

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 designate themselves as
13 controlled substance prescribing practitioners on their
14 practitioner profiles; providing an effective date;
15 requiring registered physicians to meet certain standards
16 of practice; requiring a physical examination; requiring a
17 written protocol; requiring an assessment of risk for
18 aberrant behavior; requiring a treatment plan; requiring
19 specified informed consent; requiring consultation and
20 referral in certain circumstances; requiring medical
21 records meeting certain criteria; providing an exemption
22 for physicians meeting certain criteria; amending s.
23 458.3265, F.S., relating to regulation of pain-management
24 clinics and medical doctors; amending the definition of a
25 pain-management clinic; providing definitions; providing
26 an exemption from registration for clinics owned and
27 operated by physicians or medical specialists meeting
28 certain criteria; allowing physician assistants and

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

57 | reporting requirements; amending rulemaking authority;
58 | conforming provisions to changes made by the act;
59 | providing for future expiration of provisions; amending s.
60 | 459.013, F.S.; providing that dispensing certain
61 | controlled substances in violation of specified provisions
62 | is a third-degree felony; providing penalties; amending s.
63 | 459.015, F.S.; providing that dispensing certain
64 | controlled substances in violation of specified provisions
65 | is grounds for disciplinary action; providing penalties;
66 | amending s. 465.015, F.S.; requiring a pharmacist to
67 | report to the sheriff within a specified period any
68 | instance in which a person fraudulently obtained or
69 | attempted to fraudulently obtain a controlled substance;
70 | providing criminal penalties; providing requirements for
71 | reports; amending s. 465.016, F.S.; providing additional
72 | grounds for denial of or disciplinary action against a
73 | pharmacist license; amending s. 465.018, F.S.; providing
74 | grounds for permit denial or discipline; requiring
75 | applicants to pay or make arrangements to pay amounts owed
76 | to the Department of Health; requiring an inspection;
77 | requiring permittees to maintain certain records;
78 | requiring community pharmacies to obtain a permit under
79 | chapter 465, F.S., as amended by the act by March 1, 2012,
80 | in order to dispense Schedule II and III controlled
81 | substances; amending s. 465.022, F.S.; requiring the
82 | Department of Health to adopt rules related to procedures
83 | for dispensing controlled substances; providing
84 | requirements for the issuance of a pharmacy permit;

85 requiring disclosure of financial interests; requiring
86 submission of policies and procedures and providing for
87 grounds for permit denial based on them; allowing the
88 Department of Health to phase-in the policies and
89 procedures requirement over an 18-month period beginning
90 July 1, 2011; requiring the Department of Health to deny a
91 permit to applicants under certain circumstances;
92 requiring permittees to provide notice of certain
93 management changes; requiring prescription department
94 managers to meet certain criteria; imposing duties on
95 prescription department managers; limiting the number of
96 locations a prescription department manager may manage;
97 requiring the board to adopt rules related to
98 recordkeeping; providing that permits are not
99 transferable; increasing the fee for a change of location;
100 amending s. 465.0276, F.S.; prohibiting registered
101 dispensing practitioners from dispensing certain
102 controlled substances; providing an exception for
103 dispensing controlled substances in the health care system
104 of the Department of Corrections; providing an exception
105 for dispensing within 7 days after surgery which used
106 general anesthesia; deleting a provision establishing a
107 72-hour supply limit on dispensing certain controlled
108 substances to certain patients in registered pain-
109 management clinics; amending s. 499.0051, F.S.; providing
110 criminal penalties for violations of certain provisions of
111 s. 499.0121, F.S.; amending s. 499.012, F.S.; requiring
112 wholesale distributor permit applicants to submit

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

141 amending s. 810.02, F.S.; authorizing separate judgments
142 and sentences for burglary with the intent to commit theft
143 of a controlled substance under specified provisions and
144 for any applicable possession of controlled substance
145 offense under specified provisions in certain
146 circumstances; amending s. 812.014, F.S.; authorizing
147 separate judgments and sentences for theft of a controlled
148 substance under specified provisions and for any
149 applicable possession of controlled substance offense
150 under specified provisions in certain circumstances;
151 amending s. 893.055, F.S., relating to the prescription
152 drug monitoring program; deleting obsolete dates; deleting
153 references to the Office of Drug Control; requiring
154 reports to the prescription drug monitoring system to be
155 made in 7 days rather than 15 days; prohibiting the use of
156 certain funds to implement the program; requiring the
157 State Surgeon General to appoint a board of directors for
158 the direct-support organization; conforming provisions to
159 changes made by the act; amending s. 893.065, F.S.;
160 conforming provisions to changes made by the act; amending
161 s. 893.07, F.S.; providing that law enforcement officers
162 are not required to obtain a subpoena, court order, or
163 search warrant in order to obtain access to or copies of
164 specified controlled substance inventory records;
165 requiring reporting of the discovery of the theft or loss
166 of controlled substances to the sheriff within a specified
167 period; providing criminal penalties; repealing s. 2 of
168 chapter 2009-198, Laws of Florida, relating to the Program

169 Implementation and Oversight Task Force in the Executive
 170 Office of the Governor concerning the electronic system
 171 established for the prescription drug monitoring program;
 172 providing a buyback program for undispensed controlled
 173 substance inventory held by specified licensed physicians;
 174 requiring certain certifications by the physician
 175 returning inventory to a distributor; providing an
 176 exemption to pedigree paper requirements; requiring
 177 reports of the program; providing for a declaration of a
 178 public health emergency; requiring certain actions
 179 relating to dispensing practitioners identified as posing
 180 the greatest threat to public health; providing an
 181 appropriation; providing for future repeal of program
 182 provisions; providing an effective date.

183
 184 Be It Enacted by the Legislature of the State of Florida:

185
 186 Section 1. Paragraph (mm) is added to subsection (1) of
 187 section 456.072, Florida Statutes, subsection (7) is
 188 redesignated as subsection (8), and a new subsection (7) is
 189 added to that section, to read:

190 456.072 Grounds for discipline; penalties; enforcement.—

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

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

196 (7) Any licensee who has been found to overprescribe or

197 inappropriately prescribe controlled substances in violation of
 198 s. 456.44, s. 458.331(1)(q) or (t), s. 459.015(t) or (x), s.
 199 461.013(1)(o) or (s), or s. 466.028(1)(p) or (x) shall be
 200 suspended for a period of not less than 6 months and pay a fine
 201 of not less than \$10,000 per count. Repeated violations shall
 202 result in increased penalties.

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

205 456.42 Written prescriptions for medicinal drugs.—

206 (1) A written prescription for a medicinal drug issued by
 207 a health care practitioner licensed by law to prescribe such
 208 drug must be legibly printed or typed so as to be capable of
 209 being understood by the pharmacist filling the prescription;
 210 must contain the name of the prescribing practitioner, the name
 211 and strength of the drug prescribed, the quantity of the drug
 212 prescribed, and the directions for use of the drug; must be
 213 dated; and must be signed by the prescribing practitioner on the
 214 day when issued. ~~A written prescription for a controlled~~
 215 ~~substance listed in chapter 893 must have the quantity of the~~
 216 ~~drug prescribed in both textual and numerical formats and must~~
 217 ~~be dated with the abbreviated month written out on the face of~~
 218 ~~the prescription.~~ However, a prescription that is electronically
 219 generated and transmitted must contain the name of the
 220 prescribing practitioner, the name and strength of the drug
 221 prescribed, the quantity of the drug prescribed in numerical
 222 format, and the directions for use of the drug and must be dated
 223 and signed by the prescribing practitioner only on the day
 224 issued, which signature may be in an electronic format as

225 defined in s. 668.003(4).

226 (2) A written prescription for a controlled substance
227 listed in chapter 893 must have the quantity of the drug
228 prescribed in both textual and numerical formats, must be dated
229 with the abbreviated month written out on the face of the
230 prescription, and must be either written on a standardized
231 counterfeit-proof prescription pad produced by a vendor approved
232 by the department or electronically prescribed as that term is
233 used in s. 408.0611. As a condition of being an approved vendor,
234 a prescription pad vendor must submit a monthly report to the
235 department which, at a minimum, documents the number of
236 prescription pads sold and identifies the purchasers. The
237 department may, by rule, require the reporting of additional
238 information.

239 Section 3. Section 456.44, Florida Statutes, is created to
240 read:

241 456.44 Controlled substance prescribing.-

242 (1) DEFINITIONS.-

243 (a) "Addiction medicine specialist" means a board-
244 certified psychiatrist with a subspecialty certification in
245 addiction medicine or who is eligible for such subspecialty
246 certification in addiction medicine, an addiction medicine
247 physician certified or eligible for certification by the
248 American Society of Addiction Medicine, or an osteopathic
249 physician who holds a certificate of added qualification in
250 Addiction Medicine through the American Osteopathic Association.

251
252 (b) "Adverse incident" means any incident set forth in s.

253 458.351(4)(a)-(e) or s. 459.026(4)(a)-(e).

254 (c) "Board-certified pain management physician" means a
255 physician who possesses board certification in pain medicine by
256 the American Board of Pain Medicine, board certification by the
257 American Board of Interventional Pain Physicians, or board
258 certification or subcertification in pain management by a
259 specialty board recognized by the American Association of
260 Physician Specialists or an osteopathic physician who holds a
261 certificate in Pain Management by the American Osteopathic
262 Association.

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

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

269 (2) REGISTRATION.—Effective January 1, 2012, a physician
270 licensed under chapter 458, chapter 459, chapter 461, or chapter
271 466 who prescribes any controlled substance, as defined in s.
272 893.03, for the treatment of chronic nonmalignant pain, must:

273 (a) Designate himself or herself as a controlled substance
274 prescribing practitioner on the physician's practitioner
275 profile.

276 (b) Comply with the requirements of this section and
277 applicable board rules.

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

281 licensure.

282 (a) A complete medical history and a physical examination
283 must be conducted before beginning any treatment and must be
284 documented in the medical record. The exact components of the
285 physical examination shall be left to the judgment of the
286 clinician who is expected to perform a physical examination
287 proportionate to the diagnosis that justifies a treatment. The
288 medical record must, at a minimum, document the nature and
289 intensity of the pain, current and past treatments for pain,
290 underlying or coexisting diseases or conditions, the effect of
291 the pain on physical and psychological function, a review of
292 previous medical records, previous diagnostic studies, and
293 history of alcohol and substance abuse. The medical record shall
294 also document the presence of one or more recognized medical
295 indications for the use of a controlled substance. Each
296 registrant must develop a written plan for assessing each
297 patient's risk of aberrant drug-related behavior, which may
298 include patient drug testing. Registrants must assess each
299 patient's risk for aberrant drug-related behavior and monitor
300 that risk on an ongoing basis in accordance with the plan.

301 (b) Each registrant must develop a written individualized
302 treatment plan for each patient. The treatment plan shall state
303 objectives that will be used to determine treatment success,
304 such as pain relief and improved physical and psychosocial
305 function, and shall indicate if any further diagnostic
306 evaluations or other treatments are planned. After treatment
307 begins, the physician shall adjust drug therapy to the
308 individual medical needs of each patient. Other treatment

309 modalities, including a rehabilitation program, shall be
310 considered depending on the etiology of the pain and the extent
311 to which the pain is associated with physical and psychosocial
312 impairment. The interdisciplinary nature of the treatment plan
313 shall be documented.

314 (c) The physician shall discuss the risks and benefits of
315 the use of controlled substances, including the risks of abuse
316 and addiction, as well as physical dependence and its
317 consequences, with the patient, persons designated by the
318 patient, or the patient's surrogate or guardian if the patient
319 is incompetent. The physician shall use a written controlled
320 substance agreement between the physician and the patient
321 outlining the patient's responsibilities, including, but not
322 limited to:

323 1. Number and frequency of controlled substance
324 prescriptions and refills.

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

327 3. An agreement that controlled substances for the
328 treatment of chronic nonmalignant pain shall be prescribed by a
329 single treating physician unless otherwise authorized by the
330 treating physician and documented in the medical record.

331 (d) The patient shall be seen by the physician at regular
332 intervals, not to exceed 3 months, to assess the efficacy of
333 treatment, ensure that controlled substance therapy remains
334 indicated, evaluate the patient's progress toward treatment
335 objectives, consider adverse drug effects, and review the
336 etiology of the pain. Continuation or modification of therapy

337 shall depend on the physician's evaluation of the patient's
338 progress. If treatment goals are not being achieved, despite
339 medication adjustments, the physician shall reevaluate the
340 appropriateness of continued treatment. The physician shall
341 monitor patient compliance in medication usage, related
342 treatment plans, controlled substance agreements, and
343 indications of substance abuse or diversion at a minimum of 3-
344 month intervals.

345 (e) The physician shall refer the patient as necessary for
346 additional evaluation and treatment in order to achieve
347 treatment objectives. Special attention shall be given to those
348 patients who are at risk for misusing their medications and
349 those whose living arrangements pose a risk for medication
350 misuse or diversion. The management of pain in patients with a
351 history of substance abuse or with a comorbid psychiatric
352 disorder requires extra care, monitoring, and documentation and
353 requires consultation with or referral to an addictionologist or
354 psychiatrist.

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

- 361 1. The complete medical history and a physical
362 examination, including history of drug abuse or dependence.
- 363 2. Diagnostic, therapeutic, and laboratory results.
- 364 3. Evaluations and consultations.

- 365 4. Treatment objectives.
- 366 5. Discussion of risks and benefits.
- 367 6. Treatments.
- 368 7. Medications, including date, type, dosage, and quantity
369 prescribed.
- 370 8. Instructions and agreements.
- 371 9. Periodic reviews.
- 372 10. Results of any drug testing.
- 373 11. A photocopy of the patient's government-issued photo
374 identification.
- 375 12. If a written prescription for a controlled substance
376 is given to the patient, a duplicate of the prescription.
- 377 13. The physician's full name presented in a legible
378 manner.
- 379 (g) Patients with signs or symptoms of substance abuse
380 shall be immediately referred to a board-certified pain
381 management physician, an addiction medicine specialist, or a
382 mental health addiction facility as it pertains to drug abuse or
383 addiction unless the physician is board-certified or board-
384 eligible in pain management. Throughout the period of time
385 before receiving the consultant's report, a prescribing
386 physician shall clearly and completely document medical
387 justification for continued treatment with controlled substances
388 and those steps taken to ensure medically appropriate use of
389 controlled substances by the patient. Upon receipt of the
390 consultant's written report, the prescribing physician shall
391 incorporate the consultant's recommendations for continuing,
392 modifying, or discontinuing controlled substance therapy. The

393 resulting changes in treatment shall be specifically documented
394 in the patient's medical record. Evidence or behavioral
395 indications of diversion shall be followed by discontinuation of
396 controlled substance therapy and the patient shall be discharged
397 and all results of testing and actions taken by the physician
398 shall be documented in the patient's medical record.

399
400 This subsection does not apply to a board-certified
401 anesthesiologist, physiatrist, or neurologist, or to a board-
402 certified physician who has surgical privileges at a hospital or
403 ambulatory surgery center and primarily provides surgical
404 services. This subsection does not apply to a board-certified
405 medical specialist who has also completed a fellowship in pain
406 medicine approved by the Accreditation Council for Graduate
407 Medical Education or the American Osteopathic Association, or
408 who is also board certified in pain medicine by a board approved
409 by the American Board of Medical Specialties or the American
410 Osteopathic Association and performs interventional pain
411 procedures of the type routinely billed using surgical codes.

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

414 458.3265 Pain-management clinics.—

415 (1) REGISTRATION.—

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

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

421 b. "Pain-management clinic" or "clinic" means a publicly
 422 or privately owned facility where in any month a majority of
 423 patients are prescribed opioids, benzodiazepines, barbiturates,
 424 or carisoprodol for the treatment of chronic nonmalignant pain.
 425 ~~All privately owned pain-management clinics, facilities, or~~
 426 ~~offices, hereinafter referred to as "clinics," which advertise~~
 427 ~~in any medium for any type of pain-management services, or~~
 428 ~~employ a physician who is primarily engaged in the treatment of~~
 429 ~~pain by prescribing or dispensing controlled substance~~
 430 ~~medications,~~

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

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

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

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

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

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

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

448 g. The clinic is wholly owned and operated by one or more

449 board-certified anesthesiologists, physiatrists or neurologists;
450 or

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

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

461 (c) As a part of registration, a clinic must designate a
462 physician who is responsible for complying with all requirements
463 related to registration and operation of the clinic in
464 compliance with this section. Within 10 days after termination
465 of a designated physician, the clinic must notify the department
466 of the identity of another designated physician for that clinic.
467 The designated physician shall have a full, active, and
468 unencumbered license under this chapter or chapter 459 and shall
469 practice at the clinic location for which the physician has
470 assumed responsibility. Failing to have a licensed designated
471 physician practicing at the location of the registered clinic
472 may be the basis for a summary suspension of the clinic
473 registration certificate as described in s. 456.073(8) for a
474 license or s. 120.60(6).

475 (d) The department shall deny registration to any clinic
476 that is not fully owned by a physician licensed under this

477 chapter or chapter 459 or a group of physicians, each of whom is
 478 licensed under this chapter or chapter 459; or that is not a
 479 health care clinic licensed under part X of chapter 400.

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

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

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

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

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

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

510 (h) If the registration of a pain-management clinic is
511 revoked or suspended, the designated physician of the pain-
512 management clinic, the owner or lessor of the pain-management
513 clinic property, the manager, and the proprietor shall cease to
514 operate the facility as a pain-management clinic as of the
515 effective date of the suspension or revocation.

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

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

529 (k) If the clinic's registration is revoked, any person
530 named in the registration documents of the pain-management
531 clinic, including persons owning or operating the pain-
532 management clinic, may not, as an individual or as a part of a

533 group, apply to operate a pain-management clinic for 5 years
534 after the date the registration is revoked.

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

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

540 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
541 apply to any physician who provides professional services in a
542 pain-management clinic that is required to be registered in
543 subsection (1).

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

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

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

555

556 Any physician who qualifies to practice medicine in a pain-
557 management clinic pursuant to rules adopted by the Board of
558 Medicine as of July 1, 2012, may continue to practice medicine
559 in a pain-management clinic as long as the physician continues
560 to meet the qualifications set forth in the board rules. A

561 physician who violates this paragraph is subject to disciplinary
 562 action by his or her appropriate medical regulatory board.

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

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

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

587 (e) The designated physician of a pain-management clinic
 588 shall notify the applicable board in writing of the date of

589 termination of employment within 10 days after terminating his
590 or her employment with a pain-management clinic that is required
591 to be registered under subsection (1). Each physician practicing
592 in a pain-management clinic shall advise the Board of Medicine,
593 in writing, within 10 calendar days after beginning or ending
594 his or her practice at a pain-management clinic.

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

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

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

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

606 c. Have emergency lighting and communications.

607 d. Have a reception and waiting area.

608 e. Provide a restroom.

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

611 g. Have private patient examination rooms.

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

614 i. Display a printed sign located in a conspicuous place
615 in the waiting room viewable by the public with the name and
616 contact information of the clinic's designated physician and the

617 names of all physicians practicing in the clinic.

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

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

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

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

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

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

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

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

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

639 a. Prioritized risks.

640 b. Limiting unprotected exposure to pathogens.

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

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

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

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

652 2. The clinic shall have evacuation procedures in the
653 event of an emergency, which shall include provisions for the
654 evacuation of disabled patients and employees.

655 3. The clinic shall have a written facility-specific
656 disaster plan setting forth actions that will be taken in the
657 event of clinic closure due to unforeseen disasters and shall
658 include provisions for the protection of medical records and any
659 controlled substances.

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

664 (i) The designated physician is responsible for ensuring
665 compliance with the following quality assurance requirements.
666 Each pain management clinic shall have an ongoing quality
667 assurance program that objectively and systematically monitors
668 and evaluates the quality and appropriateness of patient care,
669 evaluates methods to improve patient care, identifies and
670 corrects deficiencies within the facility, alerts the designated
671 physician to identify and resolve recurring problems, and
672 provides for opportunities to improve the facility's performance

673 and to enhance and improve the quality of care provided to the
674 public. The designated physician shall establish a quality
675 assurance program that includes the following components:

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

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

679 3. The development of measures to correct, reduce,
680 minimize, or eliminate the risk of adverse incidents to
681 patients.

682 4. The documentation of these functions and periodic
683 review no less than quarterly of such information by the
684 designated physician.

685 (j) The designated physician is responsible for ensuring
686 compliance with the following data collection and reporting
687 requirements:

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

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

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

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

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

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

701 domicile is located somewhere other than in this state. A
702 patient's domicile is the patient's fixed or permanent home to
703 which he or she intends to return even though he or she may
704 temporarily reside elsewhere.

705 (3) INSPECTION.—

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

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

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

720 (4) RULEMAKING.—

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

725 ~~(b) The department shall adopt a rule defining what~~
726 ~~constitutes practice by a designated physician at the clinic~~
727 ~~location for which the physician has assumed responsibility, as~~
728 ~~set forth in subsection (1). When adopting the rule, the~~

729 ~~department shall consider the number of clinic employees, the~~
730 ~~location of the pain management clinic, the clinic's hours of~~
731 ~~operation, and the amount of controlled substances being~~
732 ~~prescribed, dispensed, or administered at the pain management~~
733 ~~clinic.~~

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

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

- 745 ~~1. Facility operations;~~
- 746 ~~2. Physical operations;~~
- 747 ~~3. Infection control requirements;~~
- 748 ~~4. Health and safety requirements;~~
- 749 ~~5. Quality assurance requirements;~~
- 750 ~~6. Patient records;~~
- 751 ~~7. training requirements for all facility health care~~
752 ~~practitioners who are not regulated by another board.~~
- 753 ~~8. Inspections; and~~
- 754 ~~9. Data collection and reporting requirements.~~

755
756 ~~A physician is primarily engaged in the treatment of pain by~~

757 ~~prescribing or dispensing controlled substance medications when~~
 758 ~~the majority of the patients seen are prescribed or dispensed~~
 759 ~~controlled substance medications for the treatment of chronic~~
 760 ~~nonmalignant pain. Chronic nonmalignant pain is pain unrelated~~
 761 ~~to cancer which persists beyond the usual course of the disease~~
 762 ~~or the injury that is the cause of the pain or more than 90 days~~
 763 ~~after surgery.~~

764 (5) PENALTIES; ENFORCEMENT.—

765 (a) The department may impose an administrative fine on
 766 the clinic of up to \$5,000 per violation for violating the
 767 requirements of this section; chapter 499, the Florida Drug and
 768 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
 769 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
 770 Abuse Prevention and Control Act; chapter 893, the Florida
 771 Comprehensive Drug Abuse Prevention and Control Act; or the
 772 rules of the department. In determining whether a penalty is to
 773 be imposed, and in fixing the amount of the fine, the department
 774 shall consider the following factors:

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

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

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

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

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

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

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

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

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

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

805 458.327 Penalty for violations.—

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

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

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

813 458.331 Grounds for disciplinary action; action by the
814 board and department.—

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

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

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

821 459.0137 Pain-management clinics.—

822 (1) REGISTRATION.—

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

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

828 b. "Pain-management clinic" or "clinic" means a publicly
829 or privately owned facility where in any month a majority of
830 patients are prescribed opioids, benzodiazepines, barbiturates,
831 or carisoprodol for the treatment of chronic nonmalignant pain.
832 ~~All privately owned pain-management clinics, facilities, or~~
833 ~~offices, hereinafter referred to as "clinics," which advertise~~
834 ~~in any medium for any type of pain-management services, or~~
835 ~~employ an osteopathic physician who is primarily engaged in the~~
836 ~~treatment of pain by prescribing or dispensing controlled~~
837 ~~substance medications,~~

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

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

841 chapter 395;

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

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

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

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

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

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

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

867 (b) Each clinic location shall be registered separately
868 regardless of whether the clinic is operated under the same

869 business name or management as another clinic.

870 (c) As a part of registration, a clinic must designate an
871 osteopathic physician who is responsible for complying with all
872 requirements related to registration and operation of the clinic
873 in compliance with this section. Within 10 days after
874 termination of a designated osteopathic physician, the clinic
875 must notify the department of the identity of another designated
876 physician for that clinic. The designated physician shall have a
877 full, active, and unencumbered license under chapter 458 or this
878 chapter and shall practice at the clinic location for which the
879 physician has assumed responsibility. Failing to have a licensed
880 designated osteopathic physician practicing at the location of
881 the registered clinic may be the basis for a summary suspension
882 of the clinic registration certificate as described in s.
883 456.073(8) for a license or s. 120.60(6).

884 (d) The department shall deny registration to any clinic
885 that is not fully owned by a physician licensed under chapter
886 458 or this chapter or a group of physicians, each of whom is
887 licensed under chapter 458 or this chapter; or that is not a
888 health care clinic licensed under part X of chapter 400.

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

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

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

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

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

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

919 (h) If the registration of a pain-management clinic is
920 revoked or suspended, the designated physician of the pain-
921 management clinic, the owner or lessor of the pain-management
922 clinic property, the manager, and the proprietor shall cease to
923 operate the facility as a pain-management clinic as of the
924 effective date of the suspension or revocation.

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

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

938 (k) If the clinic's registration is revoked, any person
939 named in the registration documents of the pain-management
940 clinic, including persons owning or operating the pain-
941 management clinic, may not, as an individual or as a part of a
942 group, make application for a permit to operate a pain-
943 management clinic for 5 years after the date the registration is
944 revoked.

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

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

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

953 registered in subsection (1).

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

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

958 2. Effective July 1, 2012, the physician has not
959 successfully completed a pain-medicine fellowship that is
960 accredited by the Accreditation Council for Graduate Medical
961 Education or the American Osteopathic Association or a pain-
962 medicine residency that is accredited by the Accreditation
963 Council for Graduate Medical Education or the American
964 Osteopathic Association or, prior to July 1, 2012, does not
965 comply with rules adopted by the board.

966
967 Any physician who qualifies to practice medicine in a pain-
968 management clinic pursuant to rules adopted by the Board of
969 Osteopathic Medicine as of July 1, 2012, may continue to
970 practice medicine in a pain-management clinic as long as the
971 physician continues to meet the qualifications set forth in the
972 board rules. An osteopathic physician who violates this
973 paragraph is subject to disciplinary action by his or her
974 appropriate medical regulatory board.

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

979 (c) An osteopathic physician, a physician assistant, or an
980 advanced registered nurse practitioner must perform an a

981 appropriate medical ~~physical~~ examination of a patient on the
 982 same day that the physician ~~he or she dispenses or prescribes~~ a
 983 controlled substance to a patient at a pain-management clinic.
 984 If the osteopathic physician prescribes ~~or dispenses~~ more than a
 985 72-hour dose of controlled substances for the treatment of
 986 chronic nonmalignant pain, the osteopathic physician must
 987 document in the patient's record the reason for prescribing ~~or~~
 988 ~~dispensing~~ that quantity.

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

1000 (e) The designated osteopathic physician of a pain-
 1001 management clinic shall notify the applicable board in writing
 1002 of the date of termination of employment within 10 days after
 1003 terminating his or her employment with a pain-management clinic
 1004 that is required to be registered under subsection (1). Each
 1005 osteopathic physician practicing in a pain-management clinic
 1006 shall advise the Board of Osteopathic Medicine in writing within
 1007 10 calendar days after beginning or ending his or her practice
 1008 at a pain-management clinic.

1009 (f) Each osteopathic physician practicing in a pain
 1010 management clinic is responsible for ensuring compliance with
 1011 the following facility and physical operations requirements:
 1012 1. A pain-management clinic shall be located and operated
 1013 at a publicly accessible fixed location and must:
 1014 a. Display a sign that can be viewed by the public that
 1015 contains the clinic name, hours of operations, and a street
 1016 address.
 1017 b. Have a publicly listed telephone number and a dedicated
 1018 phone number to send and receive faxes with a fax machine that
 1019 shall be operational 24 hours per day.
 1020 c. Have emergency lighting and communications.
 1021 d. Have a reception and waiting area.
 1022 e. Provide a restroom.
 1023 f. Have an administrative area including room for storage
 1024 of medical records, supplies and equipment.
 1025 g. Have private patient examination rooms.
 1026 h. Have treatment rooms, if treatment is being provided to
 1027 the patient.
 1028 i. Display a printed sign located in a conspicuous place
 1029 in the waiting room viewable by the public with the name and
 1030 contact information of the clinic-designated physician and the
 1031 names of all physicians practicing in the clinic.
 1032 j. If the clinic stores and dispenses prescription drug,
 1033 comply with ss. 499.0121 and 893.07.
 1034 2. This section does not excuse an osteopathic physician
 1035 from providing any treatment or performing any medical duty
 1036 without the proper equipment and materials as required by the

1037 standard of care. This section does not supersede the level of
 1038 care, skill, and treatment recognized in general law related to
 1039 healthcare licensure.

1040 (g) Each osteopathic physician practicing in a pain
 1041 management clinic is responsible for ensuring compliance with
 1042 the following infection control requirements.

1043 1. The clinic shall maintain equipment and supplies to
 1044 support infection prevention and control activities.

1045 2. The clinic shall identify infection risks based on the
 1046 following:

1047 a. Geographic location, community, and population served.

1048 b. The care, treatment and services it provides.

1049 c. An analysis of its infection surveillance and control
 1050 data.

1051 3. The clinic shall maintain written infection prevention
 1052 policies and procedures that address the following:

1053 a. Prioritized risks.

1054 b. Limiting unprotected exposure to pathogen.

1055 c. Limiting the transmission of infections associated with
 1056 procedures performed in the clinic.

1057 d. Limiting the transmission of infections associated with
 1058 the clinic's use of medical equipment, devices, and supplies.

1059 (h) Each osteopathic physician practicing in a pain
 1060 management clinic is responsible for ensuring compliance with
 1061 the following health and safety requirements.

1062 1. The clinic, including its grounds, buildings,
 1063 furniture, appliances, and equipment shall be structurally
 1064 sound, in good repair, clean, and free from health and safety

1065 hazards.

1066 2. The clinic shall have evacuation procedures in the
 1067 event of an emergency which shall include provisions for the
 1068 evacuation of disabled patients and employees.

1069 3. The clinic shall have a written facility-specific
 1070 disaster plan which sets forth actions that will be taken in the
 1071 event of clinic closure due to unforeseen disasters and shall
 1072 include provisions for the protection of medical records and any
 1073 controlled substances.

1074 4. Each clinic shall have at least one employee on the
 1075 premises during patient care hours who is certified in Basic
 1076 Life Support and is trained in reacting to accidents and medical
 1077 emergencies until emergency medical personnel arrive.

1078 (i) The designated physician is responsible for ensuring
 1079 compliance with the following quality assurance requirements.
 1080 Each pain management clinic shall have an ongoing quality
 1081 assurance program that objectively and systematically monitors
 1082 and evaluates the quality and appropriateness of patient care,
 1083 evaluates methods to improve patient care, identifies and
 1084 corrects deficiencies within the facility, alerts the designated
 1085 physician to identify and resolve recurring problems, and
 1086 provides for opportunities to improve the facility's performance
 1087 and to enhance and improve the quality of care provided to the
 1088 public. The designated physician shall establish a quality
 1089 assurance program that includes the following components:

1090 1. The identification, investigation, and analysis of the
 1091 frequency and causes of adverse incidents to patients.

1092 2. The identification of trends or patterns of incidents.

1093 3. The development of measures to correct, reduce,
 1094 minimize, or eliminate the risk of adverse incidents to
 1095 patients.

1096 4. The documentation of these functions and periodic
 1097 review no less than quarterly of such information by the
 1098 designated physician.

1099 (j) The designated physician is responsible for ensuring
 1100 compliance with the following data collection and reporting
 1101 requirements:

1102 1. The designated physician for each pain-management
 1103 clinic shall report all adverse incidents to the department as
 1104 set forth in s. 459.026.

1105 2. The designated physician shall also report to the Board
 1106 of Osteopathic Medicine, in writing, on a quarterly basis, the
 1107 following data:

1108 a. Number of new and repeat patients seen and treated at
 1109 the clinic who are prescribed controlled substance medications
 1110 for the treatment of chronic, nonmalignant pain.

1111 b. The number of patients discharged due to drug abuse.

1112 c. The number of patients discharged due to drug
 1113 diversion.

1114 d. The number of patients treated at the pain clinic whose
 1115 domicile is located somewhere other than in this state. A
 1116 patient's domicile is the patient's fixed or permanent home to
 1117 which he or she intends to return even though he or she may
 1118 temporarily reside elsewhere.

1119 (3) INSPECTION.—

1120 (a) The department shall inspect the pain-management

1121 clinic annually, including a review of the patient records, to
 1122 ensure that it complies with this section and the rules of the
 1123 Board of Osteopathic Medicine adopted pursuant to subsection (4)
 1124 unless the clinic is accredited by a nationally recognized
 1125 accrediting agency approved by the Board of Osteopathic
 1126 Medicine.

1127 (b) During an onsite inspection, the department shall make
 1128 a reasonable attempt to discuss each violation with the owner or
 1129 designated physician of the pain-management clinic before
 1130 issuing a formal written notification.

1131 (c) Any action taken to correct a violation shall be
 1132 documented in writing by the owner or designated physician of
 1133 the pain-management clinic and verified by followup visits by
 1134 departmental personnel.

1135 (4) RULEMAKING.—

1136 (a) The department shall adopt rules necessary to
 1137 administer the registration and inspection of pain-management
 1138 clinics which establish the specific requirements, procedures,
 1139 forms, and fees.

1140 ~~(b) The department shall adopt a rule defining what~~
 1141 ~~constitutes practice by a designated osteopathic physician at~~
 1142 ~~the clinic location for which the physician has assumed~~
 1143 ~~responsibility, as set forth in subsection (1). When adopting~~
 1144 ~~the rule, the department shall consider the number of clinic~~
 1145 ~~employees, the location of the pain-management clinic, the~~
 1146 ~~clinic's hours of operation, and the amount of controlled~~
 1147 ~~substances being prescribed, dispensed, or administered at the~~
 1148 ~~pain-management clinic.~~

1149 ~~(c) The Board of Osteopathic Medicine shall adopt a rule~~
 1150 ~~establishing the maximum number of prescriptions for Schedule II~~
 1151 ~~or Schedule III controlled substances or the controlled~~
 1152 ~~substance Alprazolam which may be written at any one registered~~
 1153 ~~pain-management clinic during any 24-hour period.~~

1154 (b)~~(d)~~ The Board of Osteopathic Medicine shall adopt rules
 1155 setting forth ~~standards of practice for osteopathic physicians~~
 1156 ~~practicing in privately owned pain-management clinics that~~
 1157 ~~primarily engage in the treatment of pain by prescribing or~~
 1158 ~~dispensing controlled substance medications. Such rules shall~~
 1159 ~~address, but need not be limited to:~~

- 1160 ~~1. Facility operations;~~
- 1161 ~~2. Physical operations;~~
- 1162 ~~3. Infection control requirements;~~
- 1163 ~~4. Health and safety requirements;~~
- 1164 ~~5. Quality assurance requirements;~~
- 1165 ~~6. Patient records;~~
- 1166 ~~7. training requirements for all facility health care~~
 1167 ~~practitioners who are not regulated by another board.~~
- 1168 ~~8. Inspections; and~~
- 1169 ~~9. Data collection and reporting requirements.~~

1171 ~~An osteopathic physician is primarily engaged in the treatment~~
 1172 ~~of pain by prescribing or dispensing controlled substance~~
 1173 ~~medications when the majority of the patients seen are~~
 1174 ~~prescribed or dispensed controlled substance medications for the~~
 1175 ~~treatment of chronic nonmalignant pain. Chronic nonmalignant~~
 1176 ~~pain is pain unrelated to cancer which persists beyond the usual~~

1177 ~~course of the disease or the injury that is the cause of the~~
 1178 ~~pain or more than 90 days after surgery.~~

1179 (5) PENALTIES; ENFORCEMENT.—

1180 (a) The department may impose an administrative fine on
 1181 the clinic of up to \$5,000 per violation for violating the
 1182 requirements of this section; chapter 499, the Florida Drug and
 1183 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
 1184 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
 1185 Abuse Prevention and Control Act; chapter 893, the Florida
 1186 Comprehensive Drug Abuse Prevention and Control Act; or the
 1187 rules of the department. In determining whether a penalty is to
 1188 be imposed, and in fixing the amount of the fine, the department
 1189 shall consider the following factors:

1190 1. The gravity of the violation, including the probability
 1191 that death or serious physical or emotional harm to a patient
 1192 has resulted, or could have resulted, from the pain-management
 1193 clinic's actions or the actions of the osteopathic physician,
 1194 the severity of the action or potential harm, and the extent to
 1195 which the provisions of the applicable laws or rules were
 1196 violated.

1197 2. What actions, if any, the owner or designated
 1198 osteopathic physician took to correct the violations.

1199 3. Whether there were any previous violations at the pain-
 1200 management clinic.

1201 4. The financial benefits that the pain-management clinic
 1202 derived from committing or continuing to commit the violation.

1203 (b) Each day a violation continues after the date fixed
 1204 for termination of the violation as ordered by the department

1205 constitutes an additional, separate, and distinct violation.

1206 (c) The department may impose a fine and, in the case of
 1207 an owner-operated pain-management clinic, revoke or deny a pain-
 1208 management clinic's registration, if the clinic's designated
 1209 osteopathic physician knowingly and intentionally misrepresents
 1210 actions taken to correct a violation.

1211 (d) An owner or designated osteopathic physician of a
 1212 pain-management clinic who concurrently operates an unregistered
 1213 pain-management clinic is subject to an administrative fine of
 1214 \$5,000 per day.

1215 (e) If the owner of a pain-management clinic that requires
 1216 registration fails to apply to register the clinic upon a change
 1217 of ownership and operates the clinic under the new ownership,
 1218 the owner is subject to a fine of \$5,000.

1219 (6) EXPIRATION.—This section expires January 1, 2016.

1220 Section 8. Paragraph (f) is added to subsection (1) of
 1221 section 459.013, Florida Statutes, to read:

1222 459.013 Penalty for violations.—

1223 (1) Each of the following acts constitutes a felony of the
 1224 third degree, punishable as provided in s. 775.082, s. 775.083,
 1225 or s. 775.084:

1226 (f) Dispensing a controlled substance listed in Schedule
 1227 II or Schedule III in violation of s. 465.0276.

1228 Section 9. Paragraph (tt) is added to subsection (1) of
 1229 section 459.015, Florida Statutes, to read:

1230 459.015 Grounds for disciplinary action; action by the
 1231 board and department.—

1232 (1) The following acts constitute grounds for denial of a

1233 license or disciplinary action, as specified in s. 456.072(2):

1234 (tt) Dispensing a controlled substance listed in Schedule
 1235 II or Schedule III in violation of s. 465.0276.

1236 Section 10. Subsections (3) and (4) of section 465.015,
 1237 Florida Statutes, are renumbered as subsections (4) and (5),
 1238 respectively, a new subsection (3) is added to that section, and
 1239 present subsection (4) of that section is amended, to read:

1240 465.015 Violations and penalties.—

1241 (3) It is unlawful for any pharmacist to fail to report to
 1242 the sheriff of the county where the pharmacy is located within
 1243 24 hours after learning of any instance in which a person
 1244 obtained or attempted to obtain a controlled substance, as
 1245 defined in s. 893.02, that the pharmacist knew or reasonably
 1246 should have known was obtained or attempted to be obtained from
 1247 the pharmacy through fraudulent methods or representations. Any
 1248 pharmacist who fails to make such a report within 24 hours after
 1249 learning of the fraud or attempted fraud commits a misdemeanor
 1250 of the first degree, punishable as provided in s. 775.082 or s.
 1251 775.083. A sufficient report of the fraudulent obtaining of
 1252 controlled substances under this subsection shall contain, at a
 1253 minimum, a copy of the prescription used or presented and a
 1254 narrative, including all information available to the pharmacy
 1255 concerning the transaction, such as the name and telephone
 1256 number of the prescribing physician; the name, description, and
 1257 any personal identification information pertaining to the person
 1258 who presented the prescription; and all other material
 1259 information, such as photographic or video surveillance of the
 1260 transaction.

1261 (5)~~(4)~~ Any person who violates any provision of subsection
 1262 (1) or subsection (4) ~~(3)~~ commits a misdemeanor of the first
 1263 degree, punishable as provided in s. 775.082 or s. 775.083. Any
 1264 person who violates any provision of subsection (2) commits a
 1265 felony of the third degree, punishable as provided in s.
 1266 775.082, s. 775.083, or s. 775.084. In any warrant, information,
 1267 or indictment, it shall not be necessary to negative any
 1268 exceptions, and the burden of any exception shall be upon the
 1269 defendant.

1270 Section 11. Paragraph (t) is added to subsection (1) of
 1271 section 465.016, Florida Statutes, to read:

1272 465.016 Disciplinary actions.—

1273 (1) The following acts constitute grounds for denial of a
 1274 license or disciplinary action, as specified in s. 456.072(2):

1275 (t) Committing an error or omission during the performance
 1276 of a specific function of prescription drug processing, which
 1277 includes, for purposes of this paragraph:

- 1278 1. Receiving, interpreting, or clarifying a prescription.
- 1279 2. Entering prescription data into the pharmacy's record.
- 1280 3. Verifying or validating a prescription.
- 1281 4. Performing pharmaceutical calculations.
- 1282 5. Performing prospective drug review as defined by the
 1283 board.
- 1284 6. Obtaining refill and substitution authorizations.
- 1285 7. Interpreting or acting on clinical data.
- 1286 8. Performing therapeutic interventions.
- 1287 9. Providing drug information concerning a patient's
 1288 prescription.

1289 10. Providing patient counseling.

1290 Section 12. Section 465.018, Florida Statutes, is amended
1291 to read:

1292 465.018 Community pharmacies; permits.—

1293 (1) Any person desiring a permit to operate a community
1294 pharmacy shall apply to the department.

1295 (2) If the board office certifies that the application
1296 complies with the laws of the state and the rules of the board
1297 governing pharmacies, the department shall issue the permit. No
1298 permit shall be issued unless a licensed pharmacist is
1299 designated as the prescription department manager ~~responsible~~
1300 ~~for maintaining all drug records, providing for the security of~~
1301 ~~the prescription department, and following such other rules as~~
1302 ~~relate to the practice of the profession of pharmacy. The~~
1303 ~~permittee and the newly designated prescription department~~
1304 ~~manager shall notify the department within 10 days of any change~~
1305 ~~in prescription department manager.~~

1306 (3) The board may suspend or revoke the permit of, or may
1307 refuse to issue a permit to:

1308 (a) Any person who has been disciplined or who has
1309 abandoned a permit or allowed a permit to become void after
1310 written notice that disciplinary proceedings had been or would
1311 be brought against the permit;

1312 (b) Any person who is an officer, director, or person
1313 interested directly or indirectly in a person or business entity
1314 that has had a permit disciplined or abandoned or become void
1315 after written notice that disciplinary proceedings had been or
1316 would be brought against the permit; or

1317 (c) Any person who is or has been an officer of a business
1318 entity, or who was interested directly or indirectly in a
1319 business entity, the permit of which has been disciplined or
1320 abandoned or become null and void after written notice that
1321 disciplinary proceedings had been or would be brought against
1322 the permit.

1323 (4) In addition to any other remedies provided by law, the
1324 board may deny the application or suspend or revoke the license,
1325 registration, or certificate of any entity regulated or licensed
1326 by it if the applicant, licensee, registrant, or licenseholder,
1327 or, in the case of a corporation, partnership, or other business
1328 entity, if any officer, director, agent, or managing employee of
1329 that business entity or any affiliated person, partner, or
1330 shareholder having an ownership interest equal to 5 percent or
1331 greater in that business entity, has failed to pay all
1332 outstanding fines, liens, or overpayments assessed by final
1333 order of the department, unless a repayment plan is approved by
1334 the department; or for failure to comply with any repayment
1335 plan.

1336 (5) In reviewing any application requesting a change of
1337 ownership or a change of licensee or registrant, the transferor
1338 shall, before board approval of the change, repay or make
1339 arrangements to repay any amounts owed to the department. If the
1340 transferor fails to repay or make arrangements to repay the
1341 amounts owed to the department, the license or registration may
1342 not be issued to the transferee until repayment or until
1343 arrangements for repayment are made.

1344 (6) Passing an onsite inspection is a prerequisite to the

1345 issuance of an initial permit or a permit for a change of
 1346 location. The department must make the inspection within 90 days
 1347 before issuance of the permit.

1348 (7) Community pharmacies that dispense controlled
 1349 substances must maintain a record of all controlled substance
 1350 dispensing consistent with the requirements of s. 893.07 and
 1351 must make the record available to the department and law
 1352 enforcement agencies upon request.

1353 Section 13. In order to dispense controlled substances
 1354 listed in Schedule II or Schedule III, as provided in s. 893.03,
 1355 Florida Statutes, on or after March 1, 2012, a community
 1356 pharmacy permittee must be permitted pursuant to chapter 465,
 1357 Florida Statutes, as amended by this act and any rules adopted
 1358 thereunder.

1359 Section 14. Section 465.022, Florida Statutes, is amended
 1360 to read:

1361 465.022 Pharmacies; general requirements; fees.—

1362 (1) The board shall adopt rules pursuant to ss. 120.536(1)
 1363 and 120.54 to implement the provisions of this chapter. Such
 1364 rules shall include, but shall not be limited to, rules relating
 1365 to:

1366 (a) General drug safety measures.

1367 (b) Minimum standards for the physical facilities of
 1368 pharmacies.

1369 (c) Safe storage of floor-stock drugs.

1370 (d) Functions of a pharmacist in an institutional
 1371 pharmacy, consistent with the size and scope of the pharmacy.

1372 (e) Procedures for the safe storage and handling of

1373 radioactive drugs.

1374 (f) Procedures for the distribution and disposition of
1375 medicinal drugs distributed pursuant to s. 499.028.

1376 (g) Procedures for transfer of prescription files and
1377 medicinal drugs upon the change of ownership or closing of a
1378 pharmacy.

1379 (h) Minimum equipment which a pharmacy shall at all times
1380 possess to fill prescriptions properly.

1381 (i) Procedures for the dispensing of controlled substances
1382 to minimize dispensing based on fraudulent representations or
1383 invalid practitioner-patient relationships.

1384 (2) A pharmacy permit may ~~shall~~ be issued only to a
1385 natural person who is at least 18 years of age, to a partnership
1386 comprised of at least one natural person and all of whose
1387 partners are all at least 18 years of age, to a government
1388 agency, or to a business entity that is properly registered with
1389 the Secretary of State, if required by law, and has been issued
1390 a federal employer tax identification number ~~corporation that is~~
1391 ~~registered pursuant to chapter 607 or chapter 617 whose~~
1392 ~~officers, directors, and shareholders are at least 18 years of~~
1393 ~~age.~~ Permits issued to business entities may be issued only to
1394 entities whose affiliated persons, members, partners, officers,
1395 directors, and agents, including persons required to be
1396 fingerprinted under subsection (3), are not less than 18 years
1397 of age.

1398 (3) Any person or business entity, ~~partnership, or~~
1399 ~~corporation~~ before engaging in the operation of a pharmacy,
1400 shall file with the board a sworn application on forms provided

1401 by the department. For purposes of this section, any person
 1402 required to provide fingerprints under this subsection is an
 1403 affiliated person within the meaning of s. 465.023(1).

1404 (a) An application for a pharmacy permit must include a
 1405 set of fingerprints from each person having an ownership
 1406 interest of 5 percent or greater and from any person who,
 1407 directly or indirectly, manages, oversees, or controls the
 1408 operation of the applicant, including officers and members of
 1409 the board of directors of an applicant that is a corporation.
 1410 The applicant must provide payment in the application for the
 1411 cost of state and national criminal history records checks.

1412 1. For corporations having more than \$100 million of
 1413 business taxable assets in this state, in lieu of these
 1414 fingerprint requirements, the department shall require the
 1415 prescription department manager or consultant pharmacist of
 1416 record who will be directly involved in the management and
 1417 operation of the pharmacy to submit a set of fingerprints.

1418 2. A representative of a corporation described in
 1419 subparagraph 1. satisfies the requirement to submit a set of his
 1420 or her fingerprints if the fingerprints are on file with the
 1421 department or the Agency for Health Care Administration, meet
 1422 the fingerprint specifications for submission by the Department
 1423 of Law Enforcement, and are available to the department.

1424 (b) The department shall submit the fingerprints provided
 1425 by the applicant to the Department of Law Enforcement for a
 1426 state criminal history records check. The Department of Law
 1427 Enforcement shall forward the fingerprints to the Federal Bureau
 1428 of Investigation for a national criminal history records check.

1429 (c) In addition to those documents required by the
 1430 department or board, each applicant with any financial or
 1431 ownership interest greater than 5 percent in the subject of the
 1432 application must submit a signed affidavit disclosing any
 1433 financial or ownership interest greater than 5 percent in any
 1434 pharmacy permitted in the past 5 years, which pharmacy has
 1435 closed voluntarily or involuntarily, has filed a voluntary
 1436 relinquishment of its permit, has had its permit suspended or
 1437 revoked, or has had an injunction issued against it by a
 1438 regulatory agency. The affidavit must disclose the reason such
 1439 entity was closed, whether voluntary or involuntary.

1440 (4) An application for a pharmacy permit must include the
 1441 applicant's written policies and procedures for preventing
 1442 controlled substance dispensing based on fraudulent
 1443 representations or invalid practitioner-patient relationships.
 1444 The board must review the policies and procedures and may deny a
 1445 permit if the policies and procedures are insufficient to
 1446 reasonably prevent such dispensing. The department may phase in
 1447 the submission and review of policies and procedures over one
 1448 18-month period beginning July 1, 2011.

1449 (5)~~(4)~~ The department or board shall deny an application
 1450 for a pharmacy permit if the applicant or an affiliated person,
 1451 partner, officer, director, or prescription department manager
 1452 or consultant pharmacist of record of the applicant ~~has:~~

1453 (a) Has obtained a permit by misrepresentation or fraud.~~†~~

1454 (b) Has attempted to procure, or has procured, a permit
 1455 for any other person by making, or causing to be made, any false
 1456 representation.~~†~~

1457 (c) Has been convicted of, or entered a plea of guilty or
 1458 nolo contendere to, regardless of adjudication, a crime in any
 1459 jurisdiction which relates to the practice of, or the ability to
 1460 practice, the profession of pharmacy.~~†~~

1461 (d) Has been convicted of, or entered a plea of guilty or
 1462 nolo contendere to, regardless of adjudication, a crime in any
 1463 jurisdiction which relates to health care fraud.~~†~~

1464 (e) Has been convicted of, or entered a plea of guilty or
 1465 nolo contendere to, regardless of adjudication, a felony under
 1466 chapter 409, chapter 817, or chapter 893, or a similar felony
 1467 offense committed in another state or jurisdiction, since July
 1468 1, 2009. Been terminated for cause, pursuant to the appeals
 1469 procedures established by the state or Federal Government, from
 1470 any state Medicaid program or the federal Medicare program,
 1471 unless the applicant has been in good standing with a state
 1472 Medicaid program or the federal Medicare program for the most
 1473 recent 5 years and the termination occurred at least 20 years
 1474 ago; or

1475 (f) Has been convicted of, or entered a plea of guilty or
 1476 nolo contendere to, regardless of adjudication, a felony under
 1477 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1,
 1478 2009.

1479 (g) Has been terminated for cause from the Florida
 1480 Medicaid program pursuant to s. 409.913, unless the applicant
 1481 has been in good standing with the Florida Medicaid program for
 1482 the most recent 5-year period.

1483 (h) Has been terminated for cause, pursuant to the appeals
 1484 procedures established by the state, from any other state

1485 Medicaid program, unless the applicant has been in good standing
 1486 with a state Medicaid program for the most recent 5-year period
 1487 and the termination occurred at least 20 years before the date
 1488 of the application.

1489 (i) Is currently listed on the United States Department of
 1490 Health and Human Services Office of Inspector General's List of
 1491 Excluded Individuals and Entities.

1492 (j)~~(f)~~ Has dispensed any medicinal drug based upon a
 1493 communication that purports to be a prescription as defined by
 1494 s. 465.003(14) or s. 893.02 when the pharmacist knows or has
 1495 reason to believe that the purported prescription is not based
 1496 upon a valid practitioner-patient relationship that includes a
 1497 documented patient evaluation, including history and a physical
 1498 examination adequate to establish the diagnosis for which any
 1499 drug is prescribed and any other requirement established by
 1500 board rule under chapter 458, chapter 459, chapter 461, chapter
 1501 463, chapter 464, or chapter 466.

1502 (k) Has violated or failed to comply with any provision of
 1503 this chapter; chapter 499, the Florida Drug and Cosmetic Act;
 1504 chapter 893; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
 1505 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
 1506 Abuse Prevention and Control Act; or any rules or regulations
 1507 promulgated thereunder.

1508
 1509 For felonies in which the defendant entered a plea of guilty or
 1510 nolo contendere in an agreement with the court to enter a
 1511 pretrial intervention or drug diversion program, the department
 1512 may not approve or deny the application for a renewal of a

1513 license, certificate, or registration until the final resolution
1514 of the case.

1515 ~~(6)(5)~~ After the application has been filed with the board
1516 and the permit fee provided in this section has been received,
1517 the board shall cause the application to be fully investigated,
1518 both as to the qualifications of the applicant and the
1519 prescription department manager or consultant pharmacist
1520 designated to be in charge and as to the premises and location
1521 described in the application.

1522 ~~(7)(6)~~ The Board of Pharmacy shall have the authority to
1523 determine whether a bona fide transfer of ownership is present
1524 and that the sale of a pharmacy is not being accomplished for
1525 the purpose of avoiding an administrative prosecution.

1526 ~~(8)(7)~~ Upon the completion of the investigation of an
1527 application, the board shall approve or deny ~~disapprove~~ the
1528 application. If approved, the permit shall be issued by the
1529 department.

1530 ~~(9)(8)~~ A permittee must notify the department, on a form
1531 approved by the board, within 10 days after any change in
1532 prescription department manager or consultant pharmacist of
1533 record. ~~Permits issued by the department are not transferable.~~

1534 ~~(10)~~ A permittee must notify the department of the
1535 identity of the prescription department manager within 10 days
1536 after employment. The prescription department manager must
1537 comply with the following requirements:

1538 ~~(a)~~ The prescription department manager of a permittee
1539 must obtain and maintain all drug records required by any state
1540 or federal law to be obtained by a pharmacy, including, but not

1541 limited to, records required by or under this chapter, chapter
 1542 499, or chapter 893. The prescription department manager must
 1543 ensure the permittee's compliance with all rules adopted under
 1544 those chapters as they relate to the practice of the profession
 1545 of pharmacy and the sale of prescription drugs.

1546 (b) The prescription department manager must ensure the
 1547 security of the prescription department. The prescription
 1548 department manager must notify the board of any theft or
 1549 significant loss of any controlled substances within 1 business
 1550 day after discovery of the theft or loss.

1551 (c) A registered pharmacist may not serve as the
 1552 prescription department manager in more than one location unless
 1553 approved by the board.

1554 (11) The board shall adopt rules that require the keeping
 1555 of such records of prescription drugs as are necessary for the
 1556 protection of public health, safety, and welfare.

1557 (a) All required records documenting prescription drug
 1558 distributions shall be readily available or immediately
 1559 retrievable during an inspection by the department.

1560 (b) The records must be maintained for 4 years after the
 1561 creation or receipt of the record, whichever is later.

1562 (12) Permits issued by the department are not
 1563 transferable.

1564 (13)~~(9)~~ The board shall set the fees for the following:

- 1565 (a) Initial permit fee not to exceed \$250.
- 1566 (b) Biennial permit renewal not to exceed \$250.
- 1567 (c) Delinquent fee not to exceed \$100.
- 1568 (d) Change of location fee not to exceed \$250 ~~\$100~~.

1569 Section 15. Paragraph (b) of subsection (1) of section
 1570 465.0276, Florida Statutes, is amended to read:

1571 465.0276 Dispensing practitioner.—

1572 (1)

1573 (b) A practitioner registered under this section may not
 1574 dispense a controlled substance listed in Schedule II or
 1575 Schedule III as provided in s. 893.03 ~~A practitioner registered~~
 1576 ~~under this section may not dispense more than a 72-hour supply~~
 1577 ~~of a controlled substance listed in Schedule II, Schedule III,~~
 1578 ~~Schedule IV, or Schedule V of s. 893.03 for any patient who pays~~
 1579 ~~for the medication by cash, check, or credit card in a clinic~~
 1580 ~~registered under s. 458.3265 or s. 459.0137. A practitioner who~~
 1581 ~~violates this paragraph commits a felony of the third degree,~~
 1582 ~~punishable as provided in s. 775.082, s. 775.083, or s. 775.084.~~

1583 This paragraph does not apply to:

1584 ~~1. A practitioner who dispenses medication to a workers'~~
 1585 ~~compensation patient pursuant to chapter 440.~~

1586 ~~2. A practitioner who dispenses medication to an insured~~
 1587 ~~patient who pays by cash, check, or credit card to cover any~~
 1588 ~~applicable copayment or deductible.~~

1589 ~~1.3.~~ The dispensing of complimentary packages of medicinal
 1590 drugs to the practitioner's own patients in the regular course
 1591 of her or his practice without the payment of a fee or
 1592 remuneration of any kind, whether direct or indirect, as
 1593 provided in subsection (5).

1594 2. The dispensing of controlled substances in the health
 1595 care system of the Department of Corrections.

1596 3. Controlled substances dispensed within 7 days after

1597 surgery for which general anesthesia was used.

1598 Section 16. Subsections (16) and (17) are added to section
1599 499.0051, Florida Statutes, to read:

1600 499.0051 Criminal acts.—

1601 (16) FALSE REPORT.—Any person who submits a report
1602 required by s. 499.0121(14) knowing that such report contains a
1603 false statement commits a felony of the third degree, punishable
1604 as provided in s. 775.082, s. 775.083, or s. 775.084.

1605 (17) CONTROLLED SUBSTANCE DISTRIBUTION.—Any wholesale
1606 distributor who distributes controlled substances in violation
1607 of s. 499.0121(14) commits a felony of the third degree,
1608 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
1609 In addition to any other fine that may be imposed, a wholesale
1610 distributor convicted of such a violation may be sentenced to
1611 pay a fine that does not exceed three times the gross monetary
1612 value gained from such violation, plus court costs and the
1613 reasonable costs of investigation and prosecution.

1614 Section 17. Paragraph (o) is added to subsection (8) of
1615 section 499.012, Florida Statutes, to read:

1616 499.012 Permit application requirements.—

1617 (8) An application for a permit or to renew a permit for a
1618 prescription drug wholesale distributor or an out-of-state
1619 prescription drug wholesale distributor submitted to the
1620 department must include:

1621 (o) Documentation of the credentialing policies and
1622 procedures required by s. 499.0121(14).

1623 Section 18. Subsections (14) and (15) are added to section
1624 499.0121, Florida Statutes, to read:

1625 499.0121 Storage and handling of prescription drugs;
1626 recordkeeping.—The department shall adopt rules to implement
1627 this section as necessary to protect the public health, safety,
1628 and welfare. Such rules shall include, but not be limited to,
1629 requirements for the storage and handling of prescription drugs
1630 and for the establishment and maintenance of prescription drug
1631 distribution records.

1632 (14) DISTRIBUTION REPORTING.—Each wholesale distributor
1633 shall submit a report to the department of its receipts and
1634 distributions of controlled substances listed in Schedule II,
1635 Schedule III, Schedule IV, or Schedule V as provided in s.
1636 893.03. Wholesale distributor facilities located within this
1637 state shall report all transactions involving controlled
1638 substances, and wholesale distributor facilities located outside
1639 this state shall report all distributions to entities located in
1640 this state. If the wholesale distributor did not have any
1641 controlled substance distributions for the month, a report shall
1642 be sent indicating that no distributions occurred in the period.
1643 The report shall be submitted monthly by the 20th of the next
1644 month, in the electronic format used for controlled substance
1645 reporting to the Automation of Reports and Consolidated Orders
1646 System division of the federal Drug Enforcement Administration.
1647 Submission of electronic data must be made in a secured web
1648 environment that allows for manual or automated transmission.
1649 Upon successful transmission, an acknowledgement page must be
1650 displayed to confirm receipt. The report must contain the
1651 following information:

1652 (a) The federal Drug Enforcement Administration

1653 registration number of the wholesale distributing location.

1654 (b) The federal Drug Enforcement Administration
 1655 registration number of the entity to which the drugs are
 1656 distributed or from which the drugs are received.

1657 (c) The transaction code that indicates the type of
 1658 transaction.

1659 (d) The National Drug Code identifier of the product and
 1660 the quantity distributed or received.

1661 (e) The Drug Enforcement Administration Form 222 number or
 1662 Controlled Substance Ordering System Identifier on all schedule
 1663 II transactions.

1664 (f) The date of the transaction.

1665

1666 The department must share the reported data with the Department
 1667 of Law Enforcement and local law enforcement agencies upon
 1668 request and must monitor purchasing to identify purchasing
 1669 levels that are inconsistent with the purchasing entity's
 1670 clinical needs. The Department of Law Enforcement shall
 1671 investigate purchases at levels that are inconsistent with the
 1672 purchasing entity's clinical needs to determine whether
 1673 violations of chapter 893 have occurred.

1674 (15) DUE DILIGENCE OF PURCHASERS.—

1675 (a) Each wholesale distributor must establish and maintain
 1676 policies and procedures to credential physicians licensed under
 1677 chapter 458, chapter 459, chapter 459, chapter 461, or chapter
 1678 466 and pharmacies that would purchase or otherwise receive from
 1679 the wholesale distributor controlled substances listed in
 1680 Schedule II or Schedule III as provided in s. 893.03. The

1681 wholesale distributor shall maintain records of such
 1682 credentialing and make the records available to the department
 1683 upon request. Such credentialing must, at a minimum, include:
 1684 1. A determination of the clinical nature of the receiving
 1685 entity, including any specialty practice area.
 1686 2. A review of the receiving entity's history of Schedule
 1687 II and Schedule III controlled substance purchasing from the
 1688 wholesale distributor.
 1689 3. A determination that the receiving entity's Schedule II
 1690 and Schedule III controlled substance purchasing history, if
 1691 any, is consistent with and reasonable for that entity's
 1692 clinical business needs.
 1693 4. Conduct of a level 2 background screening pursuant to
 1694 chapter 435 through the department on any person who owns a
 1695 controlling interest in or, directly or indirectly, manages,
 1696 oversees, or controls the operation of the entity, including
 1697 officers and members of the board of directors of an entity that
 1698 is a corporation. This requirement does not apply to publicly
 1699 traded entities or entities having more than \$100 million of
 1700 business taxable assets in this state. For such entities,
 1701 wholesale distributors must require current documentation of all
 1702 state and federal licenses and permits.
 1703 (b) A wholesale distributor must take reasonable measures
 1704 to identify its customers, understand the normal and expected
 1705 transactions conducted by those customers, and identify those
 1706 transactions that are suspicious in nature. A wholesale
 1707 distributor must establish internal policies and procedures for
 1708 identifying suspicious orders and preventing suspicious

1709 transactions. A wholesale distributor must assess orders for
1710 greater than 5,000 unit doses of any one controlled substance in
1711 any one month to determine whether the purchase is reasonable.
1712 In making such assessments, a wholesale distributor may consider
1713 the purchasing entity's clinical business needs, location, and
1714 population served, in addition to other factors established in
1715 the distributor's policies and procedures. A wholesale
1716 distributor must report to the department any regulated
1717 transaction involving an extraordinary quantity of a listed
1718 chemical, an uncommon method of payment or delivery, or any
1719 other circumstance that the regulated person believes may
1720 indicate that the listed chemical will be used in violation of
1721 the law. For each reported transaction that is completed, the
1722 wholesale distributor must document the basis for determining
1723 the transaction was reasonable.

1724 (c) A wholesale distributor may not distribute controlled
1725 substances to an entity if any criminal history record check for
1726 any person associated with that entity shows the person has been
1727 convicted of, or entered a plea of guilty or nolo contendere to,
1728 regardless of adjudication, a crime in any jurisdiction related
1729 to controlled substances, the practice of pharmacy, or the
1730 dispensing of medicinal drugs.

1731 (d) A wholesale distributor may not distribute more than
1732 5,000 unit doses each of hydrocodone, morphine, oxycodone,
1733 methadone, or any one benzodiazepine, or any derivative,
1734 precursor, or component of these drugs to a retail pharmacy in
1735 any given month. The department shall assess national data from
1736 the Automation of Reports and Consolidated Orders System of the

1737 federal Drug Enforcement Administration, excluding Florida data,
 1738 and identify the national average of grams of hydrocodone,
 1739 morphine, oxycodone, and methadone distributed per pharmacy
 1740 registrant per month in the most recent year for which data is
 1741 available. The department shall report the average for each of
 1742 these drugs to the Governor, the President of the Senate, and
 1743 the Speaker of the House of Representatives by January 1, 2012.
 1744 The department shall assess the data reported pursuant to
 1745 subsection (14) and identify the statewide average of grams of
 1746 each benzodiazapine distributed per community pharmacy per
 1747 month. The department shall report the average for each
 1748 benzodiazapine to the Governor, the President of the Senate, and
 1749 the Speaker of the House of Representatives by January 1, 2012.

1750 Section 19. Paragraphs (o) and (p) are added to subsection
 1751 (1) of section 499.05, Florida Statutes, to read:

1752 499.05 Rules.—

1753 (1) The department shall adopt rules to implement and
 1754 enforce this part with respect to:

1755 (o) Wholesale distributor reporting requirements of s.
 1756 499.0121(14).

1757 (p) Wholesale distributor credentialing and distribution
 1758 requirements of s. 499.0121(15).

1759 Section 20. Subsections (8) and (9) are added to section
 1760 499.067, Florida Statutes, to read:

1761 499.067 Denial, suspension, or revocation of permit,
 1762 certification, or registration.—

1763 (8) The department may deny, suspend, or revoke a permit
 1764 if it finds the permittee has not complied with the

1765 credentialing requirements of s. 499.0121(15).

1766 (9) The department may deny, suspend, or revoke a permit
 1767 if it finds the permittee has not complied with the reporting
 1768 requirements of, or knowingly made a false statement in a report
 1769 required by, s. 499.0121(14).

1770 Section 21. Paragraph (f) is added to subsection (3) of
 1771 section 810.02, Florida Statutes, to read:

1772 810.02 Burglary.—

1773 (3) Burglary is a felony of the second degree, punishable
 1774 as provided in s. 775.082, s. 775.083, or s. 775.084, if, in the
 1775 course of committing the offense, the offender does not make an
 1776 assault or battery and is not and does not become armed with a
 1777 dangerous weapon or explosive, and the offender enters or
 1778 remains in a:

1779 (f) Structure or conveyance when the offense intended to
 1780 be committed therein is theft of a controlled substance as
 1781 defined in s. 893.02. Notwithstanding any other law, separate
 1782 judgments and sentences for burglary with the intent to commit
 1783 theft of a controlled substance under this paragraph and for any
 1784 applicable possession of controlled substance offense under s.
 1785 893.13 or trafficking in controlled substance offense under s.
 1786 893.135 may be imposed when all such offenses involve the same
 1787 amount or amounts of a controlled substance.

1788
 1789 However, if the burglary is committed within a county that is
 1790 subject to a state of emergency declared by the Governor under
 1791 chapter 252 after the declaration of emergency is made and the
 1792 perpetration of the burglary is facilitated by conditions

1793 arising from the emergency, the burglary is a felony of the
 1794 first degree, punishable as provided in s. 775.082, s. 775.083,
 1795 or s. 775.084. As used in this subsection, the term "conditions
 1796 arising from the emergency" means civil unrest, power outages,
 1797 curfews, voluntary or mandatory evacuations, or a reduction in
 1798 the presence of or response time for first responders or
 1799 homeland security personnel. A person arrested for committing a
 1800 burglary within a county that is subject to such a state of
 1801 emergency may not be released until the person appears before a
 1802 committing magistrate at a first appearance hearing. For
 1803 purposes of sentencing under chapter 921, a felony offense that
 1804 is reclassified under this subsection is ranked one level above
 1805 the ranking under s. 921.0022 or s. 921.0023 of the offense
 1806 committed.

1807 Section 22. Paragraph (c) of subsection (2) of section
 1808 812.014, Florida Statutes, is amended to read:

1809 812.014 Theft.—

1810 (2)

1811 (c) It is grand theft of the third degree and a felony of
 1812 the third degree, punishable as provided in s. 775.082, s.
 1813 775.083, or s. 775.084, if the property stolen is:

- 1814 1. Valued at \$300 or more, but less than \$5,000.
- 1815 2. Valued at \$5,000 or more, but less than \$10,000.
- 1816 3. Valued at \$10,000 or more, but less than \$20,000.
- 1817 4. A will, codicil, or other testamentary instrument.
- 1818 5. A firearm.
- 1819 6. A motor vehicle, except as provided in paragraph (a).
- 1820 7. Any commercially farmed animal, including any animal of

1821 the equine, bovine, or swine class, or other grazing animal, and
 1822 including aquaculture species raised at a certified aquaculture
 1823 facility. If the property stolen is aquaculture species raised
 1824 at a certified aquaculture facility, then a \$10,000 fine shall
 1825 be imposed.

1826 8. Any fire extinguisher.

1827 9. Any amount of citrus fruit consisting of 2,000 or more
 1828 individual pieces of fruit.

1829 10. Taken from a designated construction site identified
 1830 by the posting of a sign as provided for in s. 810.09(2)(d).

1831 11. Any stop sign.

1832 12. Anhydrous ammonia.

1833 13. Any amount of a controlled substance as defined in s.
 1834 893.02. Notwithstanding any other law, separate judgments and
 1835 sentences for theft of a controlled substance under this
 1836 subparagraph and for any applicable possession of controlled
 1837 substance offense under s. 893.13 or trafficking in controlled
 1838 substance offense under s. 893.135 may be imposed when all such
 1839 offenses involve the same amount or amounts of a controlled
 1840 substance.

1841
 1842 However, if the property is stolen within a county that is
 1843 subject to a state of emergency declared by the Governor under
 1844 chapter 252, the property is stolen after the declaration of
 1845 emergency is made, and the perpetration of the theft is
 1846 facilitated by conditions arising from the emergency, the
 1847 offender commits a felony of the second degree, punishable as
 1848 provided in s. 775.082, s. 775.083, or s. 775.084, if the

1849 property is valued at \$5,000 or more, but less than \$10,000, as
 1850 provided under subparagraph 2., or if the property is valued at
 1851 \$10,000 or more, but less than \$20,000, as provided under
 1852 subparagraph 3. As used in this paragraph, the term "conditions
 1853 arising from the emergency" means civil unrest, power outages,
 1854 curfews, voluntary or mandatory evacuations, or a reduction in
 1855 the presence of or the response time for first responders or
 1856 homeland security personnel. For purposes of sentencing under
 1857 chapter 921, a felony offense that is reclassified under this
 1858 paragraph is ranked one level above the ranking under s.
 1859 921.0022 or s. 921.0023 of the offense committed.

1860 Section 23. Section 893.055, Florida Statutes, is amended
 1861 to read:

1862 893.055 Prescription drug monitoring program.—

1863 (1) As used in this section, the term:

1864 (a) "Patient advisory report" or "advisory report" means
 1865 information provided by the department in writing, or as
 1866 determined by the department, to a prescriber, dispenser,
 1867 pharmacy, or patient concerning the dispensing of controlled
 1868 substances. All advisory reports are for informational purposes
 1869 only and impose no obligations of any nature or any legal duty
 1870 on a prescriber, dispenser, pharmacy, or patient. The patient
 1871 advisory report shall be provided in accordance with s.

1872 893.13(7)(a)8. The advisory reports issued by the department are
 1873 not subject to discovery or introduction into evidence in any
 1874 civil or administrative action against a prescriber, dispenser,
 1875 pharmacy, or patient arising out of matters that are the subject
 1876 of the report; and a person who participates in preparing,

1877 reviewing, issuing, or any other activity related to an advisory
 1878 report may not be permitted or required to testify in any such
 1879 civil action as to any findings, recommendations, evaluations,
 1880 opinions, or other actions taken in connection with preparing,
 1881 reviewing, or issuing such a report.

1882 (b) "Controlled substance" means a controlled substance
 1883 listed in Schedule II, Schedule III, or Schedule IV in s.
 1884 893.03.

1885 (c) "Dispenser" means a pharmacy, dispensing pharmacist,
 1886 or dispensing health care practitioner.

1887 (d) "Health care practitioner" or "practitioner" means any
 1888 practitioner who is subject to licensure or regulation by the
 1889 department under chapter 458, chapter 459, chapter 461, chapter
 1890 462, chapter 464, chapter 465, or chapter 466.

1891 (e) "Health care regulatory board" means any board for a
 1892 practitioner or health care practitioner who is licensed or
 1893 regulated by the department.

1894 (f) "Pharmacy" means any pharmacy that is subject to
 1895 licensure or regulation by the department under chapter 465 and
 1896 that dispenses or delivers a controlled substance to an
 1897 individual or address in this state.

1898 (g) "Prescriber" means a prescribing physician,
 1899 prescribing practitioner, or other prescribing health care
 1900 practitioner.

1901 (h) "Active investigation" means an investigation that is
 1902 being conducted with a reasonable, good faith belief that it
 1903 could lead to the filing of administrative, civil, or criminal
 1904 proceedings, or that is ongoing and continuing and for which

1905 | there is a reasonable, good faith anticipation of securing an
 1906 | arrest or prosecution in the foreseeable future.

1907 | (i) "Law enforcement agency" means the Department of Law
 1908 | Enforcement, a Florida sheriff's department, a Florida police
 1909 | department, or a law enforcement agency of the Federal
 1910 | Government which enforces the laws of this state or the United
 1911 | States relating to controlled substances, and which its agents
 1912 | and officers are empowered by law to conduct criminal
 1913 | investigations and make arrests.

1914 | (j) "Program manager" means an employee of or a person
 1915 | contracted by the Department of Health who is designated to
 1916 | ensure the integrity of the prescription drug monitoring program
 1917 | in accordance with the requirements established in paragraphs
 1918 | (2) (a) and (b).

1919 | (2) (a) ~~By December 1, 2010,~~ The department shall design
 1920 | and establish a comprehensive electronic database system that
 1921 | has controlled substance prescriptions provided to it and that
 1922 | provides prescription information to a patient's health care
 1923 | practitioner and pharmacist who inform the department that they
 1924 | wish the patient advisory report provided to them. Otherwise,
 1925 | the patient advisory report will not be sent to the
 1926 | practitioner, pharmacy, or pharmacist. The system shall be
 1927 | designed to provide information regarding dispensed
 1928 | prescriptions of controlled substances and shall not infringe
 1929 | upon the legitimate prescribing or dispensing of a controlled
 1930 | substance by a prescriber or dispenser acting in good faith and
 1931 | in the course of professional practice. The system shall be
 1932 | consistent with standards of the American Society for Automation

1933 | in Pharmacy (ASAP). The electronic system shall also comply with
 1934 | the Health Insurance Portability and Accountability Act (HIPAA)
 1935 | as it pertains to protected health information (PHI), electronic
 1936 | protected health information (EPHI), and all other relevant
 1937 | state and federal privacy and security laws and regulations. The
 1938 | department shall establish policies and procedures as
 1939 | appropriate regarding the reporting, accessing the database,
 1940 | evaluation, management, development, implementation, operation,
 1941 | storage, and security of information within the system. The
 1942 | reporting of prescribed controlled substances shall include a
 1943 | dispensing transaction with a dispenser pursuant to chapter 465
 1944 | or through a dispensing transaction to an individual or address
 1945 | in this state with a pharmacy that is not located in this state
 1946 | but that is otherwise subject to the jurisdiction of this state
 1947 | as to that dispensing transaction. The reporting of patient
 1948 | advisory reports refers only to reports to patients, pharmacies,
 1949 | and practitioners. Separate reports that contain patient
 1950 | prescription history information and that are not patient
 1951 | advisory reports are provided to persons and entities as
 1952 | authorized in paragraphs (7) (b) and (c) and s. 893.0551.

1953 | (b) The department, when the direct support organization
 1954 | receives at least \$20,000 in nonstate moneys or the state
 1955 | receives at least \$20,000 in federal grants for the prescription
 1956 | drug monitoring program, ~~and in consultation with the Office of~~
 1957 | ~~Drug Control,~~ shall adopt rules as necessary concerning the
 1958 | reporting, accessing the database, evaluation, management,
 1959 | development, implementation, operation, security, and storage of
 1960 | information within the system, including rules for when patient

1961 advisory reports are provided to pharmacies and prescribers. The
 1962 patient advisory report shall be provided in accordance with s.
 1963 893.13(7)(a)8. The department shall work with the professional
 1964 health care licensure boards, such as the Board of Medicine, the
 1965 Board of Osteopathic Medicine, and the Board of Pharmacy; other
 1966 appropriate organizations, such as the Florida Pharmacy
 1967 Association, ~~the Office of Drug Control~~, the Florida Medical
 1968 Association, the Florida Retail Federation, and the Florida
 1969 Osteopathic Medical Association, including those relating to
 1970 pain management; and the Attorney General, the Department of Law
 1971 Enforcement, and the Agency for Health Care Administration to
 1972 develop rules appropriate for the prescription drug monitoring
 1973 program.

1974 (c) All dispensers and prescribers subject to these
 1975 reporting requirements shall be notified by the department of
 1976 the implementation date for such reporting requirements.

1977 (d) The program manager shall work with professional
 1978 health care licensure boards and the stakeholders listed in
 1979 paragraph (b) to develop rules appropriate for identifying
 1980 indicators of controlled substance abuse.

1981 (3) The pharmacy dispensing the controlled substance and
 1982 each prescriber who directly dispenses a controlled substance
 1983 shall submit to the electronic system, by a procedure and in a
 1984 format established by the department and consistent with an
 1985 ASAP-approved format, the following information for inclusion in
 1986 the database:

1987 (a) The name of the prescribing practitioner, the
 1988 practitioner's federal Drug Enforcement Administration

1989 registration number, the practitioner's National Provider
 1990 Identification (NPI) or other appropriate identifier, and the
 1991 date of the prescription.

1992 (b) The date the prescription was filled and the method of
 1993 payment, such as cash by an individual, insurance coverage
 1994 through a third party, or Medicaid payment. This paragraph does
 1995 not authorize the department to include individual credit card
 1996 numbers or other account numbers in the database.

1997 (c) The full name, address, and date of birth of the
 1998 person for whom the prescription was written.

1999 (d) The name, national drug code, quantity, and strength
 2000 of the controlled substance dispensed.

2001 (e) The full name, federal Drug Enforcement Administration
 2002 registration number, and address of the pharmacy or other
 2003 location from which the controlled substance was dispensed. If
 2004 the controlled substance was dispensed by a practitioner other
 2005 than a pharmacist, the practitioner's full name, federal Drug
 2006 Enforcement Administration registration number, and address.

2007 (f) The name of the pharmacy or practitioner, other than a
 2008 pharmacist, dispensing the controlled substance and the
 2009 practitioner's National Provider Identification (NPI).

2010 (g) Other appropriate identifying information as
 2011 determined by department rule.

2012 (4) Each time a controlled substance is dispensed to an
 2013 individual, the controlled substance shall be reported to the
 2014 department through the system as soon thereafter as possible,
 2015 but not more than 7 ~~15~~ days after the date the controlled
 2016 substance is dispensed unless an extension is approved by the

2017 department for cause as determined by rule. A dispenser must
2018 meet the reporting requirements of this section by providing the
2019 required information concerning each controlled substance that
2020 it dispensed in a department-approved, secure methodology and
2021 format. Such approved formats may include, but are not limited
2022 to, submission via the Internet, on a disc, or by use of regular
2023 mail.

2024 (5) When the following acts of dispensing or administering
2025 occur, the following are exempt from reporting under this
2026 section for that specific act of dispensing or administration:

2027 (a) A health care practitioner when administering a
2028 controlled substance directly to a patient if the amount of the
2029 controlled substance is adequate to treat the patient during
2030 that particular treatment session.

2031 (b) A pharmacist or health care practitioner when
2032 administering a controlled substance to a patient or resident
2033 receiving care as a patient at a hospital, nursing home,
2034 ambulatory surgical center, hospice, or intermediate care
2035 facility for the developmentally disabled which is licensed in
2036 this state.

2037 (c) A practitioner when administering or dispensing a
2038 controlled substance in the health care system of the Department
2039 of Corrections.

2040 (d) A practitioner when administering a controlled
2041 substance in the emergency room of a licensed hospital.

2042 (e) A health care practitioner when administering or
2043 dispensing a controlled substance to a person under the age of
2044 16.

2045 (f) A pharmacist or a dispensing practitioner when
2046 dispensing a one-time, 72-hour emergency resupply of a
2047 controlled substance to a patient.

2048 (6) The department may establish when to suspend and when
2049 to resume reporting information during a state-declared or
2050 nationally declared disaster.

2051 (7) (a) A practitioner or pharmacist who dispenses a
2052 controlled substance must submit the information required by
2053 this section in an electronic or other method in an ASAP format
2054 approved by rule of the department unless otherwise provided in
2055 this section. The cost to the dispenser in submitting the
2056 information required by this section may not be material or
2057 extraordinary. Costs not considered to be material or
2058 extraordinary include, but are not limited to, regular postage,
2059 electronic media, regular electronic mail, and facsimile
2060 charges.

2061 (b) A pharmacy, prescriber, or dispenser shall have access
2062 to information in the prescription drug monitoring program's
2063 database which relates to a patient of that pharmacy,
2064 prescriber, or dispenser in a manner established by the
2065 department as needed for the purpose of reviewing the patient's
2066 controlled substance prescription history. Other access to the
2067 program's database shall be limited to the program's manager and
2068 to the designated program and support staff, who may act only at
2069 the direction of the program manager or, in the absence of the
2070 program manager, as authorized. Access by the program manager or
2071 such designated staff is for prescription drug program
2072 management only or for management of the program's database and

2073 | its system in support of the requirements of this section and in
 2074 | furtherance of the prescription drug monitoring program.

2075 | Confidential and exempt information in the database shall be
 2076 | released only as provided in paragraph (c) and s. 893.0551.

2077 | (c) The following entities shall not be allowed direct
 2078 | access to information in the prescription drug monitoring
 2079 | program database but may request from the program manager and,
 2080 | when authorized by the program manager, the program manager's
 2081 | program and support staff, information that is confidential and
 2082 | exempt under s. 893.0551. Prior to release, the request shall be
 2083 | verified as authentic and authorized with the requesting
 2084 | organization by the program manager, the program manager's
 2085 | program and support staff, or as determined in rules by the
 2086 | department as being authentic and as having been authorized by
 2087 | the requesting entity:

2088 | 1. The department or its relevant health care regulatory
 2089 | boards responsible for the licensure, regulation, or discipline
 2090 | of practitioners, pharmacists, or other persons who are
 2091 | authorized to prescribe, administer, or dispense controlled
 2092 | substances and who are involved in a specific controlled
 2093 | substance investigation involving a designated person for one or
 2094 | more prescribed controlled substances.

2095 | 2. The Attorney General for Medicaid fraud cases involving
 2096 | prescribed controlled substances.

2097 | 3. A law enforcement agency during active investigations
 2098 | regarding potential criminal activity, fraud, or theft regarding
 2099 | prescribed controlled substances.

2100 | 4. A patient or the legal guardian or designated health

2101 care surrogate of an incapacitated patient as described in s.
 2102 893.0551 who, for the purpose of verifying the accuracy of the
 2103 database information, submits a written and notarized request
 2104 that includes the patient's full name, address, and date of
 2105 birth, and includes the same information if the legal guardian
 2106 or health care surrogate submits the request. The request shall
 2107 be validated by the department to verify the identity of the
 2108 patient and the legal guardian or health care surrogate, if the
 2109 patient's legal guardian or health care surrogate is the
 2110 requestor. Such verification is also required for any request to
 2111 change a patient's prescription history or other information
 2112 related to his or her information in the electronic database.

2113
 2114 Information in the database for the electronic prescription drug
 2115 monitoring system is not discoverable or admissible in any civil
 2116 or administrative action, except in an investigation and
 2117 disciplinary proceeding by the department or the appropriate
 2118 regulatory board.

2119 (d) Department staff are ~~The following entities shall not~~
 2120 ~~be~~ allowed direct access to information in the prescription drug
 2121 monitoring program database but may request from the program
 2122 manager and, when authorized by the program manager, the program
 2123 manager's program and support staff, information that contains
 2124 no identifying information of any patient, physician, health
 2125 care practitioner, prescriber, or dispenser and that is not
 2126 confidential and exempt_{1, ÷}

2127 ~~1. Department staff~~ for the purpose of calculating
 2128 performance measures pursuant to subsection (8).

2129 ~~2. The Program Implementation and Oversight Task Force for~~
 2130 ~~its reporting to the Governor, the President of the Senate, and~~
 2131 ~~the Speaker of the House of Representatives regarding the~~
 2132 ~~prescription drug monitoring program. This subparagraph expires~~
 2133 ~~July 1, 2012.~~

2134 (e) All transmissions of data required by this section
 2135 must comply with relevant state and federal privacy and security
 2136 laws and regulations. However, any authorized agency or person
 2137 under s. 893.0551 receiving such information as allowed by s.
 2138 893.0551 may maintain the information received for up to 24
 2139 months before purging it from his or her records or maintain it
 2140 for longer than 24 months if the information is pertinent to
 2141 ongoing health care or an active law enforcement investigation
 2142 or prosecution.

2143 (f) The program manager, upon determining a pattern
 2144 consistent with the rules established under paragraph (2) (d) and
 2145 having cause to believe a violation of s. 893.13(7) (a)8.,
 2146 (8) (a), or (8) (b) has occurred, may provide relevant information
 2147 to the applicable law enforcement agency.

2148 (8) To assist in fulfilling program responsibilities,
 2149 performance measures shall be reported annually to the Governor,
 2150 the President of the Senate, and the Speaker of the House of
 2151 Representatives by the department each December 1, beginning in
 2152 2011. Data that does not contain patient, physician, health care
 2153 practitioner, prescriber, or dispenser identifying information
 2154 may be requested during the year by department employees so that
 2155 the department may undertake public health care and safety
 2156 initiatives that take advantage of observed trends. Performance

2157 | measures may include, but are not limited to, efforts to achieve
2158 | the following outcomes:

2159 | (a) Reduction of the rate of inappropriate use of
2160 | prescription drugs through department education and safety
2161 | efforts.

2162 | (b) Reduction of the quantity of pharmaceutical controlled
2163 | substances obtained by individuals attempting to engage in fraud
2164 | and deceit.

2165 | (c) Increased coordination among partners participating in
2166 | the prescription drug monitoring program.

2167 | (d) Involvement of stakeholders in achieving improved
2168 | patient health care and safety and reduction of prescription
2169 | drug abuse and prescription drug diversion.

2170 | (9) Any person who willfully and knowingly fails to report
2171 | the dispensing of a controlled substance as required by this
2172 | section commits a misdemeanor of the first degree, punishable as
2173 | provided in s. 775.082 or s. 775.083.

2174 | (10) All costs incurred by the department in administering
2175 | the prescription drug monitoring program shall be funded through
2176 | federal grants or private funding applied for or received by the
2177 | state. The department may not commit funds for the monitoring
2178 | program without ensuring funding is available. The prescription
2179 | drug monitoring program and the implementation thereof are
2180 | contingent upon receipt of the nonstate funding. The department
2181 | and state government shall cooperate with the direct-support
2182 | organization established pursuant to subsection (11) in seeking
2183 | federal grant funds, other nonstate grant funds, gifts,
2184 | donations, or other private moneys for the department so long as

2185 the costs of doing so are not considered material. Nonmaterial
 2186 costs for this purpose include, but are not limited to, the
 2187 costs of mailing and personnel assigned to research or apply for
 2188 a grant. Notwithstanding the exemptions to competitive-
 2189 solicitation requirements under s. 287.057(3)(f), the department
 2190 shall comply with the competitive-solicitation requirements
 2191 under s. 287.057 for the procurement of any goods or services
 2192 required by this section. Funds provided, directly or
 2193 indirectly, by prescription drug manufacturers may not be used
 2194 to implement the program.

2195 (11) ~~The Office of Drug Control, in coordination with the~~
 2196 ~~department,~~ may establish a direct-support organization that has
 2197 a board consisting of at least five members to provide
 2198 assistance, funding, and promotional support for the activities
 2199 authorized for the prescription drug monitoring program.

2200 (a) As used in this subsection, the term "direct-support
 2201 organization" means an organization that is:

2202 1. A Florida corporation not for profit incorporated under
 2203 chapter 617, exempted from filing fees, and approved by the
 2204 Department of State.

2205 2. Organized and operated to conduct programs and
 2206 activities; raise funds; request and receive grants, gifts, and
 2207 bequests of money; acquire, receive, hold, and invest, in its
 2208 own name, securities, funds, objects of value, or other
 2209 property, either real or personal; and make expenditures or
 2210 provide funding to or for the direct or indirect benefit of the
 2211 department in the furtherance of the prescription drug
 2212 monitoring program.

2213 (b) The direct-support organization is not considered a
 2214 lobbying firm within the meaning of s. 11.045.

2215 (c) The State Surgeon General ~~director of the Office of~~
 2216 ~~Drug Control~~ shall appoint a board of directors for the direct-
 2217 support organization. ~~The director may designate employees of~~
 2218 ~~the Office of Drug Control, state employees other than state~~
 2219 ~~employees from the department, and any other nonstate employees~~
 2220 ~~as appropriate, to serve on the board.~~ Members of the board
 2221 shall serve at the pleasure of ~~the director of the~~ State Surgeon
 2222 General Office of Drug Control. The State Surgeon General
 2223 ~~director~~ shall provide guidance to members of the board to
 2224 ensure that moneys received by the direct-support organization
 2225 are not received from inappropriate sources. Inappropriate
 2226 sources include, but are not limited to, donors, grantors,
 2227 persons, or organizations that may monetarily or substantively
 2228 benefit from the purchase of goods or services by the department
 2229 in furtherance of the prescription drug monitoring program.

2230 (d) The direct-support organization shall operate under
 2231 written contract with the department ~~Office of Drug Control~~. The
 2232 contract must, at a minimum, provide for:

2233 1. Approval of the articles of incorporation and bylaws of
 2234 the direct-support organization by the department ~~Office of Drug~~
 2235 ~~Control~~.

2236 2. Submission of an annual budget for the approval of the
 2237 department ~~Office of Drug Control~~.

2238 3. Certification by the department ~~Office of Drug Control~~
 2239 in consultation with the department that the direct-support
 2240 organization is complying with the terms of the contract in a

2241 manner consistent with and in furtherance of the goals and
 2242 purposes of the prescription drug monitoring program and in the
 2243 best interests of the state. Such certification must be made
 2244 annually and reported in the official minutes of a meeting of
 2245 the direct-support organization.

2246 4. The reversion, without penalty, to ~~the Office of Drug~~
 2247 ~~Control, or to the state if the Office of Drug Control ceases to~~
 2248 ~~exist,~~ of all moneys and property held in trust by the direct-
 2249 support organization for the benefit of the prescription drug
 2250 monitoring program if the direct-support organization ceases to
 2251 exist or if the contract is terminated.

2252 5. The fiscal year of the direct-support organization,
 2253 which must begin July 1 of each year and end June 30 of the
 2254 following year.

2255 6. The disclosure of the material provisions of the
 2256 contract to donors of gifts, contributions, or bequests,
 2257 including such disclosure on all promotional and fundraising
 2258 publications, and an explanation to such donors of the
 2259 distinction between the department ~~Office of Drug Control~~ and
 2260 the direct-support organization.

2261 7. The direct-support organization's collecting,
 2262 expending, and providing of funds to the department for the
 2263 development, implementation, and operation of the prescription
 2264 drug monitoring program as described in this section and s. 2,
 2265 chapter 2009-198, Laws of Florida, as long as the task force is
 2266 authorized. The direct-support organization may collect and
 2267 expend funds to be used for the functions of the direct-support
 2268 organization's board of directors, as necessary and approved by

2269 | the department ~~director of the Office of Drug Control~~. In
 2270 | addition, the direct-support organization may collect and
 2271 | provide funding to the department in furtherance of the
 2272 | prescription drug monitoring program by:

2273 | a. Establishing and administering the prescription drug
 2274 | monitoring program's electronic database, including hardware and
 2275 | software.

2276 | b. Conducting studies on the efficiency and effectiveness
 2277 | of the program to include feasibility studies as described in
 2278 | subsection (13).

2279 | c. Providing funds for future enhancements of the program
 2280 | within the intent of this section.

2281 | d. Providing user training of the prescription drug
 2282 | monitoring program, including distribution of materials to
 2283 | promote public awareness and education and conducting workshops
 2284 | or other meetings, for health care practitioners, pharmacists,
 2285 | and others as appropriate.

2286 | e. Providing funds for travel expenses.

2287 | f. Providing funds for administrative costs, including
 2288 | personnel, audits, facilities, and equipment.

2289 | g. Fulfilling all other requirements necessary to
 2290 | implement and operate the program as outlined in this section.

2291 | (e) The activities of the direct-support organization must
 2292 | be consistent with the goals and mission of the department
 2293 | ~~Office of Drug Control~~, as determined by the ~~office in~~
 2294 | ~~consultation with the~~ department, and in the best interests of
 2295 | the state. The direct-support organization must obtain a written
 2296 | approval from the department ~~director of the Office of Drug~~

2297 ~~Control~~ for any activities in support of the prescription drug
 2298 monitoring program before undertaking those activities.

2299 (f) ~~The Office of Drug Control, in consultation with the~~
 2300 ~~department,~~ may permit, without charge, appropriate use of
 2301 administrative services, property, and facilities of ~~the Office~~
 2302 ~~of Drug Control~~ and the department by the direct-support
 2303 organization, subject to this section. The use must be directly
 2304 in keeping with the approved purposes of the direct-support
 2305 organization and may not be made at times or places that would
 2306 unreasonably interfere with opportunities for the public to use
 2307 such facilities for established purposes. Any moneys received
 2308 from rentals of facilities and properties managed by the ~~Office~~
 2309 ~~of Drug Control~~ and the department may be held ~~by the Office of~~
 2310 ~~Drug Control~~ or in a separate depository account in the name of
 2311 the direct-support organization and subject to the provisions of
 2312 the letter of agreement with the department ~~Office of Drug~~
 2313 ~~Control~~. The letter of agreement must provide that any funds
 2314 held in the separate depository account in the name of the
 2315 direct-support organization must revert to the department ~~Office~~
 2316 ~~of Drug Control~~ if the direct-support organization is no longer
 2317 approved by the department ~~Office of Drug Control~~ to operate in
 2318 the best interests of the state.

2319 (g) ~~The Office of Drug Control, in consultation with the~~
 2320 ~~department,~~ may adopt rules under s. 120.54 to govern the use of
 2321 administrative services, property, or facilities of the
 2322 department or office by the direct-support organization.

2323 (h) The department ~~Office of Drug Control~~ may not permit
 2324 the use of any administrative services, property, or facilities

2325 of the state by a direct-support organization if that
 2326 organization does not provide equal membership and employment
 2327 opportunities to all persons regardless of race, color,
 2328 religion, gender, age, or national origin.

2329 (i) The direct-support organization shall provide for an
 2330 independent annual financial audit in accordance with s.
 2331 215.981. Copies of the audit shall be provided to the department
 2332 ~~Office of Drug Control~~ and the Office of Policy and Budget in
 2333 the Executive Office of the Governor.

2334 (j) The direct-support organization may not exercise any
 2335 power under s. 617.0302(12) or (16).

2336 (12) A prescriber or dispenser may have access to the
 2337 information under this section which relates to a patient of
 2338 that prescriber or dispenser as needed for the purpose of
 2339 reviewing the patient's controlled drug prescription history. A
 2340 prescriber or dispenser acting in good faith is immune from any
 2341 civil, criminal, or administrative liability that might
 2342 otherwise be incurred or imposed for receiving or using
 2343 information from the prescription drug monitoring program. This
 2344 subsection does not create a private cause of action, and a
 2345 person may not recover damages against a prescriber or dispenser
 2346 authorized to access information under this subsection for
 2347 accessing or failing to access such information.

2348 (13) To the extent that funding is provided for such
 2349 purpose through federal or private grants or gifts and other
 2350 types of available moneys, the department, ~~in collaboration with~~
 2351 ~~the Office of Drug Control,~~ shall study the feasibility of
 2352 enhancing the prescription drug monitoring program for the

2353 | purposes of public health initiatives and statistical reporting
 2354 | that respects the privacy of the patient, the prescriber, and
 2355 | the dispenser. Such a study shall be conducted in order to
 2356 | further improve the quality of health care services and safety
 2357 | by improving the prescribing and dispensing practices for
 2358 | prescription drugs, taking advantage of advances in technology,
 2359 | reducing duplicative prescriptions and the overprescribing of
 2360 | prescription drugs, and reducing drug abuse. The requirements of
 2361 | the National All Schedules Prescription Electronic Reporting
 2362 | (NASPER) Act are authorized in order to apply for federal NASPER
 2363 | funding. In addition, the direct-support organization shall
 2364 | provide funding for the department, ~~in collaboration with the~~
 2365 | ~~Office of Drug Control,~~ to conduct training for health care
 2366 | practitioners and other appropriate persons in using the
 2367 | monitoring program to support the program enhancements.

2368 | (14) A pharmacist, pharmacy, or dispensing health care
 2369 | practitioner or his or her agent, before releasing a controlled
 2370 | substance to any person not known to such dispenser, shall
 2371 | require the person purchasing, receiving, or otherwise acquiring
 2372 | the controlled substance to present valid photographic
 2373 | identification or other verification of his or her identity to
 2374 | the dispenser. If the person does not have proper
 2375 | identification, the dispenser may verify the validity of the
 2376 | prescription and the identity of the patient with the prescriber
 2377 | or his or her authorized agent. Verification of health plan
 2378 | eligibility through a real-time inquiry or adjudication system
 2379 | will be considered to be proper identification. This subsection
 2380 | does not apply in an institutional setting or to a long-term

2381 care facility, including, but not limited to, an assisted living
 2382 facility or a hospital to which patients are admitted. As used
 2383 in this subsection, the term "proper identification" means an
 2384 identification that is issued by a state or the Federal
 2385 Government containing the person's photograph, printed name, and
 2386 signature or a document considered acceptable under 8 C.F.R. s.
 2387 274a.2(b)(1)(v)(A) and (B).

2388 (15) The Agency for Health Care Administration shall
 2389 continue the promotion of electronic prescribing by health care
 2390 practitioners, health care facilities, and pharmacies under s.
 2391 408.0611.

2392 (16) ~~By October 1, 2010,~~ The department shall adopt rules
 2393 pursuant to ss. 120.536(1) and 120.54 to administer the
 2394 provisions of this section, which shall include as necessary the
 2395 reporting, accessing, evaluation, management, development,
 2396 implementation, operation, and storage of information within the
 2397 monitoring program's system.

2398 Section 24. Section 893.065, Florida Statutes, is amended
 2399 to read:

2400 893.065 Counterfeit-resistant prescription blanks for
 2401 controlled substances listed in Schedule II, Schedule III, or
 2402 Schedule IV.—The Department of Health shall develop and adopt by
 2403 rule the form and content for a counterfeit-resistant
 2404 prescription blank which must ~~may~~ be used by practitioners for
 2405 the purpose of prescribing a controlled substance listed in
 2406 Schedule II, Schedule III, ~~or~~ Schedule IV, or Schedule V
 2407 pursuant to s. 456.42. The Department of Health may require the
 2408 prescription blanks to be printed on distinctive, watermarked

2409 paper and to bear the preprinted name, address, and category of
 2410 professional licensure of the practitioner and that
 2411 practitioner's federal registry number for controlled
 2412 substances. The prescription blanks may not be transferred.

2413 Section 25. Subsections (4) and (5) of section 893.07,
 2414 Florida Statutes, are amended to read:

2415 893.07 Records.—

2416 (4) Every inventory or record required by this chapter,
 2417 including prescription records, shall be maintained:

2418 (a) Separately from all other records of the registrant,
 2419 or

2420 (b) Alternatively, in the case of Schedule III, IV, or V
 2421 controlled substances, in such form that information required by
 2422 this chapter is readily retrievable from the ordinary business
 2423 records of the registrant.

2424
 2425 In either case, the records described in this subsection shall
 2426 be kept and made available for a period of at least 2 years for
 2427 inspection and copying by law enforcement officers whose duty it
 2428 is to enforce the laws of this state relating to controlled
 2429 substances. Law enforcement officers are not required to obtain
 2430 a subpoena, court order, or search warrant in order to obtain
 2431 access to or copies of such records.

2432 (5) Each person described in subsection (1) shall:

2433 (a) Maintain a record which shall contain a detailed list
 2434 of controlled substances lost, destroyed, or stolen, if any; the
 2435 kind and quantity of such controlled substances; and the date of
 2436 the discovering of such loss, destruction, or theft.

2437 (b) In the event of the discovery of the theft or loss of
 2438 controlled substances, report such theft or loss to the sheriff
 2439 of that county within 24 hours after its discovery. A person who
 2440 fails to report a theft or loss of a substance listed in s.
 2441 893.03(3), (4), or (5) within 24 hours after discovery as
 2442 required in this paragraph commits a misdemeanor of the second
 2443 degree, punishable as provided in s. 775.082 or s. 775.083. A
 2444 person who fails to report a theft or loss of a substance listed
 2445 in s. 893.03(2) within 24 hours after discovery as required in
 2446 this paragraph commits a misdemeanor of the first degree,
 2447 punishable as provided in s. 775.082 or s. 775.083.

2448 Section 26. Section 2 of chapter 2009-198, Laws of
 2449 Florida, is repealed.

2450 Section 27. (1) BUY-BACK PROGRAM.—

2451 (a) Within 10 days after the effective date of this act,
 2452 each physician licensed under chapter 458, chapter 459, chapter
 2453 461, or chapter 466, Florida Statutes, shall ensure that
 2454 undispensed inventory of controlled substances listed in
 2455 Schedule II or Schedule III as provided in s. 893.03, Florida
 2456 Statutes, purchased under the physician's Drug Enforcement
 2457 Administration number for dispensing is:

2458 1. Returned to the wholesale distributor, as defined in s.
 2459 499.003, Florida Statutes, which distributed them, with a
 2460 written certification by the physician that, from the time such
 2461 products were received by the physician until they are received
 2462 by the wholesale distributor, the products have been properly
 2463 stored, handled, and shipped in accordance with all applicable
 2464 laws, rules, regulations, and standards; and that the specific

2465 units being returned were purchased from the wholesale
2466 distributor; and identifying the corresponding sales invoice
2467 number and date of sale from that wholesale distributor; or

2468 2. Turned in to local law enforcement agencies and
2469 abandoned.

2470 (b) Wholesale distributors shall buy back the undispensed
2471 inventory of controlled substances listed in Schedule II or
2472 Schedule III as provided in s. 893.03, Florida Statutes, at the
2473 purchase price paid by the physician, physician practice,
2474 clinic, or other paying entity. A wholesale distributor may
2475 resell the inventory bought back under this section without
2476 documenting the original sale or return in the pedigree paper.
2477 Each wholesale distributor shall submit a report of its buy-back
2478 activities under this section to the Department of Health by
2479 August 1, 2011. The report shall include the following
2480 information:

2481 1. The name and address of the returning entity.

2482 2. The Florida license, registration, or permit number and
2483 Drug Enforcement Administration number of the entity that
2484 originally ordered the drugs.

2485 3. The drug name and number of unit doses returned.

2486 4. The date of return.

2487 (2) PUBLIC HEALTH EMERGENCY.—

2488 (a) The Legislature finds that:

2489 1. Prescription drug overdose has been declared a public
2490 health epidemic by the United States Centers for Disease Control
2491 and Prevention.

2492 2. Prescription drug abuse results in an average of seven

2493 deaths in this state each day.

2494 3. Physicians in this state purchased over 85 percent of
2495 the oxycodone purchased by all practitioners in the United
2496 States in 2006.

2497 4. Physicians in this state purchased over 93 percent of
2498 the methadone purchased by all practitioners in the United
2499 States in 2006.

2500 5. Some physicians in this state dispense medically
2501 unjustifiable amounts of controlled substances to addicts and
2502 people who intend to illegally sell the drugs.

2503 6. Physicians in this state who have purchased large
2504 quantities of controlled substances may have significant
2505 inventory on the effective date of this act.

2506 7. On the effective date of this act, the only legal
2507 method for a dispensing practitioner to sell or otherwise
2508 transfer controlled substances listed in Schedule II or Schedule
2509 III as provided in s. 893.03, Florida Statutes, purchased for
2510 dispensing is through the buy-back procedure or abandonment
2511 procedures of subsection (1).

2512 8. It is likely that the same physicians who purchase and
2513 dispense medically unjustifiable amounts of drugs will not
2514 legally dispose of remaining inventory.

2515 9. The actions of such dispensing practitioners may result
2516 in substantial injury to the public health.

2517 (b) Immediately on the effective date of this act, the
2518 State Health Officer shall declare a public health emergency
2519 pursuant to s. 381.00315, Florida Statutes. Pursuant to that
2520 declaration, the Department of Health, the Attorney General, the

2521 Department of Law Enforcement, and local law enforcement
 2522 agencies shall take the following actions:

2523 1. Within 2 days after the effective date of this act, in
 2524 consultation with wholesale distributors as defined in s.
 2525 499.003, Florida Statutes, the Department of Health shall
 2526 identify dispensing practitioners that purchased more than an
 2527 average of 2,000 unit doses of controlled substances listed in
 2528 Schedule II or Schedule III as provided in s. 893.03, Florida
 2529 Statutes, per month in the previous 6 months, and shall identify
 2530 the dispensing practitioners in that group who pose the greatest
 2531 threat to the public health based on an assessment of:

2532 a. The risk of noncompliance with subsection (1).
 2533 b. Purchase amounts.
 2534 c. Manner of medical practice.
 2535 d. Any other factor set by the State Health Officer.
 2536

2537 The Attorney General shall consult and coordinate with federal
 2538 law enforcement agencies. The Department of Law Enforcement
 2539 shall coordinate the efforts of local law enforcement agencies.

2540 2. On the 3rd day after the effective date of this act,
 2541 the Department of Law Enforcement or local law enforcement
 2542 agencies shall enter the business premises of the dispensing
 2543 practitioners identified as posing the greatest threat to public
 2544 health and quarantine the inventory of controlled substances
 2545 listed in Schedule II or Schedule III as provided in s. 893.03,
 2546 Florida Statutes, of such dispensing practitioners on site.

2547 3. The Department of Law Enforcement or local law
 2548 enforcement agencies shall ensure the security of such inventory

2549 24 hours a day through the 10th day after the effective date of
 2550 this act or until the inventory is validly transferred pursuant
 2551 to subsection (1), whichever is earlier.

2552 4. On the 11th day after the effective date of this act,
 2553 any remaining inventory of controlled substances listed in
 2554 Schedule II or Schedule III as provided in s. 893.03, Florida
 2555 Statutes, purchased for dispensing by practitioners is deemed
 2556 contraband under s. 893.12, Florida Statutes. The Department of
 2557 Law Enforcement or local law enforcement agencies shall seize
 2558 the inventory and comply with the provisions of s. 893.12,
 2559 Florida Statutes, to destroy it.

2560 (c) In order to implement the provisions of this
 2561 subsection, the sum of \$3 million of nonrecurring funds from the
 2562 General Revenue Fund is appropriated to the Department of Law
 2563 Enforcement for the 2010-2011 fiscal year. The Department of Law
 2564 Enforcement shall expend the appropriation by reimbursing local
 2565 law enforcement agencies for the overtime-hour costs associated
 2566 with securing the quarantined controlled substance inventory as
 2567 provided in paragraph (b) and activities related to
 2568 investigation and prosecution of crimes related to prescribed
 2569 controlled substances. If requests for reimbursement exceed the
 2570 amount appropriated, the reimbursements shall be prorated by the
 2571 hours of overtime per requesting agency at a maximum of one law
 2572 enforcement officer per quarantine site.

2573 (3) REPEAL.—This section is repealed January 1, 2013.
 2574 Section 28. This act shall take effect July 1, 2011.