Health to adopt rules related
78 | to procedures for dispensing controlled substances;
79 | providing requirements for the issuance of a pharmacy
80 | permit; requiring disclosure of financial interests;
81 | requiring submission of policies and procedures and
82 | providing for grounds for permit denial based on them;
83 | requiring the Department of Health to deny a permit to
84 | applicants under certain circumstances; requiring

85 | permittees to provide notice of certain management
86 | changes; requiring prescription department managers to
87 | meet certain criteria; imposing duties on prescription
88 | department managers; limiting the number of locations a
89 | prescription department manager may manage; requiring the
90 | board to adopt rules related to recordkeeping; providing
91 | that permits are not transferable; increasing the fee for
92 | a change of location; amending s. 465.0276, F.S.;

93 | prohibiting registered dispensing practitioners from
94 | dispensing certain controlled substances; providing an
95 | exception for dispensing controlled substances in the
96 | health care system of the Department of Corrections;
97 | deleting a provision establishing a 72-hour supply limit
98 | on dispensing certain controlled substances to certain
99 | patients in registered pain-management clinics; amending
100 | s. 499.0051, F.S.; providing criminal penalties for
101 | violations of certain provisions of s. 499.0121, F.S.;

102 | amending s. 499.012, F.S.; requiring wholesale distributor
103 | permit applicants to submit documentation of credentialing
104 | policies; amending s. 499.0121, F.S.; providing reporting
105 | requirements for wholesale distributors of certain
106 | controlled substances; requiring the Department of Health
107 | to share the reported data with law enforcement agencies;
108 | requiring the Department of Law Enforcement to make
109 | investigations based on the reported data; providing
110 | credentialing requirements for distribution of controlled
111 | substances to certain entities by wholesale distributors;
112 | requiring distributors to identify suspicious

113 transactions; requiring distributors to determine the
114 reasonableness of orders for controlled substances over
115 certain amounts; requiring distributors to report certain
116 transactions to the Department of Health; prohibiting
117 distribution to entities with certain criminal histories;
118 limiting monthly distribution amounts of certain
119 controlled substances to retail pharmacies; prohibiting
120 distribution to entities with certain criminal
121 backgrounds; amending s. 499.05, F.S.; authorizing
122 rulemaking concerning specified controlled substance
123 wholesale distributor reporting requirements and
124 credentialing requirements; amending s. 499.067, F.S.;
125 requiring the Department of Health to take disciplinary
126 action against wholesale distributors failing to comply
127 with specified credentialing or reporting requirements;
128 amending s. 810.02, F.S.; authorizing separate judgments
129 and sentences for burglary with the intent to commit theft
130 of a controlled substance under specified provisions and
131 for any applicable possession of controlled substance
132 offense under specified provisions in certain
133 circumstances; amending s. 812.014, F.S.; authorizing
134 separate judgments and sentences for theft of a controlled
135 substance under specified provisions and for any
136 applicable possession of controlled substance offense
137 under specified provisions in certain circumstances;
138 amending s. 893.055, F.S., relating to the prescription
139 drug monitoring program; deleting obsolete dates; deleting
140 references to the Office of Drug Control; requiring

141 reports to the prescription drug monitoring system to be
142 made in 7 days rather than 15 days; prohibiting the use of
143 certain funds to implement the program; requiring the
144 State Surgeon General to appoint a board of directors for
145 the direct-support organization; conforming provisions to
146 changes made by the act; amending s. 893.065, F.S.;
147 conforming provisions to changes made by the act; amending
148 s. 893.07, F.S.; providing that law enforcement officers
149 are not required to obtain a subpoena, court order, or
150 search warrant in order to obtain access to or copies of
151 specified controlled substance inventory records;
152 requiring reporting of the discovery of the theft or loss
153 of controlled substances to the sheriff within a specified
154 period; providing criminal penalties; repealing s. 2 of
155 chapter 2009-198, Laws of Florida, relating to the Program
156 Implementation and Oversight Task Force in the Executive
157 Office of the Governor concerning the electronic system
158 established for the prescription drug monitoring program;
159 providing a buyback program for undispensed controlled
160 substance inventory held by specified licensed physicians;
161 requiring reports of the program; providing for a
162 declaration of a public health emergency; requiring
163 certain actions relating to dispensing practitioners
164 identified as posing the greatest threat to public health;
165 providing an appropriation; providing for future repeal of
166 program provisions; providing an effective date.

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

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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) Any licensee who has been found to overprescribe or inappropriately prescribe controlled substances in violation of s. 456.44, s. 458.331(1)(q) or (t), s. 459.015(t) or (x), s. 461.013(1)(o) or (s), or s. 466.028(1)(p) or (x) 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 drug must be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription; must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed, and the directions for use of the drug; must be

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197 | dated; and must be signed by the prescribing practitioner on the
198 | day when issued. ~~A written prescription for a controlled~~
199 | ~~substance listed in chapter 893 must have the quantity of the~~
200 | ~~drug prescribed in both textual and numerical formats and must~~
201 | ~~be dated with the abbreviated month written out on the face of~~
202 | ~~the prescription.~~ However, a prescription that is electronically
203 | generated and transmitted must contain the name of the
204 | prescribing practitioner, the name and strength of the drug
205 | prescribed, the quantity of the drug prescribed in numerical
206 | format, and the directions for use of the drug and must be dated
207 | and signed by the prescribing practitioner only on the day
208 | issued, which signature may be in an electronic format as
209 | defined in s. 668.003(4).

210 | (2) A written prescription for a controlled substance
211 | listed in chapter 893 must have the quantity of the drug
212 | prescribed in both textual and numerical formats, must be dated
213 | with the abbreviated month written out on the face of the
214 | prescription, and must be either written on a standardized
215 | counterfeit-proof prescription pad produced by a vendor approved
216 | by the department or electronically prescribed as that term is
217 | used in s. 408.0611. As a condition of being an approved vendor,
218 | a prescription pad vendor must submit a monthly report to the
219 | department which, at a minimum, documents the number of
220 | prescription pads sold and identifies the purchasers. The
221 | department may, by rule, require the reporting of additional
222 | information.

223 | Section 3. Section 456.44, Florida Statutes, is created to
224 | read:

225 456.44 Controlled substance prescribing.-

226 (1) DEFINITIONS.-

227 (a) "Addiction medicine specialist" means a board-
 228 certified psychiatrist with a subspecialty certification in
 229 addiction medicine or who is eligible for such subspecialty
 230 certification in addiction medicine or an addiction medicine
 231 physician certified or eligible for certification by the
 232 American Society of Addiction Medicine.

233 (b) "Adverse incident" means any incident set forth in s.
 234 458.351(4)(a)-(e) or s. 459.026(4)(a)-(e).

235 (c) "Board-certified pain management physician" means a
 236 physician who possesses board certification by a specialty board
 237 recognized by the American Board of Medical Specialties and
 238 holds a subspecialty certification in pain medicine or who
 239 possesses board certification in pain medicine by the American
 240 Board of Pain Medicine.

241 (d) "Mental health addiction facility" means a facility
 242 licensed under chapter 394 or chapter 397.

243 (2) REGISTRATION.-Effective January 1, 2012, a physician
 244 licensed under chapter 458, chapter 459, chapter 461, or chapter
 245 466 who prescribes any controlled substance, as defined in s.
 246 893.03, for the treatment of chronic, nonmalignant pain, must:

247 (a) Register with her or his professional licensing board
 248 as a controlled substance prescribing practitioner.

249 (b) Comply with the requirements of this section and
 250 applicable board rules.

251 (3) STANDARDS OF PRACTICE.-The standards of practice in
 252 this section do not supersede the level of care, skill, and

253 treatment recognized in general law related to healthcare
254 licensure.

255 (a) A complete medical history and a physical examination
256 must be conducted before beginning any treatment and must be
257 documented in the medical record. The exact components of the
258 physical examination shall be left to the judgment of the
259 clinician who is expected to perform a physical examination
260 proportionate to the diagnosis that justifies a treatment. The
261 medical record must, at a minimum, document the nature and
262 intensity of the pain, current and past treatments for pain,
263 underlying or coexisting diseases or conditions, the effect of
264 the pain on physical and psychological function, a review of
265 previous medical records, previous diagnostic studies, and
266 history of alcohol and substance abuse. The medical record shall
267 also document the presence of one or more recognized medical
268 indications for the use of a controlled substance. Each
269 registrant must develop a written plan for assessing each
270 patient's risk of aberrant drug-related behavior, which may
271 include patient drug testing. Registrants must assess each
272 patient's risk for aberrant drug-related behavior and monitor
273 that risk on an ongoing basis in accordance with the plan.

274 (b) Each registrant must develop a written individualized
275 treatment plan for each patient. The treatment plan shall state
276 objectives that will be used to determine treatment success,
277 such as pain relief and improved physical and psychosocial
278 function, and shall indicate if any further diagnostic
279 evaluations or other treatments are planned. After treatment
280 begins, the physician shall adjust drug therapy to the

281 individual medical needs of each patient. Other treatment
282 modalities, including a rehabilitation program, shall be
283 considered depending on the etiology of the pain and the extent
284 to which the pain is associated with physical and psychosocial
285 impairment. The interdisciplinary nature of the treatment plan
286 shall be documented.

287 (c) The physician shall discuss the risks and benefits of
288 the use of controlled substances, including the risks of abuse
289 and addiction, as well as physical dependence and its
290 consequences, with the patient, persons designated by the
291 patient, or the patient's surrogate or guardian if the patient
292 is incompetent. The physician shall use a written controlled
293 substance agreement between the physician and the patient
294 outlining the patient's responsibilities, including, but not
295 limited to:

296 1. Number and frequency of controlled substance
297 prescriptions and refills.

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

300 3. An agreement that controlled substances for the
301 treatment of chronic nonmalignant pain shall be prescribed by a
302 single treating physician unless otherwise authorized by the
303 treating physician and documented in the medical record.

304 (d) The patient shall be seen by the physician at regular
305 intervals, not to exceed 3 months, to assess the efficacy of
306 treatment, ensure that controlled substance therapy remains
307 indicated, evaluate the patient's progress toward treatment
308 objectives, consider adverse drug effects, and review the

309 etiology of the pain. Continuation or modification of therapy
310 shall depend on the physician's evaluation of the patient's
311 progress. If treatment goals are not being achieved, despite
312 medication adjustments, the physician shall reevaluate the
313 appropriateness of continued treatment. The physician shall
314 monitor patient compliance in medication usage, related
315 treatment plans, controlled substance agreements, and
316 indications of substance abuse or diversion at a minimum of 3-
317 month intervals.

318 (e) The physician shall refer the patient as necessary for
319 additional evaluation and treatment in order to achieve
320 treatment objectives. Special attention shall be given to those
321 patients who are at risk for misusing their medications and
322 those whose living arrangements pose a risk for medication
323 misuse or diversion. The management of pain in patients with a
324 history of substance abuse or with a comorbid psychiatric
325 disorder requires extra care, monitoring, and documentation and
326 requires consultation with or referral to an addictionologist or
327 psychiatrist.

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

- 334 1. The complete medical history and a physical
335 examination, including history of drug abuse or dependence.
336 2. Diagnostic, therapeutic, and laboratory results.

- 337 3. Evaluations and consultations.
- 338 4. Treatment objectives.
- 339 5. Discussion of risks and benefits.
- 340 6. Treatments.
- 341 7. Medications, including date, type, dosage, and quantity
342 prescribed.
- 343 8. Instructions and agreements.
- 344 9. Periodic reviews.
- 345 10. Results of any drug testing.
- 346 11. A photocopy of the patient's government-issued photo
347 identification.
- 348 12. If a written prescription for a controlled substance
349 is given to the patient, a duplicate of the prescription.
- 350 13. The physician's full name presented in a legible
351 manner.
- 352 (g) Registrants must maintain a current and accurate log
353 of all prescriptions for controlled substances. The log must not
354 contain patient identifiable information, but must distinguish
355 unduplicated patients. Registrants must make the log available
356 to the department and law enforcement agencies upon request.
- 357 (h) Patients with signs or symptoms of substance abuse
358 shall be immediately referred to a board-certified pain
359 management physician, an addiction medicine specialist, or a
360 mental health addiction facility as it pertains to drug abuse or
361 addiction unless the physician is board-certified or board-
362 eligible in pain management. Throughout the period of time
363 before receiving the consultant's report, a prescribing
364 physician shall clearly and completely document medical

365 justification for continued treatment with controlled substances
 366 and those steps taken to ensure medically appropriate use of
 367 controlled substances by the patient. Upon receipt of the
 368 consultant's written report, the prescribing physician shall
 369 incorporate the consultant's recommendations for continuing,
 370 modifying, or discontinuing controlled substance therapy. The
 371 resulting changes in treatment shall be specifically documented
 372 in the patient's medical record. Evidence or behavioral
 373 indications of diversion shall be followed by discontinuation of
 374 controlled substance therapy and the patient shall be discharged
 375 and all results of testing and actions taken by the physician
 376 shall be documented in the patient's medical record.

377
 378 This subsection does not apply to a board-certified physician
 379 who has completed a fellowship in pain medicine approved by the
 380 American Accreditation Council for Graduate Medical Education or
 381 who is board-certified in pain medicine by a board approved by
 382 the American Board of Medical Specialties and performs
 383 interventional pain procedures of the type routinely billed
 384 using surgical codes.

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

387 458.3265 Pain-management clinics.—

388 (1) REGISTRATION.—

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

390 a. "Chronic nonmalignant pain" means pain unrelated to
 391 cancer or rheumatoid arthritis which persists beyond the usual
 392 course of disease or the injury that is the cause of the pain or

393 more than 90 days after surgery.

394 b. "Pain-management clinic" or "clinic" means a publicly
 395 or privately owned facility where in any month a majority of
 396 patients are prescribed opioids, benzodiazepines, barbiturates,
 397 or carisoprodol for the treatment of chronic nonmalignant pain.

398 ~~All privately owned pain management clinics, facilities, or~~
 399 ~~offices, hereinafter referred to as "clinics," which advertise~~
 400 ~~in any medium for any type of pain-management services, or~~
 401 ~~employ a physician who is primarily engaged in the treatment of~~
 402 ~~pain by prescribing or dispensing controlled substance~~
 403 ~~medications,~~

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

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

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

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

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

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

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

421 g. The clinic is wholly owned and operated by a board-
422 certified anesthesiologist, physiatrist, neurologist, or another
423 medical specialist who has completed a fellowship in pain
424 medicine approved by the Accreditation Council for Graduate
425 Medical Education or who is board certified in pain medicine by
426 a board approved by the American Board of Medical Specialties,
427 and that medical specialist performs interventional pain
428 procedures of the type routinely billed using surgical codes, or
429 the clinic is wholly owned and operated by a group of such
430 specialists.

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

434 (c) As a part of registration, a clinic must designate a
435 physician who is responsible for complying with all requirements
436 related to registration and operation of the clinic in
437 compliance with this section. Within 10 days after termination
438 of a designated physician, the clinic must notify the department
439 of the identity of another designated physician for that clinic.
440 The designated physician shall have a full, active, and
441 unencumbered license under this chapter or chapter 459 and shall
442 practice at the clinic location for which the physician has
443 assumed responsibility. Failing to have a licensed designated
444 physician practicing at the location of the registered clinic
445 may be the basis for a summary suspension of the clinic
446 registration certificate as described in s. 456.073(8) for a
447 license or s. 120.60(6).

448 (d) The department shall deny registration to any clinic

449 that is not fully owned by a physician licensed under this
450 chapter or chapter 459 or a group of physicians, each of whom is
451 licensed under this chapter or chapter 459; or that is not a
452 health care clinic licensed under part X of chapter 400.

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

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

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

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

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

477 forfeiture of a bond when charged with a crime.

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

483 (h) If the registration of a pain-management clinic is
484 revoked or suspended, the designated physician of the pain-
485 management clinic, the owner or lessor of the pain-management
486 clinic property, the manager, and the proprietor shall cease to
487 operate the facility as a pain-management clinic as of the
488 effective date of the suspension or revocation.

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

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

502 (k) If the clinic's registration is revoked, any person
503 named in the registration documents of the pain-management
504 clinic, including persons owning or operating the pain-

505 management clinic, may not, as an individual or as a part of a
 506 group, apply to operate a pain-management clinic for 5 years
 507 after the date the registration is revoked.

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

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

513 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
 514 apply to any physician who provides professional services in a
 515 pain-management clinic that is required to be registered in
 516 subsection (1).

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

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

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

528
 529 Any physician who qualifies to practice medicine in a pain-
 530 management clinic pursuant to rules adopted by the Board of
 531 Medicine as of July 1, 2012, may continue to practice medicine
 532 in a pain-management clinic as long as the physician continues

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533 to meet the qualifications set forth in the board rules. A
534 physician who violates this paragraph is subject to disciplinary
535 action by his or her appropriate medical regulatory board.

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

540 (c) A physician must perform a physical examination of a
541 patient on the same day that he or she ~~dispenses or~~ prescribes a
542 controlled substance to a patient at a pain-management clinic.
543 If the physician prescribes ~~or dispenses~~ more than a 72-hour
544 dose of controlled substances for the treatment of chronic
545 nonmalignant pain, the physician must document in the patient's
546 record the reason for prescribing ~~or dispensing~~ that quantity.

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

558 (e) The designated physician of a pain-management clinic
559 shall notify the applicable board in writing of the date of
560 termination of employment within 10 days after terminating his

561 or her employment with a pain-management clinic that is required
562 to be registered under subsection (1). Each physician practicing
563 in a pain-management clinic shall advise the Board of Medicine,
564 in writing, within 10 calendar days after beginning or ending
565 his or her practice at a pain-management clinic.

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

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

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

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

577 c. Have emergency lighting and communications.

578 d. Have a reception and waiting area.

579 e. Provide a restroom.

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

582 g. Have private patient examination rooms.

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

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

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

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

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

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

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

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

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

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

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

610 a. Prioritized risks.

611 b. Limiting unprotected exposure to pathogens.

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

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

616 (h) Each physician practicing in a pain management clinic

617 is responsible for ensuring compliance with the following health
618 and safety requirements:

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

623 2. The clinic shall have evacuation procedures in the
624 event of an emergency, which shall include provisions for the
625 evacuation of disabled patients and employees.

626 3. The clinic shall have a written facility-specific
627 disaster plan setting forth actions that will be taken in the
628 event of clinic closure due to unforeseen disasters and shall
629 include provisions for the protection of medical records and any
630 controlled substances.

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

635 (i) The designated physician is responsible for ensuring
636 compliance with the following quality assurance requirements.
637 Each pain management clinic shall have an ongoing quality
638 assurance program that objectively and systematically monitors
639 and evaluates the quality and appropriateness of patient care,
640 evaluates methods to improve patient care, identifies and
641 corrects deficiencies within the facility, alerts the designated
642 physician to identify and resolve recurring problems, and
643 provides for opportunities to improve the facility's performance
644 and to enhance and improve the quality of care provided to the

645 public. The designated physician shall establish a quality
646 assurance program that includes the following components:

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

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

650 3. The development of measures to correct, reduce,
651 minimize, or eliminate the risk of adverse incidents to
652 patients.

653 4. The documentation of these functions and periodic
654 review no less than quarterly of such information by the
655 designated physician.

656 (j) The designated physician is responsible for ensuring
657 compliance with the following data collection and reporting
658 requirements:

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

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

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

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

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

671 d. The number of patients treated at the pain clinic whose
672 domicile is located somewhere other than in this state. A

673 patient's domicile is the patient's fixed or permanent home to
674 which he or she intends to return even though he or she may
675 temporarily reside elsewhere.

676 (3) INSPECTION.—

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

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

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

691 (4) RULEMAKING.—

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

696 ~~(b) The department shall adopt a rule defining what~~
697 ~~constitutes practice by a designated physician at the clinic~~
698 ~~location for which the physician has assumed responsibility, as~~
699 ~~set forth in subsection (1). When adopting the rule, the~~
700 ~~department shall consider the number of clinic employees, the~~

701 ~~location of the pain management clinic, the clinic's hours of~~
 702 ~~operation, and the amount of controlled substances being~~
 703 ~~prescribed, dispensed, or administered at the pain management~~
 704 ~~clinic.~~

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

710 (b)~~(d)~~ The Board of Medicine shall adopt rules setting
 711 forth standards of practice for physicians practicing in
 712 privately owned pain management clinics that primarily engage in
 713 the treatment of pain by prescribing or dispensing controlled
 714 substance medications. Such rules shall address, but need not be
 715 limited to:

- 716 1. ~~Facility operations;~~
- 717 2. ~~Physical operations;~~
- 718 3. ~~Infection control requirements;~~
- 719 4. ~~Health and safety requirements;~~
- 720 5. ~~Quality assurance requirements;~~
- 721 6. ~~Patient records;~~
- 722 7. training requirements for all facility health care
 723 practitioners who are not regulated by another board. 7
- 724 8. ~~Inspections; and~~
- 725 9. ~~Data collection and reporting requirements.~~

726
 727 ~~A physician is primarily engaged in the treatment of pain by~~
 728 ~~prescribing or dispensing controlled substance medications when~~

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729 ~~the majority of the patients seen are prescribed or dispensed~~
730 ~~controlled substance medications for the treatment of chronic~~
731 ~~nonmalignant pain. Chronic nonmalignant pain is pain unrelated~~
732 ~~to cancer which persists beyond the usual course of the disease~~
733 ~~or the injury that is the cause of the pain or more than 90 days~~
734 ~~after surgery.~~

735 (5) PENALTIES; ENFORCEMENT.—

736 (a) The department may impose an administrative fine on
737 the clinic of up to \$5,000 per violation for violating the
738 requirements of this section; chapter 499, the Florida Drug and
739 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
740 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
741 Abuse Prevention and Control Act; chapter 893, the Florida
742 Comprehensive Drug Abuse Prevention and Control Act; or the
743 rules of the department. In determining whether a penalty is to
744 be imposed, and in fixing the amount of the fine, the department
745 shall consider the following factors:

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

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

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

756 4. The financial benefits that the pain-management clinic

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757 derived from committing or continuing to commit the violation.

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

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

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

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

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

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

776 458.327 Penalty for violations.—

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

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

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

784 458.331 Grounds for disciplinary action; action by the

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785 board and department.—

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

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

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

792 459.0137 Pain-management clinics.—

793 (1) REGISTRATION.—

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

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

799 b. "Pain-management clinic" or "clinic" means a publicly
800 or privately owned facility where in any month a majority of
801 patients are prescribed opioids, benzodiazepines, barbiturates,
802 or carisoprodol for the treatment of chronic nonmalignant pain.

803 ~~All privately owned pain-management clinics, facilities, or~~
804 ~~offices, hereinafter referred to as "clinics," which advertise~~
805 ~~in any medium for any type of pain-management services, or~~
806 ~~employ an osteopathic physician who is primarily engaged in the~~
807 ~~treatment of pain by prescribing or dispensing controlled~~
808 ~~substance medications,~~

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

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

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

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

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

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

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

826 g. The clinic is wholly owned and operated by a board-
827 certified anesthesiologist, physiatrist, neurologist, or another
828 medical specialist who has completed a fellowship in pain
829 medicine approved by the Accreditation Council for Graduate
830 Medical Education or who is board certified in pain medicine by
831 a board approved by the American Board of Medical Specialties,
832 and that medical specialist performs interventional pain
833 procedures of the type routinely billed using surgical codes, or
834 the clinic is wholly owned and operated by a group of such
835 specialists.

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

839 (c) As a part of registration, a clinic must designate an
840 osteopathic physician who is responsible for complying with all

841 requirements related to registration and operation of the clinic
842 in compliance with this section. Within 10 days after
843 termination of a designated osteopathic physician, the clinic
844 must notify the department of the identity of another designated
845 physician for that clinic. The designated physician shall have a
846 full, active, and unencumbered license under chapter 458 or this
847 chapter and shall practice at the clinic location for which the
848 physician has assumed responsibility. Failing to have a licensed
849 designated osteopathic physician practicing at the location of
850 the registered clinic may be the basis for a summary suspension
851 of the clinic registration certificate as described in s.
852 456.073(8) for a license or s. 120.60(6).

853 (d) The department shall deny registration to any clinic
854 that is not fully owned by a physician licensed under chapter
855 458 or this chapter or a group of physicians, each of whom is
856 licensed under chapter 458 or this chapter; or that is not a
857 health care clinic licensed under part X of chapter 400.

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

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

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

866 3. Who has been convicted of or pleaded guilty or nolo
867 contendere to, regardless of adjudication, an offense that
868 constitutes a felony for receipt of illicit and diverted drugs,

869 including a controlled substance listed in Schedule I, Schedule
870 II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in
871 this state, any other state, or the United States.

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

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

888 (h) If the registration of a pain-management clinic is
889 revoked or suspended, the designated physician of the pain-
890 management clinic, the owner or lessor of the pain-management
891 clinic property, the manager, and the proprietor shall cease to
892 operate the facility as a pain-management clinic as of the
893 effective date of the suspension or revocation.

894 (i) If a pain-management clinic registration is revoked or
895 suspended, the designated physician of the pain-management
896 clinic, the owner or lessor of the clinic property, the manager,

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897 or the proprietor is responsible for removing all signs and
898 symbols identifying the premises as a pain-management clinic.

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

907 (k) If the clinic's registration is revoked, any person
908 named in the registration documents of the pain-management
909 clinic, including persons owning or operating the pain-
910 management clinic, may not, as an individual or as a part of a
911 group, make application for a permit to operate a pain-
912 management clinic for 5 years after the date the registration is
913 revoked.

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

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

919 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
920 apply to any osteopathic physician who provides professional
921 services in a pain-management clinic that is required to be
922 registered in subsection (1).

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

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

927 2. Effective July 1, 2012, the physician has not
 928 successfully completed a pain-medicine fellowship that is
 929 accredited by the Accreditation Council for Graduate Medical
 930 Education or the American Osteopathic Association or a pain-
 931 medicine residency that is accredited by the Accreditation
 932 Council for Graduate Medical Education or the American
 933 Osteopathic Association or, prior to July 1, 2012, does not
 934 comply with rules adopted by the board.

935
 936 Any physician who qualifies to practice medicine in a pain-
 937 management clinic pursuant to rules adopted by the Board of
 938 Osteopathic Medicine as of July 1, 2012, may continue to
 939 practice medicine in a pain-management clinic as long as the
 940 physician continues to meet the qualifications set forth in the
 941 board rules. An osteopathic physician who violates this
 942 paragraph is subject to disciplinary action by his or her
 943 appropriate medical regulatory board.

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

948 (c) An osteopathic physician must perform a physical
 949 examination of a patient on the same day that he or she
 950 ~~dispenses or~~ prescribes a controlled substance to a patient at a
 951 pain-management clinic. If the osteopathic physician prescribes
 952 ~~or dispenses~~ more than a 72-hour dose of controlled substances

953 | for the treatment of chronic nonmalignant pain, the osteopathic
 954 | physician must document in the patient's record the reason for
 955 | prescribing ~~or dispensing~~ that quantity.

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

967 | (e) The designated osteopathic physician of a pain-
 968 | management clinic shall notify the applicable board in writing
 969 | of the date of termination of employment within 10 days after
 970 | terminating his or her employment with a pain-management clinic
 971 | that is required to be registered under subsection (1). Each
 972 | osteopathic physician practicing in a pain-management clinic
 973 | shall advise the Board of Osteopathic Medicine in writing within
 974 | 10 calendar days after beginning or ending his or her practice
 975 | at a pain-management clinic.

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

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

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

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

987 c. Have emergency lighting and communications.

988 d. Have a reception and waiting area.

989 e. Provide a restroom.

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

992 g. Have private patient examination rooms.

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

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

999 j. If the clinic stores and dispenses prescription drug,
1000 comply with ss. 499.0121 and 893.07.

1001 2. This section does not excuse an osteopathic physician
1002 from providing any treatment or performing any medical duty
1003 without the proper equipment and materials as required by the
1004 standard of care. This section does not supersede the level of
1005 care, skill, and treatment recognized in general law related to
1006 healthcare licensure.

1007 (g) Each osteopathic physician practicing in a pain
1008 management clinic is responsible for ensuring compliance with

1009 the following infection control requirements.

1010 1. The clinic shall maintain equipment and supplies to

1011 support infection prevention and control activities.

1012 2. The clinic shall identify infection risks based on the

1013 following:

1014 a. Geographic location, community, and population served.

1015 b. The care, treatment and services it provides.

1016 c. An analysis of its infection surveillance and control

1017 data.

1018 3. The clinic shall maintain written infection prevention

1019 policies and procedures that address the following:

1020 a. Prioritized risks.

1021 b. Limiting unprotected exposure to pathogen.

1022 c. Limiting the transmission of infections associated with

1023 procedures performed in the clinic.

1024 d. Limiting the transmission of infections associated with

1025 the clinic's use of medical equipment, devices, and supplies.

1026 (h) Each osteopathic physician practicing in a pain

1027 management clinic is responsible for ensuring compliance with

1028 the following health and safety requirements.

1029 1. The clinic, including its grounds, buildings,

1030 furniture, appliances, and equipment shall be structurally

1031 sound, in good repair, clean, and free from health and safety

1032 hazards.

1033 2. The clinic shall have evacuation procedures in the

1034 event of an emergency which shall include provisions for the

1035 evacuation of disabled patients and employees.

1036 3. The clinic shall have a written facility-specific

1037 disaster plan which sets forth actions that will be taken in the
 1038 event of clinic closure due to unforeseen disasters and shall
 1039 include provisions for the protection of medical records and any
 1040 controlled substances.

1041 4. Each clinic shall have at least one employee on the
 1042 premises during patient care hours who is certified in Basic
 1043 Life Support and is trained in reacting to accidents and medical
 1044 emergencies until emergency medical personnel arrive.

1045 (i) The designated physician is responsible for ensuring
 1046 compliance with the following quality assurance requirements.
 1047 Each pain management clinic shall have an ongoing quality
 1048 assurance program that objectively and systematically monitors
 1049 and evaluates the quality and appropriateness of patient care,
 1050 evaluates methods to improve patient care, identifies and
 1051 corrects deficiencies within the facility, alerts the designated
 1052 physician to identify and resolve recurring problems, and
 1053 provides for opportunities to improve the facility's performance
 1054 and to enhance and improve the quality of care provided to the
 1055 public. The designated physician shall establish a quality
 1056 assurance program that includes the following components:

1057 1. The identification, investigation, and analysis of the
 1058 frequency and causes of adverse incidents to patients.

1059 2. The identification of trends or patterns of incidents.

1060 3. The development of measures to correct, reduce,
 1061 minimize, or eliminate the risk of adverse incidents to
 1062 patients.

1063 4. The documentation of these functions and periodic
 1064 review no less than quarterly of such information by the

1065 designated physician.

1066 (j) The designated physician is responsible for ensuring
 1067 compliance with the following data collection and reporting
 1068 requirements:

1069 1. The designated physician for each pain-management
 1070 clinic shall report all adverse incidents to the department as
 1071 set forth in s. 459.026.

1072 2. The designated physician shall also report to the Board
 1073 of Osteopathic Medicine, in writing, on a quarterly basis, the
 1074 following data:

1075 a. Number of new and repeat patients seen and treated at
 1076 the clinic who are prescribed controlled substance medications
 1077 for the treatment of chronic, nonmalignant pain.

1078 b. The number of patients discharged due to drug abuse.

1079 c. The number of patients discharged due to drug
 1080 diversion.

1081 d. The number of patients treated at the pain clinic whose
 1082 domicile is located somewhere other than in this state. A
 1083 patient's domicile is the patient's fixed or permanent home to
 1084 which he or she intends to return even though he or she may
 1085 temporarily reside elsewhere.

1086 (3) INSPECTION.—

1087 (a) The department shall inspect the pain-management
 1088 clinic annually, including a review of the patient records, to
 1089 ensure that it complies with this section and the rules of the
 1090 Board of Osteopathic Medicine adopted pursuant to subsection (4)
 1091 unless the clinic is accredited by a nationally recognized
 1092 accrediting agency approved by the Board of Osteopathic

1093 Medicine.

1094 (b) During an onsite inspection, the department shall make
 1095 a reasonable attempt to discuss each violation with the owner or
 1096 designated physician of the pain-management clinic before
 1097 issuing a formal written notification.

1098 (c) Any action taken to correct a violation shall be
 1099 documented in writing by the owner or designated physician of
 1100 the pain-management clinic and verified by followup visits by
 1101 departmental personnel.

1102 (4) RULEMAKING.—

1103 (a) The department shall adopt rules necessary to
 1104 administer the registration and inspection of pain-management
 1105 clinics which establish the specific requirements, procedures,
 1106 forms, and fees.

1107 ~~(b) The department shall adopt a rule defining what~~
 1108 ~~constitutes practice by a designated osteopathic physician at~~
 1109 ~~the clinic location for which the physician has assumed~~
 1110 ~~responsibility, as set forth in subsection (1). When adopting~~
 1111 ~~the rule, the department shall consider the number of clinic~~
 1112 ~~employees, the location of the pain-management clinic, the~~
 1113 ~~clinic's hours of operation, and the amount of controlled~~
 1114 ~~substances being prescribed, dispensed, or administered at the~~
 1115 ~~pain-management clinic.~~

1116 ~~(c) The Board of Osteopathic Medicine shall adopt a rule~~
 1117 ~~establishing the maximum number of prescriptions for Schedule II~~
 1118 ~~or Schedule III controlled substances or the controlled~~
 1119 ~~substance Alprazolam which may be written at any one registered~~
 1120 ~~pain-management clinic during any 24-hour period.~~

1121 (b)~~(d)~~ The Board of Osteopathic Medicine shall adopt rules
 1122 setting forth ~~standards of practice for osteopathic physicians~~
 1123 ~~practicing in privately owned pain-management clinics that~~
 1124 ~~primarily engage in the treatment of pain by prescribing or~~
 1125 ~~dispensing controlled substance medications. Such rules shall~~
 1126 ~~address, but need not be limited to:~~

- 1127 ~~1. Facility operations;~~
- 1128 ~~2. Physical operations;~~
- 1129 ~~3. Infection control requirements;~~
- 1130 ~~4. Health and safety requirements;~~
- 1131 ~~5. Quality assurance requirements;~~
- 1132 ~~6. Patient records;~~
- 1133 ~~7. training requirements for all facility health care~~
 1134 ~~practitioners who are not regulated by another board.~~7
- 1135 ~~8. Inspections; and~~
- 1136 ~~9. Data collection and reporting requirements.~~

1137
 1138 ~~An osteopathic physician is primarily engaged in the treatment~~
 1139 ~~of pain by prescribing or dispensing controlled substance~~
 1140 ~~medications when the majority of the patients seen are~~
 1141 ~~prescribed or dispensed controlled substance medications for the~~
 1142 ~~treatment of chronic nonmalignant pain. Chronic nonmalignant~~
 1143 ~~pain is pain unrelated to cancer which persists beyond the usual~~
 1144 ~~course of the disease or the injury that is the cause of the~~
 1145 ~~pain or more than 90 days after surgery.~~

1146 (5) PENALTIES; ENFORCEMENT.—

1147 (a) The department may impose an administrative fine on
 1148 the clinic of up to \$5,000 per violation for violating the

1149 requirements of this section; chapter 499, the Florida Drug and
 1150 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
 1151 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
 1152 Abuse Prevention and Control Act; chapter 893, the Florida
 1153 Comprehensive Drug Abuse Prevention and Control Act; or the
 1154 rules of the department. In determining whether a penalty is to
 1155 be imposed, and in fixing the amount of the fine, the department
 1156 shall consider the following factors:

1157 1. The gravity of the violation, including the probability
 1158 that death or serious physical or emotional harm to a patient
 1159 has resulted, or could have resulted, from the pain-management
 1160 clinic's actions or the actions of the osteopathic physician,
 1161 the severity of the action or potential harm, and the extent to
 1162 which the provisions of the applicable laws or rules were
 1163 violated.

1164 2. What actions, if any, the owner or designated
 1165 osteopathic physician took to correct the violations.

1166 3. Whether there were any previous violations at the pain-
 1167 management clinic.

1168 4. The financial benefits that the pain-management clinic
 1169 derived from committing or continuing to commit the violation.

1170 (b) Each day a violation continues after the date fixed
 1171 for termination of the violation as ordered by the department
 1172 constitutes an additional, separate, and distinct violation.

1173 (c) The department may impose a fine and, in the case of
 1174 an owner-operated pain-management clinic, revoke or deny a pain-
 1175 management clinic's registration, if the clinic's designated
 1176 osteopathic physician knowingly and intentionally misrepresents

1177 actions taken to correct a violation.

1178 (d) An owner or designated osteopathic physician of a
 1179 pain-management clinic who concurrently operates an unregistered
 1180 pain-management clinic is subject to an administrative fine of
 1181 \$5,000 per day.

1182 (e) If the owner of a pain-management clinic that requires
 1183 registration fails to apply to register the clinic upon a change
 1184 of ownership and operates the clinic under the new ownership,
 1185 the owner is subject to a fine of \$5,000.

1186 (6) EXPIRATION.—This section expires January 1, 2016.

1187 Section 8. Paragraph (f) is added to subsection (1) of
 1188 section 459.013, Florida Statutes, to read:

1189 459.013 Penalty for violations.—

1190 (1) Each of the following acts constitutes a felony of the
 1191 third degree, punishable as provided in s. 775.082, s. 775.083,
 1192 or s. 775.084:

1193 (f) Dispensing a controlled substance listed in Schedule
 1194 II or Schedule III in violation of s. 465.0276.

1195 Section 9. Paragraph (tt) is added to subsection (1) of
 1196 section 459.015, Florida Statutes, to read:

1197 459.015 Grounds for disciplinary action; action by the
 1198 board and department.—

1199 (1) The following acts constitute grounds for denial of a
 1200 license or disciplinary action, as specified in s. 456.072(2):

1201 (tt) Dispensing a controlled substance listed in Schedule
 1202 II or Schedule III in violation of s. 465.0276.

1203 Section 10. Subsections (3) and (4) of section 465.015,
 1204 Florida Statutes, are renumbered as subsections (4) and (5),

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1205 respectively, a new subsection (3) is added to that section, and
 1206 present subsection (4) of that section is amended, to read:

1207 465.015 Violations and penalties.—

1208 (3) It is unlawful for any pharmacist to fail to report to
 1209 the sheriff of the county where the pharmacy is located within
 1210 24 hours after learning of any instance in which a person
 1211 obtained or attempted to obtain a controlled substance, as
 1212 defined in s. 893.02, that the pharmacist knew or reasonably
 1213 should have known was obtained or attempted to be obtained from
 1214 the pharmacy through fraudulent methods or representations. Any
 1215 pharmacist who fails to make such a report within 24 hours after
 1216 learning of the fraud or attempted fraud commits a misdemeanor
 1217 of the first degree, punishable as provided in s. 775.082 or s.
 1218 775.083. A sufficient report of the fraudulent obtaining of
 1219 controlled substances under this subsection shall contain, at a
 1220 minimum, a copy of the prescription used or presented and a
 1221 narrative, including all information available to the pharmacy
 1222 concerning the transaction, such as the name and telephone
 1223 number of the prescribing physician; the name, description, and
 1224 any personal identification information pertaining to the person
 1225 who presented the prescription; and all other material
 1226 information, such as photographic or video surveillance of the
 1227 transaction.

1228 (5)~~(4)~~ Any person who violates any provision of subsection
 1229 (1) or subsection (4) ~~(3)~~ commits a misdemeanor of the first
 1230 degree, punishable as provided in s. 775.082 or s. 775.083. Any
 1231 person who violates any provision of subsection (2) commits a
 1232 felony of the third degree, punishable as provided in s.

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1233 775.082, s. 775.083, or s. 775.084. In any warrant, information,
 1234 or indictment, it shall not be necessary to negative any
 1235 exceptions, and the burden of any exception shall be upon the
 1236 defendant.

1237 Section 11. Paragraph (t) is added to subsection (1) of
 1238 section 465.016, Florida Statutes, to read:

1239 465.016 Disciplinary actions.—

1240 (1) The following acts constitute grounds for denial of a
 1241 license or disciplinary action, as specified in s. 456.072(2):

1242 (t) Committing an error or omission during the performance
 1243 of a specific function of prescription drug processing, which
 1244 includes, for purposes of this paragraph:

1245 1. Receiving, interpreting, or clarifying a prescription.

1246 2. Entering prescription data into the pharmacy's record.

1247 3. Verifying or validating a prescription.

1248 4. Performing pharmaceutical calculations.

1249 5. Performing prospective drug review as defined by the
 1250 board.

1251 6. Obtaining refill and substitution authorizations.

1252 7. Interpreting or acting on clinical data.

1253 8. Performing therapeutic interventions.

1254 9. Providing drug information concerning a patient's
 1255 prescription.

1256 10. Providing patient counseling.

1257 Section 12. Section 465.018, Florida Statutes, is amended
 1258 to read:

1259 465.018 Community pharmacies; permits.—

1260 (1) Any person desiring a permit to operate a community

1261 pharmacy shall apply to the department.

1262 (2) If the board office certifies that the application
 1263 complies with the laws of the state and the rules of the board
 1264 governing pharmacies, the department shall issue the permit. No
 1265 permit shall be issued unless a licensed pharmacist is
 1266 designated as the prescription department manager ~~responsible~~
 1267 ~~for maintaining all drug records, providing for the security of~~
 1268 ~~the prescription department, and following such other rules as~~
 1269 ~~relate to the practice of the profession of pharmacy. The~~
 1270 ~~permittee and the newly designated prescription department~~
 1271 ~~manager shall notify the department within 10 days of any change~~
 1272 ~~in prescription department manager.~~

1273 (3) The board may suspend or revoke the permit of, or may
 1274 refuse to issue a permit to:

1275 (a) Any person who has been disciplined or who has
 1276 abandoned a permit or allowed a permit to become void after
 1277 written notice that disciplinary proceedings had been or would
 1278 be brought against the permit;

1279 (b) Any person who is an officer, director, or person
 1280 interested directly or indirectly in a person or business entity
 1281 that has had a permit disciplined or abandoned or become void
 1282 after written notice that disciplinary proceedings had been or
 1283 would be brought against the permit; or

1284 (c) Any person who is or has been an officer of a business
 1285 entity, or who was interested directly or indirectly in a
 1286 business entity, the permit of which has been disciplined or
 1287 abandoned or become null and void after written notice that
 1288 disciplinary proceedings had been or would be brought against

1289 the permit.

1290 (4) In addition to any other remedies provided by law, the
 1291 board may deny the application or suspend or revoke the license,
 1292 registration, or certificate of any entity regulated or licensed
 1293 by it if the applicant, licensee, registrant, or licenseholder,
 1294 or, in the case of a corporation, partnership, or other business
 1295 entity, if any officer, director, agent, or managing employee of
 1296 that business entity or any affiliated person, partner, or
 1297 shareholder having an ownership interest equal to 5 percent or
 1298 greater in that business entity, has failed to pay all
 1299 outstanding fines, liens, or overpayments assessed by final
 1300 order of the department, unless a repayment plan is approved by
 1301 the department; or for failure to comply with any repayment
 1302 plan.

1303 (5) In reviewing any application requesting a change of
 1304 ownership or a change of licensee or registrant, the transferor
 1305 shall, before board approval of the change, repay or make
 1306 arrangements to repay any amounts owed to the department. If the
 1307 transferor fails to repay or make arrangements to repay the
 1308 amounts owed to the department, the license or registration may
 1309 not be issued to the transferee until repayment or until
 1310 arrangements for repayment are made.

1311 (6) Passing an onsite inspection is a prerequisite to the
 1312 issuance of an initial permit or a permit for a change of
 1313 location. The department must make the inspection within 90 days
 1314 before issuance of the permit.

1315 (7) Effective January 1, 2012, a pharmacy permitted under
 1316 this section may not dispense a controlled substance listed in

1317 Schedule II or Schedule III as provided in s. 893.03 unless the
 1318 pharmacy:

1319 (a) Is wholly owned by a corporation whose shares are
 1320 publicly traded on a recognized stock exchange;

1321 (b) Is wholly owned by a corporation having more than \$100
 1322 million of business taxable assets in this state;

1323 (c) Is wholly owned or operated by a licensed hospice,
 1324 hospital, or nursing facility, or provides services exclusively
 1325 to patients of a licensed hospice, hospital, or nursing
 1326 facility;

1327 (d) Has been continuously permitted for at least 10 years;
 1328 or

1329 (e) Received or renewed a permit pursuant to the
 1330 requirements of this chapter.

1331
 1332 Community pharmacies that dispense controlled substances must
 1333 maintain a record of all controlled substance dispensing
 1334 consistent with the requirements of s. 893.07 and must make the
 1335 record available to the department and law enforcement agencies
 1336 upon request.

1337 Section 13. Section 465.022, Florida Statutes, is amended
 1338 to read:

1339 465.022 Pharmacies; general requirements; fees.—

1340 (1) The board shall adopt rules pursuant to ss. 120.536(1)
 1341 and 120.54 to implement the provisions of this chapter. Such
 1342 rules shall include, but shall not be limited to, rules relating
 1343 to:

1344 (a) General drug safety measures.

1345 (b) Minimum standards for the physical facilities of
1346 pharmacies.

1347 (c) Safe storage of floor-stock drugs.

1348 (d) Functions of a pharmacist in an institutional
1349 pharmacy, consistent with the size and scope of the pharmacy.

1350 (e) Procedures for the safe storage and handling of
1351 radioactive drugs.

1352 (f) Procedures for the distribution and disposition of
1353 medicinal drugs distributed pursuant to s. 499.028.

1354 (g) Procedures for transfer of prescription files and
1355 medicinal drugs upon the change of ownership or closing of a
1356 pharmacy.

1357 (h) Minimum equipment which a pharmacy shall at all times
1358 possess to fill prescriptions properly.

1359 (i) Procedures for the dispensing of controlled substances
1360 to minimize dispensing based on fraudulent representations or
1361 invalid practitioner-patient relationships.

1362 (2) A pharmacy permit may ~~shall~~ be issued only to a
1363 natural person who is at least 18 years of age, to a partnership
1364 comprised of at least one natural person and all of whose
1365 partners are ~~all~~ at least 18 years of age, to a government
1366 agency, or to a business entity that is properly registered with
1367 the Secretary of State, if required by law, and has been issued
1368 a federal employer tax identification number ~~corporation that is~~
1369 ~~registered pursuant to chapter 607 or chapter 617 whose~~
1370 ~~officers, directors, and shareholders are at least 18 years of~~
1371 ~~age.~~ Permits issued to business entities may be issued only to
1372 entities whose affiliated persons, members, partners, officers,

1373 directors, and agents, including persons required to be
 1374 fingerprinted under subsection (3), are not less than 18 years
 1375 of age.

1376 (3) Any person or business entity, ~~partnership, or~~
 1377 ~~corporation~~ before engaging in the operation of a pharmacy,
 1378 shall file with the board a sworn application on forms provided
 1379 by the department. For purposes of this section, any person
 1380 required to provide fingerprints under this subsection is an
 1381 affiliated person within the meaning of s. 465.023(1).

1382 (a) An application for a pharmacy permit must include a
 1383 set of fingerprints from each person having an ownership
 1384 interest of 5 percent or greater and from any person who,
 1385 directly or indirectly, manages, oversees, or controls the
 1386 operation of the applicant, including officers and members of
 1387 the board of directors of an applicant that is a corporation.
 1388 The applicant must provide payment in the application for the
 1389 cost of state and national criminal history records checks.

1390 1. For corporations having more than \$100 million of
 1391 business taxable assets in this state, in lieu of these
 1392 fingerprint requirements, the department shall require the
 1393 prescription department manager or consultant pharmacist of
 1394 record who will be directly involved in the management and
 1395 operation of the pharmacy to submit a set of fingerprints.

1396 2. A representative of a corporation described in
 1397 subparagraph 1. satisfies the requirement to submit a set of his
 1398 or her fingerprints if the fingerprints are on file with the
 1399 department or the Agency for Health Care Administration, meet
 1400 the fingerprint specifications for submission by the Department

1401 of Law Enforcement, and are available to the department.

1402 (b) The department shall submit the fingerprints provided
 1403 by the applicant to the Department of Law Enforcement for a
 1404 state criminal history records check. The Department of Law
 1405 Enforcement shall forward the fingerprints to the Federal Bureau
 1406 of Investigation for a national criminal history records check.

1407 (c) In addition to those documents required by the
 1408 department or board, each applicant with any financial or
 1409 ownership interest greater than 5 percent in the subject of the
 1410 application must submit a signed affidavit disclosing any
 1411 financial or ownership interest greater than 5 percent in any
 1412 pharmacy permitted in the past 5 years, which pharmacy has
 1413 closed voluntarily or involuntarily, has filed a voluntary
 1414 relinquishment of its permit, has had its permit suspended or
 1415 revoked, or has had an injunction issued against it by a
 1416 regulatory agency. The affidavit must disclose the reason such
 1417 entity was closed, whether voluntary or involuntary.

1418 (4) An application for a pharmacy permit must include the
 1419 applicant's written policies and procedures for preventing
 1420 controlled substance dispensing based on fraudulent
 1421 representations or invalid practitioner-patient relationships.
 1422 The board must review the policies and procedures and may deny a
 1423 permit if the policies and procedures are insufficient to
 1424 reasonably prevent such dispensing.

1425 (5)~~(4)~~ The department or board shall deny an application
 1426 for a pharmacy permit if the applicant or an affiliated person,
 1427 partner, officer, director, or prescription department manager
 1428 or consultant pharmacist of record of the applicant has:

1429 (a) Has obtained a permit by misrepresentation or fraud.~~†~~

1430 (b) Has attempted to procure, or has procured, a permit
 1431 for any other person by making, or causing to be made, any false
 1432 representation.~~†~~

1433 (c) Has been convicted of, or entered a plea of guilty or
 1434 nolo contendere to, regardless of adjudication, a crime in any
 1435 jurisdiction which relates to the practice of, or the ability to
 1436 practice, the profession of pharmacy.~~†~~

1437 (d) Has been convicted of, or entered a plea of guilty or
 1438 nolo contendere to, regardless of adjudication, a crime in any
 1439 jurisdiction which relates to health care fraud.~~†~~

1440 (e) Has been convicted of, or entered a plea of guilty or
 1441 nolo contendere to, regardless of adjudication, a felony under
 1442 chapter 409, chapter 817, or chapter 893, or a similar felony
 1443 offense committed in another state or jurisdiction, since July
 1444 1, 2009. ~~Been terminated for cause, pursuant to the appeals~~
 1445 ~~procedures established by the state or Federal Government, from~~
 1446 ~~any state Medicaid program or the federal Medicare program,~~
 1447 ~~unless the applicant has been in good standing with a state~~
 1448 ~~Medicaid program or the federal Medicare program for the most~~
 1449 ~~recent 5 years and the termination occurred at least 20 years~~
 1450 ~~ago; or~~

1451 (f) Has been convicted of, or entered a plea of guilty or
 1452 nolo contendere to, regardless of adjudication, a felony under
 1453 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1,
 1454 2009.

1455 (g) Has been terminated for cause from the Florida
 1456 Medicaid program pursuant to s. 409.913, unless the applicant

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1457 has been in good standing with the Florida Medicaid program for
1458 the most recent 5-year period.

1459 (h) Has been terminated for cause, pursuant to the appeals
1460 procedures established by the state, from any other state
1461 Medicaid program, unless the applicant has been in good standing
1462 with a state Medicaid program for the most recent 5-year period
1463 and the termination occurred at least 20 years before the date
1464 of the application.

1465 (i) Is currently listed on the United States Department of
1466 Health and Human Services Office of Inspector General's List of
1467 Excluded Individuals and Entities.

1468 (j)~~(f)~~ Has dispensed any medicinal drug based upon a
1469 communication that purports to be a prescription as defined by
1470 s. 465.003(14) or s. 893.02 when the pharmacist knows or has
1471 reason to believe that the purported prescription is not based
1472 upon a valid practitioner-patient relationship that includes a
1473 documented patient evaluation, including history and a physical
1474 examination adequate to establish the diagnosis for which any
1475 drug is prescribed and any other requirement established by
1476 board rule under chapter 458, chapter 459, chapter 461, chapter
1477 463, chapter 464, or chapter 466.

1478 (k) Has violated or failed to comply with any provision of
1479 this chapter; chapter 499, the Florida Drug and Cosmetic Act;
1480 chapter 893; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
1481 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
1482 Abuse Prevention and Control Act; or any rules or regulations
1483 promulgated thereunder.

1484

1485 For felonies in which the defendant entered a plea of guilty or
1486 nolo contendere in an agreement with the court to enter a
1487 pretrial intervention or drug diversion program, the department
1488 may not approve or deny the application for a renewal of a
1489 license, certificate, or registration until the final resolution
1490 of the case.

1491 (6)~~(5)~~ After the application has been filed with the board
1492 and the permit fee provided in this section has been received,
1493 the board shall cause the application to be fully investigated,
1494 both as to the qualifications of the applicant and the
1495 prescription department manager or consultant pharmacist
1496 designated to be in charge and as to the premises and location
1497 described in the application.

1498 (7)~~(6)~~ The Board of Pharmacy shall have the authority to
1499 determine whether a bona fide transfer of ownership is present
1500 and that the sale of a pharmacy is not being accomplished for
1501 the purpose of avoiding an administrative prosecution.

1502 (8)~~(7)~~ Upon the completion of the investigation of an
1503 application, the board shall approve or deny ~~disapprove~~ the
1504 application. If approved, the permit shall be issued by the
1505 department.

1506 (9)~~(8)~~ A permittee must notify the department, on a form
1507 approved by the board, within 10 days after any change in
1508 prescription department manager or consultant pharmacist of
1509 record. ~~Permits issued by the department are not transferable.~~

1510 (10) A permittee must notify the department of the
1511 identity of the prescription department manager within 10 days
1512 after employment. The prescription department manager must

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1513 comply with the following requirements:

1514 (a) The prescription department manager of a permittee
1515 must obtain and maintain all drug records required by any state
1516 or federal law to be obtained by a pharmacy, including, but not
1517 limited to, records required by or under this chapter, chapter
1518 499, or chapter 893. The prescription department manager must
1519 ensure the permittee's compliance with all rules adopted under
1520 those chapters as they relate to the practice of the profession
1521 of pharmacy and the sale of prescription drugs.

1522 (b) The prescription department manager must ensure the
1523 security of the prescription department. The prescription
1524 department manager must notify the board of any theft or
1525 significant loss of any controlled substances within 1 business
1526 day after discovery of the theft or loss.

1527 (c) A registered pharmacist may not serve as the
1528 prescription department manager in more than one location unless
1529 approved by the board.

1530 (11) The board shall adopt rules that require the keeping
1531 of such records of prescription drugs as are necessary for the
1532 protection of public health, safety, and welfare.

1533 (a) All required records documenting prescription drug
1534 distributions shall be readily available or immediately
1535 retrievable during an inspection by the department.

1536 (b) The records must be maintained for 4 years after the
1537 creation or receipt of the record, whichever is later.

1538 (12) Permits issued by the department are not
1539 transferable.

1540 (13)-(9) The board shall set the fees for the following:

1541 (a) Initial permit fee not to exceed \$250.
 1542 (b) Biennial permit renewal not to exceed \$250.
 1543 (c) Delinquent fee not to exceed \$100.
 1544 (d) Change of location fee not to exceed \$250 ~~\$100~~.
 1545 Section 14. Paragraph (b) of subsection (1) of section
 1546 465.0276, Florida Statutes, is amended to read:
 1547 465.0276 Dispensing practitioner.—
 1548 (1)
 1549 (b) A practitioner registered under this section may not
 1550 dispense a controlled substance listed in Schedule II or
 1551 Schedule III as provided in s. 893.03 ~~A practitioner registered~~
 1552 ~~under this section may not dispense more than a 72-hour supply~~
 1553 ~~of a controlled substance listed in Schedule II, Schedule III,~~
 1554 ~~Schedule IV, or Schedule V of s. 893.03 for any patient who pays~~
 1555 ~~for the medication by cash, check, or credit card in a clinic~~
 1556 ~~registered under s. 458.3265 or s. 459.0137. A practitioner who~~
 1557 ~~violates this paragraph commits a felony of the third degree,~~
 1558 ~~punishable as provided in s. 775.082, s. 775.083, or s. 775.084.~~
 1559 This paragraph does not apply to:
 1560 1. ~~A practitioner who dispenses medication to a workers'~~
 1561 ~~compensation patient pursuant to chapter 440.~~
 1562 2. ~~A practitioner who dispenses medication to an insured~~
 1563 ~~patient who pays by cash, check, or credit card to cover any~~
 1564 ~~applicable copayment or deductible.~~
 1565 1.3. The dispensing of complimentary packages of medicinal
 1566 drugs to the practitioner's own patients in the regular course
 1567 of her or his practice without the payment of a fee or
 1568 remuneration of any kind, whether direct or indirect, as

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1569 provided in subsection (5).

1570 2. The dispensing of controlled substances in the health
1571 care system of the Department of Corrections.

1572 Section 15. Subsections (16) and (17) are added to section
1573 499.0051, Florida Statutes, to read:

1574 499.0051 Criminal acts.—

1575 (16) FALSE REPORT.—Any person who submits a report
1576 required by s. 499.0121(14) knowing that such report contains a
1577 false statement commits a felony of the third degree, punishable
1578 as provided in s. 775.082, s. 775.083, or s. 775.084.

1579 (17) CONTROLLED SUBSTANCE DISTRIBUTION.—Any wholesale
1580 distributor who distributes controlled substances in violation
1581 of s. 499.0121(14) commits a felony of the third degree,
1582 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
1583 In addition to any other fine that may be imposed, a wholesale
1584 distributor convicted of such a violation may be sentenced to
1585 pay a fine that does not exceed three times the gross monetary
1586 value gained from such violation, plus court costs and the
1587 reasonable costs of investigation and prosecution.

1588 Section 16. Paragraph (o) is added to subsection (8) of
1589 section 499.012, Florida Statutes, to read:

1590 499.012 Permit application requirements.—

1591 (8) An application for a permit or to renew a permit for a
1592 prescription drug wholesale distributor or an out-of-state
1593 prescription drug wholesale distributor submitted to the
1594 department must include:

1595 (o) Documentation of the credentialing policies and
1596 procedures required by s. 499.0121(14).

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1597 Section 17. Subsections (14) and (15) are added to section
1598 499.0121, Florida Statutes, to read:

1599 499.0121 Storage and handling of prescription drugs;
1600 recordkeeping.—The department shall adopt rules to implement
1601 this section as necessary to protect the public health, safety,
1602 and welfare. Such rules shall include, but not be limited to,
1603 requirements for the storage and handling of prescription drugs
1604 and for the establishment and maintenance of prescription drug
1605 distribution records.

1606 (14) DISTRIBUTION REPORTING.—Each wholesale distributor
1607 shall submit a report to the department of its receipts and
1608 distributions of controlled substances listed in Schedule II,
1609 Schedule III, Schedule IV, or Schedule V as provided in s.
1610 893.03. Wholesale distributor facilities located within this
1611 state shall report all transactions involving controlled
1612 substances, and wholesale distributor facilities located outside
1613 this state shall report all distributions to entities located in
1614 this state. If the wholesale distributor did not have any
1615 controlled substance distributions for the month, a report shall
1616 be sent indicating that no distributions occurred in the period.
1617 The report shall be submitted monthly by the 20th of the next
1618 month, in the electronic format used for controlled substance
1619 reporting to the Automation of Reports and Consolidated Orders
1620 System division of the federal Drug Enforcement Administration.
1621 Submission of electronic data must be made in a secured web
1622 environment that allows for manual or automated transmission.
1623 Upon successful transmission, an acknowledgement page must be
1624 displayed to confirm receipt. The report must contain the

1625 following information:

1626 (a) The federal Drug Enforcement Administration
 1627 registration number of the wholesale distributing location.

1628 (b) The federal Drug Enforcement Administration
 1629 registration number of the entity to which the drugs are
 1630 distributed or from which the drugs are received.

1631 (c) The transaction code that indicates the type of
 1632 transaction.

1633 (d) The National Drug Code identifier of the product and
 1634 the quantity distributed or received.

1635 (e) The Drug Enforcement Administration Form 222 number or
 1636 Controlled Substance Ordering System Identifier on all schedule
 1637 II transactions.

1638 (f) The date of the transaction.

1639
 1640 The department must share the reported data with the Department
 1641 of Law Enforcement and local law enforcement agencies upon
 1642 request and must monitor purchasing to identify purchasing
 1643 levels that are inconsistent with the purchasing entity's
 1644 clinical needs. The Department of Law Enforcement shall
 1645 investigate purchases at levels that are inconsistent with the
 1646 purchasing entity's clinical needs to determine whether
 1647 violations of chapter 893 have occurred.

1648 (15) DUE DILIGENCE OF PURCHASERS.—

1649 (a) Each wholesale distributor must establish and maintain
 1650 policies and procedures to credential physicians licensed under
 1651 chapter 459, chapter 459, chapter 461, or chapter 466 and
 1652 pharmacies that would purchase or otherwise receive from the

1653 wholesale distributor controlled substances listed in Schedule
 1654 II or Schedule III as provided in s. 893.03. The wholesale
 1655 distributor shall maintain records of such credentialing and
 1656 make the records available to the department upon request. Such
 1657 credentialing must, at a minimum, include:

1658 1. A determination of the clinical nature of the receiving
 1659 entity, including any specialty practice area.

1660 2. A review of the receiving entity's history of Schedule
 1661 II and Schedule III controlled substance purchasing from the
 1662 wholesale distributor.

1663 3. A determination that the receiving entity's Schedule II
 1664 and Schedule III controlled substance purchasing history, if
 1665 any, is consistent with and reasonable for that entity's
 1666 clinical business needs.

1667 4. Documentation of a level 2 background screening
 1668 pursuant to chapter 435 through the department on any person who
 1669 owns a controlling interest in or, directly or indirectly,
 1670 manages, oversees, or controls the operation of the entity,
 1671 including officers and members of the board of directors of an
 1672 entity that is a corporation. This requirement does not apply to
 1673 publicly traded entities or entities having more than \$100
 1674 million of business taxable assets in this state. For such
 1675 entities, wholesale distributors must require current
 1676 documentation of all state and federal licenses and permits.

1677 (b) A wholesale distributor must take reasonable measures
 1678 to identify its customers, understand the normal and expected
 1679 transactions conducted by those customers, and identify those
 1680 transactions that are suspicious in nature. A wholesale

1681 distributor must establish internal policies and procedures for
1682 identifying suspicious orders and preventing suspicious
1683 transactions. A wholesale distributor must assess orders for
1684 greater than 5,000 unit doses of any one controlled substance in
1685 any one month to determine whether the purchase is reasonable.
1686 In making such assessments, a wholesale distributor may consider
1687 the purchasing entity's clinical business needs, location, and
1688 population served, in addition to other factors established in
1689 the distributor's policies and procedures. A wholesale
1690 distributor must report to the department any regulated
1691 transaction involving an extraordinary quantity of a listed
1692 chemical, an uncommon method of payment or delivery, or any
1693 other circumstance that the regulated person believes may
1694 indicate that the listed chemical will be used in violation of
1695 the law. For each reported transaction that is completed, the
1696 wholesale distributor must document the basis for determining
1697 the transaction was reasonable.

1698 (c) A wholesale distributor may not distribute controlled
1699 substances to an entity if any criminal history record check for
1700 any person associated with that entity shows the person has been
1701 convicted of, or entered a plea of guilty or nolo contendere to,
1702 regardless of adjudication, a crime in any jurisdiction related
1703 to controlled substances, the practice of pharmacy, or the
1704 dispensing of medicinal drugs.

1705 (d) A wholesale distributor may not distribute more than
1706 5,000 unit doses each of hydrocodone, morphine, oxycodone,
1707 methadone, or any one benzodiazepine, or any derivative,
1708 precursor, or component of these drugs to a retail pharmacy in

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1709 any given month.

1710 Section 18. Paragraphs (o) and (p) are added to subsection
1711 (1) of section 499.05, Florida Statutes, to read:

1712 499.05 Rules.—

1713 (1) The department shall adopt rules to implement and
1714 enforce this part with respect to:

1715 (o) Wholesale distributor reporting requirements of s.
1716 499.0121(14).

1717 (p) Wholesale distributor credentialing and distribution
1718 requirements of s. 499.0121(15).

1719 Section 19. Subsections (8) and (9) are added to section
1720 499.067, Florida Statutes, to read:

1721 499.067 Denial, suspension, or revocation of permit,
1722 certification, or registration.—

1723 (8) The department shall deny, suspend, or revoke a permit
1724 if it finds the permittee has not complied with the
1725 credentialing requirements of s. 499.0121(15).

1726 (9) The department shall deny, suspend, or revoke a permit
1727 if it finds the permittee has not complied with the reporting
1728 requirements of, or knowingly made a false statement in a report
1729 required by, s. 499.0121(14).

1730 Section 20. Paragraph (f) is added to subsection (3) of
1731 section 810.02, Florida Statutes, to read:

1732 810.02 Burglary.—

1733 (3) Burglary is a felony of the second degree, punishable
1734 as provided in s. 775.082, s. 775.083, or s. 775.084, if, in the
1735 course of committing the offense, the offender does not make an
1736 assault or battery and is not and does not become armed with a

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1737 dangerous weapon or explosive, and the offender enters or
1738 remains in a:

1739 (f) Structure or conveyance when the offense intended to
1740 be committed therein is theft of a controlled substance as
1741 defined in s. 893.02. Notwithstanding any other law, separate
1742 judgments and sentences for burglary with the intent to commit
1743 theft of a controlled substance under this paragraph and for any
1744 applicable possession of controlled substance offense under s.
1745 893.13 or trafficking in controlled substance offense under s.
1746 893.135 may be imposed when all such offenses involve the same
1747 amount or amounts of a controlled substance.

1748
1749 However, if the burglary is committed within a county that is
1750 subject to a state of emergency declared by the Governor under
1751 chapter 252 after the declaration of emergency is made and the
1752 perpetration of the burglary is facilitated by conditions
1753 arising from the emergency, the burglary is a felony of the
1754 first degree, punishable as provided in s. 775.082, s. 775.083,
1755 or s. 775.084. As used in this subsection, the term "conditions
1756 arising from the emergency" means civil unrest, power outages,
1757 curfews, voluntary or mandatory evacuations, or a reduction in
1758 the presence of or response time for first responders or
1759 homeland security personnel. A person arrested for committing a
1760 burglary within a county that is subject to such a state of
1761 emergency may not be released until the person appears before a
1762 committing magistrate at a first appearance hearing. For
1763 purposes of sentencing under chapter 921, a felony offense that
1764 is reclassified under this subsection is ranked one level above

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1765 the ranking under s. 921.0022 or s. 921.0023 of the offense
 1766 committed.

1767 Section 21. Paragraph (c) of subsection (2) of section
 1768 812.014, Florida Statutes, is amended to read:

1769 812.014 Theft.—

1770 (2)

1771 (c) It is grand theft of the third degree and a felony of
 1772 the third degree, punishable as provided in s. 775.082, s.
 1773 775.083, or s. 775.084, if the property stolen is:

- 1774 1. Valued at \$300 or more, but less than \$5,000.
- 1775 2. Valued at \$5,000 or more, but less than \$10,000.
- 1776 3. Valued at \$10,000 or more, but less than \$20,000.
- 1777 4. A will, codicil, or other testamentary instrument.
- 1778 5. A firearm.
- 1779 6. A motor vehicle, except as provided in paragraph (a).
- 1780 7. Any commercially farmed animal, including any animal of
 1781 the equine, bovine, or swine class, or other grazing animal, and
 1782 including aquaculture species raised at a certified aquaculture
 1783 facility. If the property stolen is aquaculture species raised
 1784 at a certified aquaculture facility, then a \$10,000 fine shall
 1785 be imposed.
- 1786 8. Any fire extinguisher.
- 1787 9. Any amount of citrus fruit consisting of 2,000 or more
 1788 individual pieces of fruit.
- 1789 10. Taken from a designated construction site identified
 1790 by the posting of a sign as provided for in s. 810.09(2)(d).
- 1791 11. Any stop sign.
- 1792 12. Anhydrous ammonia.

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1793 13. Any amount of a controlled substance as defined in s.
1794 893.02. Notwithstanding any other law, separate judgments and
1795 sentences for theft of a controlled substance under this
1796 subparagraph and for any applicable possession of controlled
1797 substance offense under s. 893.13 or trafficking in controlled
1798 substance offense under s. 893.135 may be imposed when all such
1799 offenses involve the same amount or amounts of a controlled
1800 substance.

1801
1802 However, if the property is stolen within a county that is
1803 subject to a state of emergency declared by the Governor under
1804 chapter 252, the property is stolen after the declaration of
1805 emergency is made, and the perpetration of the theft is
1806 facilitated by conditions arising from the emergency, the
1807 offender commits a felony of the second degree, punishable as
1808 provided in s. 775.082, s. 775.083, or s. 775.084, if the
1809 property is valued at \$5,000 or more, but less than \$10,000, as
1810 provided under subparagraph 2., or if the property is valued at
1811 \$10,000 or more, but less than \$20,000, as provided under
1812 subparagraph 3. As used in this paragraph, the term "conditions
1813 arising from the emergency" means civil unrest, power outages,
1814 curfews, voluntary or mandatory evacuations, or a reduction in
1815 the presence of or the response time for first responders or
1816 homeland security personnel. For purposes of sentencing under
1817 chapter 921, a felony offense that is reclassified under this
1818 paragraph is ranked one level above the ranking under s.
1819 921.0022 or s. 921.0023 of the offense committed.

1820 Section 22. Section 893.055, Florida Statutes, is amended

1821 to read:

1822 893.055 Prescription drug monitoring program.—

1823 (1) As used in this section, the term:

1824 (a) "Patient advisory report" or "advisory report" means
 1825 information provided by the department in writing, or as
 1826 determined by the department, to a prescriber, dispenser,
 1827 pharmacy, or patient concerning the dispensing of controlled
 1828 substances. All advisory reports are for informational purposes
 1829 only and impose no obligations of any nature or any legal duty
 1830 on a prescriber, dispenser, pharmacy, or patient. The patient
 1831 advisory report shall be provided in accordance with s.

1832 893.13(7)(a)8. The advisory reports issued by the department are
 1833 not subject to discovery or introduction into evidence in any
 1834 civil or administrative action against a prescriber, dispenser,
 1835 pharmacy, or patient arising out of matters that are the subject
 1836 of the report; and a person who participates in preparing,
 1837 reviewing, issuing, or any other activity related to an advisory
 1838 report may not be permitted or required to testify in any such
 1839 civil action as to any findings, recommendations, evaluations,
 1840 opinions, or other actions taken in connection with preparing,
 1841 reviewing, or issuing such a report.

1842 (b) "Controlled substance" means a controlled substance
 1843 listed in Schedule II, Schedule III, or Schedule IV in s.

1844 893.03.

1845 (c) "Dispenser" means a pharmacy, dispensing pharmacist,
 1846 or dispensing health care practitioner.

1847 (d) "Health care practitioner" or "practitioner" means any
 1848 practitioner who is subject to licensure or regulation by the

1849 department under chapter 458, chapter 459, chapter 461, chapter
 1850 462, chapter 464, chapter 465, or chapter 466.

1851 (e) "Health care regulatory board" means any board for a
 1852 practitioner or health care practitioner who is licensed or
 1853 regulated by the department.

1854 (f) "Pharmacy" means any pharmacy that is subject to
 1855 licensure or regulation by the department under chapter 465 and
 1856 that dispenses or delivers a controlled substance to an
 1857 individual or address in this state.

1858 (g) "Prescriber" means a prescribing physician,
 1859 prescribing practitioner, or other prescribing health care
 1860 practitioner.

1861 (h) "Active investigation" means an investigation that is
 1862 being conducted with a reasonable, good faith belief that it
 1863 could lead to the filing of administrative, civil, or criminal
 1864 proceedings, or that is ongoing and continuing and for which
 1865 there is a reasonable, good faith anticipation of securing an
 1866 arrest or prosecution in the foreseeable future.

1867 (i) "Law enforcement agency" means the Department of Law
 1868 Enforcement, a Florida sheriff's department, a Florida police
 1869 department, or a law enforcement agency of the Federal
 1870 Government which enforces the laws of this state or the United
 1871 States relating to controlled substances, and which its agents
 1872 and officers are empowered by law to conduct criminal
 1873 investigations and make arrests.

1874 (j) "Program manager" means an employee of or a person
 1875 contracted by the Department of Health who is designated to
 1876 ensure the integrity of the prescription drug monitoring program

1877 in accordance with the requirements established in paragraphs
 1878 (2) (a) and (b) .

1879 (2) (a) ~~By December 1, 2010,~~ The department shall design
 1880 and establish a comprehensive electronic database system that
 1881 has controlled substance prescriptions provided to it and that
 1882 provides prescription information to a patient's health care
 1883 practitioner and pharmacist who inform the department that they
 1884 wish the patient advisory report provided to them. Otherwise,
 1885 the patient advisory report will not be sent to the
 1886 practitioner, pharmacy, or pharmacist. The system shall be
 1887 designed to provide information regarding dispensed
 1888 prescriptions of controlled substances and shall not infringe
 1889 upon the legitimate prescribing or dispensing of a controlled
 1890 substance by a prescriber or dispenser acting in good faith and
 1891 in the course of professional practice. The system shall be
 1892 consistent with standards of the American Society for Automation
 1893 in Pharmacy (ASAP). The electronic system shall also comply with
 1894 the Health Insurance Portability and Accountability Act (HIPAA)
 1895 as it pertains to protected health information (PHI), electronic
 1896 protected health information (EPHI), and all other relevant
 1897 state and federal privacy and security laws and regulations. The
 1898 department shall establish policies and procedures as
 1899 appropriate regarding the reporting, accessing the database,
 1900 evaluation, management, development, implementation, operation,
 1901 storage, and security of information within the system. The
 1902 reporting of prescribed controlled substances shall include a
 1903 dispensing transaction with a dispenser pursuant to chapter 465
 1904 or through a dispensing transaction to an individual or address

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1905 in this state with a pharmacy that is not located in this state
 1906 but that is otherwise subject to the jurisdiction of this state
 1907 as to that dispensing transaction. The reporting of patient
 1908 advisory reports refers only to reports to patients, pharmacies,
 1909 and practitioners. Separate reports that contain patient
 1910 prescription history information and that are not patient
 1911 advisory reports are provided to persons and entities as
 1912 authorized in paragraphs (7) (b) and (c) and s. 893.0551.

1913 (b) The department, when the direct support organization
 1914 receives at least \$20,000 in nonstate moneys or the state
 1915 receives at least \$20,000 in federal grants for the prescription
 1916 drug monitoring program, ~~and in consultation with the Office of~~
 1917 ~~Drug Control~~, shall adopt rules as necessary concerning the
 1918 reporting, accessing the database, evaluation, management,
 1919 development, implementation, operation, security, and storage of
 1920 information within the system, including rules for when patient
 1921 advisory reports are provided to pharmacies and prescribers. The
 1922 patient advisory report shall be provided in accordance with s.
 1923 893.13(7) (a)8. The department shall work with the professional
 1924 health care licensure boards, such as the Board of Medicine, the
 1925 Board of Osteopathic Medicine, and the Board of Pharmacy; other
 1926 appropriate organizations, such as the Florida Pharmacy
 1927 Association, ~~the Office of Drug Control~~, the Florida Medical
 1928 Association, the Florida Retail Federation, and the Florida
 1929 Osteopathic Medical Association, including those relating to
 1930 pain management; and the Attorney General, the Department of Law
 1931 Enforcement, and the Agency for Health Care Administration to
 1932 develop rules appropriate for the prescription drug monitoring

1933 program.

1934 (c) All dispensers and prescribers subject to these
 1935 reporting requirements shall be notified by the department of
 1936 the implementation date for such reporting requirements.

1937 (d) The program manager shall work with professional
 1938 health care licensure boards and the stakeholders listed in
 1939 paragraph (b) to develop rules appropriate for identifying
 1940 indicators of controlled substance abuse.

1941 (3) The pharmacy dispensing the controlled substance and
 1942 each prescriber who directly dispenses a controlled substance
 1943 shall submit to the electronic system, by a procedure and in a
 1944 format established by the department and consistent with an
 1945 ASAP-approved format, the following information for inclusion in
 1946 the database:

1947 (a) The name of the prescribing practitioner, the
 1948 practitioner's federal Drug Enforcement Administration
 1949 registration number, the practitioner's National Provider
 1950 Identification (NPI) or other appropriate identifier, and the
 1951 date of the prescription.

1952 (b) The date the prescription was filled and the method of
 1953 payment, such as cash by an individual, insurance coverage
 1954 through a third party, or Medicaid payment. This paragraph does
 1955 not authorize the department to include individual credit card
 1956 numbers or other account numbers in the database.

1957 (c) The full name, address, and date of birth of the
 1958 person for whom the prescription was written.

1959 (d) The name, national drug code, quantity, and strength
 1960 of the controlled substance dispensed.

1961 (e) The full name, federal Drug Enforcement Administration
 1962 registration number, and address of the pharmacy or other
 1963 location from which the controlled substance was dispensed. If
 1964 the controlled substance was dispensed by a practitioner other
 1965 than a pharmacist, the practitioner's full name, federal Drug
 1966 Enforcement Administration registration number, and address.

1967 (f) The name of the pharmacy or practitioner, other than a
 1968 pharmacist, dispensing the controlled substance and the
 1969 practitioner's National Provider Identification (NPI).

1970 (g) Other appropriate identifying information as
 1971 determined by department rule.

1972 (4) Each time a controlled substance is dispensed to an
 1973 individual, the controlled substance shall be reported to the
 1974 department through the system as soon thereafter as possible,
 1975 but not more than 7 ~~15~~ days after the date the controlled
 1976 substance is dispensed unless an extension is approved by the
 1977 department for cause as determined by rule. A dispenser must
 1978 meet the reporting requirements of this section by providing the
 1979 required information concerning each controlled substance that
 1980 it dispensed in a department-approved, secure methodology and
 1981 format. Such approved formats may include, but are not limited
 1982 to, submission via the Internet, on a disc, or by use of regular
 1983 mail.

1984 (5) When the following acts of dispensing or administering
 1985 occur, the following are exempt from reporting under this
 1986 section for that specific act of dispensing or administration:

1987 (a) A health care practitioner when administering a
 1988 controlled substance directly to a patient if the amount of the

1989 controlled substance is adequate to treat the patient during
 1990 that particular treatment session.

1991 (b) A pharmacist or health care practitioner when
 1992 administering a controlled substance to a patient or resident
 1993 receiving care as a patient at a hospital, nursing home,
 1994 ambulatory surgical center, hospice, or intermediate care
 1995 facility for the developmentally disabled which is licensed in
 1996 this state.

1997 (c) A practitioner when administering or dispensing a
 1998 controlled substance in the health care system of the Department
 1999 of Corrections.

2000 (d) A practitioner when administering a controlled
 2001 substance in the emergency room of a licensed hospital.

2002 (e) A health care practitioner when administering or
 2003 dispensing a controlled substance to a person under the age of
 2004 16.

2005 (f) A pharmacist or a dispensing practitioner when
 2006 dispensing a one-time, 72-hour emergency resupply of a
 2007 controlled substance to a patient.

2008 (6) The department may establish when to suspend and when
 2009 to resume reporting information during a state-declared or
 2010 nationally declared disaster.

2011 (7) (a) A practitioner or pharmacist who dispenses a
 2012 controlled substance must submit the information required by
 2013 this section in an electronic or other method in an ASAP format
 2014 approved by rule of the department unless otherwise provided in
 2015 this section. The cost to the dispenser in submitting the
 2016 information required by this section may not be material or

2017 extraordinary. Costs not considered to be material or
 2018 extraordinary include, but are not limited to, regular postage,
 2019 electronic media, regular electronic mail, and facsimile
 2020 charges.

2021 (b) A pharmacy, prescriber, or dispenser shall have access
 2022 to information in the prescription drug monitoring program's
 2023 database which relates to a patient of that pharmacy,
 2024 prescriber, or dispenser in a manner established by the
 2025 department as needed for the purpose of reviewing the patient's
 2026 controlled substance prescription history. Other access to the
 2027 program's database shall be limited to the program's manager and
 2028 to the designated program and support staff, who may act only at
 2029 the direction of the program manager or, in the absence of the
 2030 program manager, as authorized. Access by the program manager or
 2031 such designated staff is for prescription drug program
 2032 management only or for management of the program's database and
 2033 its system in support of the requirements of this section and in
 2034 furtherance of the prescription drug monitoring program.

2035 Confidential and exempt information in the database shall be
 2036 released only as provided in paragraph (c) and s. 893.0551.

2037 (c) The following entities shall not be allowed direct
 2038 access to information in the prescription drug monitoring
 2039 program database but may request from the program manager and,
 2040 when authorized by the program manager, the program manager's
 2041 program and support staff, information that is confidential and
 2042 exempt under s. 893.0551. Prior to release, the request shall be
 2043 verified as authentic and authorized with the requesting
 2044 organization by the program manager, the program manager's

2045 program and support staff, or as determined in rules by the
 2046 department as being authentic and as having been authorized by
 2047 the requesting entity:

2048 1. The department or its relevant health care regulatory
 2049 boards responsible for the licensure, regulation, or discipline
 2050 of practitioners, pharmacists, or other persons who are
 2051 authorized to prescribe, administer, or dispense controlled
 2052 substances and who are involved in a specific controlled
 2053 substance investigation involving a designated person for one or
 2054 more prescribed controlled substances.

2055 2. The Attorney General for Medicaid fraud cases involving
 2056 prescribed controlled substances.

2057 3. A law enforcement agency during active investigations
 2058 regarding potential criminal activity, fraud, or theft regarding
 2059 prescribed controlled substances.

2060 4. A patient or the legal guardian or designated health
 2061 care surrogate of an incapacitated patient as described in s.
 2062 893.0551 who, for the purpose of verifying the accuracy of the
 2063 database information, submits a written and notarized request
 2064 that includes the patient's full name, address, and date of
 2065 birth, and includes the same information if the legal guardian
 2066 or health care surrogate submits the request. The request shall
 2067 be validated by the department to verify the identity of the
 2068 patient and the legal guardian or health care surrogate, if the
 2069 patient's legal guardian or health care surrogate is the
 2070 requestor. Such verification is also required for any request to
 2071 change a patient's prescription history or other information
 2072 related to his or her information in the electronic database.

2073
 2074 Information in the database for the electronic prescription drug
 2075 monitoring system is not discoverable or admissible in any civil
 2076 or administrative action, except in an investigation and
 2077 disciplinary proceeding by the department or the appropriate
 2078 regulatory board.

2079 (d) Department staff are ~~The following entities shall not~~
 2080 ~~be~~ allowed direct access to information in the prescription drug
 2081 monitoring program database but may request from the program
 2082 manager and, when authorized by the program manager, the program
 2083 manager's program and support staff, information that contains
 2084 no identifying information of any patient, physician, health
 2085 care practitioner, prescriber, or dispenser and that is not
 2086 confidential and exempt,÷

2087 1. ~~Department staff~~ for the purpose of calculating
 2088 performance measures pursuant to subsection (8).

2089 2. ~~The Program Implementation and Oversight Task Force for~~
 2090 ~~its reporting to the Governor, the President of the Senate, and~~
 2091 ~~the Speaker of the House of Representatives regarding the~~
 2092 ~~prescription drug monitoring program. This subparagraph expires~~
 2093 ~~July 1, 2012.~~

2094 (e) All transmissions of data required by this section
 2095 must comply with relevant state and federal privacy and security
 2096 laws and regulations. However, any authorized agency or person
 2097 under s. 893.0551 receiving such information as allowed by s.
 2098 893.0551 may maintain the information received for up to 24
 2099 months before purging it from his or her records or maintain it
 2100 for longer than 24 months if the information is pertinent to

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2101 ongoing health care or an active law enforcement investigation
2102 or prosecution.

2103 (f) The program manager, upon determining a pattern
2104 consistent with the rules established under paragraph (2)(d) and
2105 having cause to believe a violation of s. 893.13(7)(a)8.,
2106 (8)(a), or (8)(b) has occurred, may provide relevant information
2107 to the applicable law enforcement agency.

2108 (8) To assist in fulfilling program responsibilities,
2109 performance measures shall be reported annually to the Governor,
2110 the President of the Senate, and the Speaker of the House of
2111 Representatives by the department each December 1, beginning in
2112 2011. Data that does not contain patient, physician, health care
2113 practitioner, prescriber, or dispenser identifying information
2114 may be requested during the year by department employees so that
2115 the department may undertake public health care and safety
2116 initiatives that take advantage of observed trends. Performance
2117 measures may include, but are not limited to, efforts to achieve
2118 the following outcomes:

2119 (a) Reduction of the rate of inappropriate use of
2120 prescription drugs through department education and safety
2121 efforts.

2122 (b) Reduction of the quantity of pharmaceutical controlled
2123 substances obtained by individuals attempting to engage in fraud
2124 and deceit.

2125 (c) Increased coordination among partners participating in
2126 the prescription drug monitoring program.

2127 (d) Involvement of stakeholders in achieving improved
2128 patient health care and safety and reduction of prescription

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2129 drug abuse and prescription drug diversion.

2130 (9) Any person who willfully and knowingly fails to report
 2131 the dispensing of a controlled substance as required by this
 2132 section commits a misdemeanor of the first degree, punishable as
 2133 provided in s. 775.082 or s. 775.083.

2134 (10) All costs incurred by the department in administering
 2135 the prescription drug monitoring program shall be funded through
 2136 federal grants or private funding applied for or received by the
 2137 state. The department may not commit funds for the monitoring
 2138 program without ensuring funding is available. The prescription
 2139 drug monitoring program and the implementation thereof are
 2140 contingent upon receipt of the nonstate funding. The department
 2141 and state government shall cooperate with the direct-support
 2142 organization established pursuant to subsection (11) in seeking
 2143 federal grant funds, other nonstate grant funds, gifts,
 2144 donations, or other private moneys for the department so long as
 2145 the costs of doing so are not considered material. Nonmaterial
 2146 costs for this purpose include, but are not limited to, the
 2147 costs of mailing and personnel assigned to research or apply for
 2148 a grant. Notwithstanding the exemptions to competitive-
 2149 solicitation requirements under s. 287.057(3)(f), the department
 2150 shall comply with the competitive-solicitation requirements
 2151 under s. 287.057 for the procurement of any goods or services
 2152 required by this section. Funds provided, directly or
 2153 indirectly, by prescription drug manufacturers may not be used
 2154 to implement the program.

2155 (11) ~~The Office of Drug Control, in coordination with the~~
 2156 ~~department,~~ may establish a direct-support organization that has

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2157 a board consisting of at least five members to provide
 2158 assistance, funding, and promotional support for the activities
 2159 authorized for the prescription drug monitoring program.

2160 (a) As used in this subsection, the term "direct-support
 2161 organization" means an organization that is:

2162 1. A Florida corporation not for profit incorporated under
 2163 chapter 617, exempted from filing fees, and approved by the
 2164 Department of State.

2165 2. Organized and operated to conduct programs and
 2166 activities; raise funds; request and receive grants, gifts, and
 2167 bequests of money; acquire, receive, hold, and invest, in its
 2168 own name, securities, funds, objects of value, or other
 2169 property, either real or personal; and make expenditures or
 2170 provide funding to or for the direct or indirect benefit of the
 2171 department in the furtherance of the prescription drug
 2172 monitoring program.

2173 (b) The direct-support organization is not considered a
 2174 lobbying firm within the meaning of s. 11.045.

2175 (c) The State Surgeon General ~~director of the Office of~~
 2176 ~~Drug Control~~ shall appoint a board of directors for the direct-
 2177 support organization. ~~The director may designate employees of~~
 2178 ~~the Office of Drug Control, state employees other than state~~
 2179 ~~employees from the department, and any other nonstate employees~~
 2180 ~~as appropriate, to serve on the board.~~ Members of the board
 2181 shall serve at the pleasure of ~~the director of the~~ State Surgeon
 2182 General Office of Drug Control. The State Surgeon General
 2183 ~~director~~ shall provide guidance to members of the board to
 2184 ensure that moneys received by the direct-support organization

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2185 are not received from inappropriate sources. Inappropriate
 2186 sources include, but are not limited to, donors, grantors,
 2187 persons, or organizations that may monetarily or substantively
 2188 benefit from the purchase of goods or services by the department
 2189 in furtherance of the prescription drug monitoring program.

2190 (d) The direct-support organization shall operate under
 2191 written contract with the department ~~Office of Drug Control~~. The
 2192 contract must, at a minimum, provide for:

2193 1. Approval of the articles of incorporation and bylaws of
 2194 the direct-support organization by the department ~~Office of Drug~~
 2195 ~~Control~~.

2196 2. Submission of an annual budget for the approval of the
 2197 department ~~Office of Drug Control~~.

2198 3. Certification by the department ~~Office of Drug Control~~
 2199 in consultation with the department that the direct-support
 2200 organization is complying with the terms of the contract in a
 2201 manner consistent with and in furtherance of the goals and
 2202 purposes of the prescription drug monitoring program and in the
 2203 best interests of the state. Such certification must be made
 2204 annually and reported in the official minutes of a meeting of
 2205 the direct-support organization.

2206 4. The reversion, without penalty, to ~~the Office of Drug~~
 2207 ~~Control, or to the state if the Office of Drug Control ceases to~~
 2208 ~~exist~~, of all moneys and property held in trust by the direct-
 2209 support organization for the benefit of the prescription drug
 2210 monitoring program if the direct-support organization ceases to
 2211 exist or if the contract is terminated.

2212 5. The fiscal year of the direct-support organization,

2213 | which must begin July 1 of each year and end June 30 of the
 2214 | following year.

2215 | 6. The disclosure of the material provisions of the
 2216 | contract to donors of gifts, contributions, or bequests,
 2217 | including such disclosure on all promotional and fundraising
 2218 | publications, and an explanation to such donors of the
 2219 | distinction between the department ~~Office of Drug Control~~ and
 2220 | the direct-support organization.

2221 | 7. The direct-support organization's collecting,
 2222 | expending, and providing of funds to the department for the
 2223 | development, implementation, and operation of the prescription
 2224 | drug monitoring program as described in this section and s. 2,
 2225 | chapter 2009-198, Laws of Florida, as long as the task force is
 2226 | authorized. The direct-support organization may collect and
 2227 | expend funds to be used for the functions of the direct-support
 2228 | organization's board of directors, as necessary and approved by
 2229 | the department ~~director of the Office of Drug Control~~. In
 2230 | addition, the direct-support organization may collect and
 2231 | provide funding to the department in furtherance of the
 2232 | prescription drug monitoring program by:

2233 | a. Establishing and administering the prescription drug
 2234 | monitoring program's electronic database, including hardware and
 2235 | software.

2236 | b. Conducting studies on the efficiency and effectiveness
 2237 | of the program to include feasibility studies as described in
 2238 | subsection (13).

2239 | c. Providing funds for future enhancements of the program
 2240 | within the intent of this section.

2241 d. Providing user training of the prescription drug
 2242 monitoring program, including distribution of materials to
 2243 promote public awareness and education and conducting workshops
 2244 or other meetings, for health care practitioners, pharmacists,
 2245 and others as appropriate.

2246 e. Providing funds for travel expenses.

2247 f. Providing funds for administrative costs, including
 2248 personnel, audits, facilities, and equipment.

2249 g. Fulfilling all other requirements necessary to
 2250 implement and operate the program as outlined in this section.

2251 (e) The activities of the direct-support organization must
 2252 be consistent with the goals and mission of the department
 2253 ~~Office of Drug Control~~, as determined by the ~~office in~~
 2254 ~~consultation with the~~ department, and in the best interests of
 2255 the state. The direct-support organization must obtain a written
 2256 approval from the department director ~~of the Office of Drug~~
 2257 ~~Control~~ for any activities in support of the prescription drug
 2258 monitoring program before undertaking those activities.

2259 (f) ~~The Office of Drug Control, in consultation with the~~
 2260 ~~department,~~ may permit, without charge, appropriate use of
 2261 administrative services, property, and facilities of ~~the Office~~
 2262 ~~of Drug Control~~ and the department by the direct-support
 2263 organization, subject to this section. The use must be directly
 2264 in keeping with the approved purposes of the direct-support
 2265 organization and may not be made at times or places that would
 2266 unreasonably interfere with opportunities for the public to use
 2267 such facilities for established purposes. Any moneys received
 2268 from rentals of facilities and properties managed by the ~~Office~~

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2269 ~~of Drug Control and the~~ department may be held ~~by the Office of~~
2270 ~~Drug Control or~~ in a separate depository account in the name of
2271 the direct-support organization and subject to the provisions of
2272 the letter of agreement with the department ~~Office of Drug~~
2273 ~~Control~~. The letter of agreement must provide that any funds
2274 held in the separate depository account in the name of the
2275 direct-support organization must revert to the department ~~Office~~
2276 ~~of Drug Control~~ if the direct-support organization is no longer
2277 approved by the department ~~Office of Drug Control~~ to operate in
2278 the best interests of the state.

2279 (g) ~~The Office of Drug Control, in consultation with the~~
2280 ~~department,~~ may adopt rules under s. 120.54 to govern the use of
2281 administrative services, property, or facilities of the
2282 department or office by the direct-support organization.

2283 (h) The department ~~Office of Drug Control~~ may not permit
2284 the use of any administrative services, property, or facilities
2285 of the state by a direct-support organization if that
2286 organization does not provide equal membership and employment
2287 opportunities to all persons regardless of race, color,
2288 religion, gender, age, or national origin.

2289 (i) The direct-support organization shall provide for an
2290 independent annual financial audit in accordance with s.
2291 215.981. Copies of the audit shall be provided to the department
2292 ~~Office of Drug Control~~ and the Office of Policy and Budget in
2293 the Executive Office of the Governor.

2294 (j) The direct-support organization may not exercise any
2295 power under s. 617.0302(12) or (16).

2296 (12) A prescriber or dispenser may have access to the

2297 information under this section which relates to a patient of
 2298 that prescriber or dispenser as needed for the purpose of
 2299 reviewing the patient's controlled drug prescription history. A
 2300 prescriber or dispenser acting in good faith is immune from any
 2301 civil, criminal, or administrative liability that might
 2302 otherwise be incurred or imposed for receiving or using
 2303 information from the prescription drug monitoring program. This
 2304 subsection does not create a private cause of action, and a
 2305 person may not recover damages against a prescriber or dispenser
 2306 authorized to access information under this subsection for
 2307 accessing or failing to access such information.

2308 (13) To the extent that funding is provided for such
 2309 purpose through federal or private grants or gifts and other
 2310 types of available moneys, the department, ~~in collaboration with~~
 2311 ~~the Office of Drug Control,~~ shall study the feasibility of
 2312 enhancing the prescription drug monitoring program for the
 2313 purposes of public health initiatives and statistical reporting
 2314 that respects the privacy of the patient, the prescriber, and
 2315 the dispenser. Such a study shall be conducted in order to
 2316 further improve the quality of health care services and safety
 2317 by improving the prescribing and dispensing practices for
 2318 prescription drugs, taking advantage of advances in technology,
 2319 reducing duplicative prescriptions and the overprescribing of
 2320 prescription drugs, and reducing drug abuse. The requirements of
 2321 the National All Schedules Prescription Electronic Reporting
 2322 (NASPER) Act are authorized in order to apply for federal NASPER
 2323 funding. In addition, the direct-support organization shall
 2324 provide funding for the department, ~~in collaboration with the~~

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2325 ~~Office of Drug Control,~~ to conduct training for health care
 2326 practitioners and other appropriate persons in using the
 2327 monitoring program to support the program enhancements.

2328 (14) A pharmacist, pharmacy, or dispensing health care
 2329 practitioner or his or her agent, before releasing a controlled
 2330 substance to any person not known to such dispenser, shall
 2331 require the person purchasing, receiving, or otherwise acquiring
 2332 the controlled substance to present valid photographic
 2333 identification or other verification of his or her identity to
 2334 the dispenser. If the person does not have proper
 2335 identification, the dispenser may verify the validity of the
 2336 prescription and the identity of the patient with the prescriber
 2337 or his or her authorized agent. Verification of health plan
 2338 eligibility through a real-time inquiry or adjudication system
 2339 will be considered to be proper identification. This subsection
 2340 does not apply in an institutional setting or to a long-term
 2341 care facility, including, but not limited to, an assisted living
 2342 facility or a hospital to which patients are admitted. As used
 2343 in this subsection, the term "proper identification" means an
 2344 identification that is issued by a state or the Federal
 2345 Government containing the person's photograph, printed name, and
 2346 signature or a document considered acceptable under 8 C.F.R. s.
 2347 274a.2 (b) (1) (v) (A) and (B).

2348 (15) The Agency for Health Care Administration shall
 2349 continue the promotion of electronic prescribing by health care
 2350 practitioners, health care facilities, and pharmacies under s.
 2351 408.0611.

2352 (16) ~~By October 1, 2010,~~ The department shall adopt rules

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2353 | pursuant to ss. 120.536(1) and 120.54 to administer the
 2354 | provisions of this section, which shall include as necessary the
 2355 | reporting, accessing, evaluation, management, development,
 2356 | implementation, operation, and storage of information within the
 2357 | monitoring program's system.

2358 | Section 23. Section 893.065, Florida Statutes, is amended
 2359 | to read:

2360 | 893.065 Counterfeit-resistant prescription blanks for
 2361 | controlled substances listed in Schedule II, Schedule III, or
 2362 | Schedule IV.—The Department of Health shall develop and adopt by
 2363 | rule the form and content for a counterfeit-resistant
 2364 | prescription blank which must ~~may~~ be used by practitioners for
 2365 | the purpose of prescribing a controlled substance listed in
 2366 | Schedule II, Schedule III, ~~or~~ Schedule IV, or Schedule V
 2367 | pursuant to s. 456.42. The Department of Health may require the
 2368 | prescription blanks to be printed on distinctive, watermarked
 2369 | paper and to bear the preprinted name, address, and category of
 2370 | professional licensure of the practitioner and that
 2371 | practitioner's federal registry number for controlled
 2372 | substances. The prescription blanks may not be transferred.

2373 | Section 24. Subsections (4) and (5) of section 893.07,
 2374 | Florida Statutes, are amended to read:

2375 | 893.07 Records.—

2376 | (4) Every inventory or record required by this chapter,
 2377 | including prescription records, shall be maintained:

2378 | (a) Separately from all other records of the registrant,

2379 | or

2380 | (b) Alternatively, in the case of Schedule III, IV, or V

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2381 controlled substances, in such form that information required by
2382 this chapter is readily retrievable from the ordinary business
2383 records of the registrant.

2384
2385 In either case, the records described in this subsection shall
2386 be kept and made available for a period of at least 2 years for
2387 inspection and copying by law enforcement officers whose duty it
2388 is to enforce the laws of this state relating to controlled
2389 substances. Law enforcement officers are not required to obtain
2390 a subpoena, court order, or search warrant in order to obtain
2391 access to or copies of such records.

2392 (5) Each person described in subsection (1) shall:

2393 (a) Maintain a record which shall contain a detailed list
2394 of controlled substances lost, destroyed, or stolen, if any; the
2395 kind and quantity of such controlled substances; and the date of
2396 the discovering of such loss, destruction, or theft.

2397 (b) In the event of the discovery of the theft or loss of
2398 controlled substances, report such theft or loss to the sheriff
2399 of that county within 24 hours after its discovery. A person who
2400 fails to report a theft or loss of a substance listed in s.
2401 893.03(3), (4), or (5) within 24 hours after discovery as
2402 required in this paragraph commits a misdemeanor of the second
2403 degree, punishable as provided in s. 775.082 or s. 775.083. A
2404 person who fails to report a theft or loss of a substance listed
2405 in s. 893.03(2) within 24 hours after discovery as required in
2406 this paragraph commits a misdemeanor of the first degree,
2407 punishable as provided in s. 775.082 or s. 775.083.

2408 Section 25. Section 2 of chapter 2009-198, Laws of

2409 Florida, is repealed.
 2410 Section 26. (1) BUY-BACK PROGRAM.—
 2411 (a) Within 10 days after the effective date of this act,
 2412 each physician licensed under chapter 458, chapter 459, chapter
 2413 461, or chapter 466, Florida Statutes, shall ensure that
 2414 undispensed inventory of controlled substances listed in
 2415 Schedule II or Schedule III as provided in s. 893.03, Florida
 2416 Statutes, purchased under the physician's Drug Enforcement
 2417 Administration number for dispensing is:
 2418 1. Returned to the wholesale distributor, as defined in s.
 2419 499.003, Florida Statutes, which distributed them; or
 2420 2. Turned in to local law enforcement agencies and
 2421 abandoned.
 2422 (b) Wholesale distributors shall buy back the undispensed
 2423 inventory of controlled substances listed in Schedule II or
 2424 Schedule III as provided in s. 893.03, Florida Statutes, at the
 2425 purchase price paid by the physician, physician practice,
 2426 clinic, or other paying entity. Each wholesale distributor shall
 2427 submit a report of its activities under this section to the
 2428 Department of Health by August 1, 2011. The report shall include
 2429 the following information:
 2430 1. The name and address of the returning entity.
 2431 2. The Florida license, registration, or permit number and
 2432 Drug Enforcement Administration number of the entity that
 2433 originally ordered the drugs.
 2434 3. The drug name and number of unit doses returned.
 2435 4. The date of return.
 2436 (2) PUBLIC HEALTH EMERGENCY.—

- 2437 (a) The Legislature finds that:
- 2438 1. Prescription drug overdose has been declared a public
 2439 health epidemic by the United States Centers for Disease Control
 2440 and Prevention.
- 2441 2. Prescription drug abuse results in an average of seven
 2442 deaths in this state each day.
- 2443 3. Physicians in this state purchased over 85 percent of
 2444 the oxycodone purchased by all practitioners in the United
 2445 States in 2006.
- 2446 4. Physicians in this state purchased over 93 percent of
 2447 the methadone purchased by all practitioners in the United
 2448 States in 2006.
- 2449 5. Some physicians in this state dispense medically
 2450 unjustifiable amounts of controlled substances to addicts and
 2451 people who intend to illegally sell the drugs.
- 2452 6. Physicians in this state who have purchased large
 2453 quantities of controlled substances may have significant
 2454 inventory on the effective date of this act.
- 2455 7. On the effective date of this act, the only legal
 2456 method for a dispensing practitioner to sell or otherwise
 2457 transfer controlled substances listed in Schedule II or Schedule
 2458 III as provided in s. 893.03, Florida Statutes, purchased for
 2459 dispensing is through the buy-back procedure or abandonment
 2460 procedures of subsection (1).
- 2461 8. It is likely that the same physicians who purchase and
 2462 dispense medically unjustifiable amounts of drugs will not
 2463 legally dispose of remaining inventory.
- 2464 9. The actions of such dispensing practitioners may result

2465 in substantial injury to the public health.

2466 (b) Immediately on the effective date of this act, the
 2467 State Health Officer shall declare a public health emergency
 2468 pursuant to s. 381.00315, Florida Statutes. Pursuant to that
 2469 declaration, the Department of Health, the Attorney General, the
 2470 Department of Law Enforcement, and local law enforcement
 2471 agencies shall take the following actions:

2472 1. Within 2 days after the effective date of this act, in
 2473 consultation with wholesale distributors as defined in s.
 2474 499.003, Florida Statutes, the Department of Health shall
 2475 identify dispensing practitioners that purchased more than an
 2476 average of 2,000 unit doses of controlled substances listed in
 2477 Schedule II or Schedule III as provided in s. 893.03, Florida
 2478 Statutes, per month in the previous 6 months, and shall identify
 2479 the dispensing practitioners in that group who pose the greatest
 2480 threat to the public health based on an assessment of:

- 2481 a. The risk of noncompliance with subsection (1).
- 2482 b. Purchase amounts.
- 2483 c. Manner of medical practice.
- 2484 d. Any other factor set by the State Health Officer.

2485
 2486 The Attorney General shall consult and coordinate with federal
 2487 law enforcement agencies. The Department of Law Enforcement
 2488 shall coordinate the efforts of local law enforcement agencies.

2489 2. On the 3rd day after the effective date of this act,
 2490 the Department of Law Enforcement or local law enforcement
 2491 agencies shall enter the business premises of the dispensing
 2492 practitioners identified as posing the greatest threat to public

2493 health and quarantine the inventory of controlled substances
 2494 listed in Schedule II or Schedule III as provided in s. 893.03,
 2495 Florida Statutes, of such dispensing practitioners on site.

2496 3. The Department of Law Enforcement or local law
 2497 enforcement agencies shall ensure the security of such inventory
 2498 24 hours a day through the 10th day after the effective date of
 2499 this act or until the inventory is validly transferred pursuant
 2500 to subsection (1), whichever is earlier.

2501 4. On the 11th day after the effective date of this act,
 2502 any remaining inventory of controlled substances listed in
 2503 Schedule II or Schedule III as provided in s. 893.03, Florida
 2504 Statutes, purchased for dispensing by practitioners is deemed
 2505 contraband under s. 893.12, Florida Statutes. The Department of
 2506 Law Enforcement or local law enforcement agencies shall seize
 2507 the inventory and comply with the provisions of s. 893.12,
 2508 Florida Statutes, to destroy it.

2509 (c) In order to implement the provisions of this
 2510 subsection, the sum of \$3 million of nonrecurring funds from the
 2511 General Revenue Fund is appropriated to the Department of Law
 2512 Enforcement for the 2010-2011 fiscal year. The Department of Law
 2513 Enforcement shall expend the appropriation by reimbursing local
 2514 law enforcement agencies for the overtime-hour costs associated
 2515 with securing the quarantined controlled substance inventory as
 2516 provided in paragraph (b) and activities related to
 2517 investigation and prosecution of crimes related to prescribed
 2518 controlled substances. If requests for reimbursement exceed the
 2519 amount appropriated, the reimbursements shall be prorated by the
 2520 hours of overtime per requesting agency at a maximum of one law

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2521 enforcement officer per quarantine site.

2522 (3) REPEAL.—This section is repealed January 1, 2013.

2523 Section 27. This act shall take effect July 1, 2011.