

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

documentation of credentialing policies; amending s. 499.0121, F.S.; providing reporting requirements for wholesale distributors of certain controlled substances; requiring the Department of Health to share the reported data with law enforcement agencies; requiring the Department of Law Enforcement to make investigations based on the reported data; providing credentialing requirements for distribution of controlled substances to certain entities by wholesale distributors; requiring distributors to identify suspicious transactions; requiring distributors to determine the reasonableness of orders for controlled substances over certain amounts; requiring distributors to report certain transactions to the Department of Health; prohibiting distribution to entities with certain criminal histories; limiting monthly distribution amounts of certain controlled substances to retail pharmacies; requiring the department to assess data; requiring the department to report certain data to the Governor, President of the Senate, and Speaker of the House of Representatives by certain dates; prohibiting distribution to entities with certain criminal backgrounds; amending s. 499.05, F.S.; authorizing rulemaking concerning specified controlled substance wholesale distributor reporting requirements and credentialing requirements; amending s. 499.067, F.S.; authorizing the Department of Health to take disciplinary action against wholesale distributors failing to comply 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

CS/CS/HB 7095, Engrossed 1

2011

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

CS/CS/HB 7095, Engrossed 1

2011

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

CS/CS/HB 7095, Engrossed 1

2011

defined in s. 668.003(4).

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

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

456.44 Controlled substance prescribing.—

(1) DEFINITIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

365 5. Discussion of risks and benefits.

366 6. Treatments.

367 7. Medications, including date, type, dosage, and quantity
368 prescribed.

369 8. Instructions and agreements.

370 9. Periodic reviews.

371 10. Results of any drug testing.

372 11. A photocopy of the patient's government-issued photo
373 identification.

374 12. If a written prescription for a controlled substance
375 is given to the patient, a duplicate of the prescription.

376 13. The physician's full name presented in a legible
377 manner.

378 (g) Patients with signs or symptoms of substance abuse
379 shall be immediately referred to a board-certified pain
380 management physician, an addiction medicine specialist, or a
381 mental health addiction facility as it pertains to drug abuse or
382 addiction unless the physician is board-certified or board-
383 eligible in pain management. Throughout the period of time
384 before receiving the consultant's report, a prescribing
385 physician shall clearly and completely document medical
386 justification for continued treatment with controlled substances
387 and those steps taken to ensure medically appropriate use of
388 controlled substances by the patient. Upon receipt of the
389 consultant's written report, the prescribing physician shall
390 incorporate the consultant's recommendations for continuing,
391 modifying, or discontinuing controlled substance therapy. The
392 resulting changes in treatment shall be specifically documented

CS/CS/HB 7095, Engrossed 1

2011

in the patient's medical record. Evidence or behavioral
indications of diversion shall be followed by discontinuation of
controlled substance therapy and the patient shall be discharged
and all results of testing and actions taken by the physician
shall be documented in the patient's medical record.

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

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

458.3265 Pain-management clinics.—

(1) REGISTRATION.—

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

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

b. "Pain-management clinic" or "clinic" means a publicly

421 or privately owned facility where in any month a majority of
422 patients are prescribed opioids, benzodiazepines, barbiturates,
423 or carisoprodol for the treatment of chronic nonmalignant pain.

424 ~~All privately owned pain-management clinics, facilities, or~~
425 ~~offices, hereinafter referred to as "clinics," which advertise~~
426 ~~in any medium for any type of pain-management services, or~~
427 ~~employ a physician who is primarily engaged in the treatment of~~
428 ~~pain by prescribing or dispensing controlled substance~~
429 ~~medications,~~

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

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

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

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

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

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

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

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

449 or

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

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

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

474 (d) The department shall deny registration to any clinic
475 that is not fully owned by a physician licensed under this
476 chapter or chapter 459 or a group of physicians, each of whom is

CS/CS/HB 7095, Engrossed 1

2011

477 licensed under this chapter or chapter 459; or that is not a
478 health care clinic licensed under part X of chapter 400.

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

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

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

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

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

504 (g) The department may revoke the clinic's certificate of

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

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

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

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

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

533 after the date the registration is revoked.

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

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

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

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

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

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

554
555 Any physician who qualifies to practice medicine in a pain-
556 management clinic pursuant to rules adopted by the Board of
557 Medicine as of July 1, 2012, may continue to practice medicine
558 in a pain-management clinic as long as the physician continues
559 to meet the qualifications set forth in the board rules. A
560 physician who violates this paragraph is subject to disciplinary

561 action by his or her appropriate medical regulatory board.

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

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

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

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

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

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

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

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

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

605 c. Have emergency lighting and communications.

606 d. Have a reception and waiting area.

607 e. Provide a restroom.

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

610 g. Have private patient examination rooms.

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

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

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

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

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

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

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

632 a. Geographic location, community, and population served.
633 b. The care, treatment, and services it provides.
634 c. An analysis of its infection surveillance and control
635 data.

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

638 a. Prioritized risks.
639 b. Limiting unprotected exposure to pathogens.
640 c. Limiting the transmission of infections associated with
641 procedures performed in the clinic.
642 d. Limiting the transmission of infections associated with
643 the clinic's use of medical equipment, devices, and supplies.

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

645 is responsible for ensuring compliance with the following health
646 and safety requirements:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

701 patient's domicile is the patient's fixed or permanent home to
702 which he or she intends to return even though he or she may
703 temporarily reside elsewhere.

704 (3) INSPECTION.—

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

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

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

719 (4) RULEMAKING.—

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

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

CS/CS/HB 7095, Engrossed 1

2011

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

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

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

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

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

CS/CS/HB 7095, Engrossed 1

2011

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

(5) PENALTIES; ENFORCEMENT.—

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

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

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

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

4. The financial benefits that the pain-management clinic

785 derived from committing or continuing to commit the violation.

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

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

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

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

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

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

804 458.327 Penalty for violations.—

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

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

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

812 458.331 Grounds for disciplinary action; action by the

CS/CS/HB 7095, Engrossed 1

2011

board and department.—

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

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

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

459.0137 Pain-management clinics.—

(1) REGISTRATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

896 3. Who has been convicted of or pleaded guilty or nolo

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

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

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

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

924 (i) If a pain-management clinic registration is revoked or

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

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

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

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

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

949 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
950 apply to any osteopathic physician who provides professional
951 services in a pain-management clinic that is required to be
952 registered in subsection (1).

CS/CS/HB 7095, Engrossed 1

2011

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

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

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

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

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

(c) An osteopathic physician, a physician assistant, or an advanced registered nurse practitioner must perform an appropriate medical ~~physical~~ examination of a patient on the

CS/CS/HB 7095, Engrossed 1

2011

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

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

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

1008 (f) Each osteopathic physician practicing in a pain

1009 management clinic is responsible for ensuring compliance with
1010 the following facility and physical operations requirements:

1011 1. A pain-management clinic shall be located and operated
1012 at a publicly accessible fixed location and must:

1013 a. Display a sign that can be viewed by the public that
1014 contains the clinic name, hours of operations, and a street
1015 address.

1016 b. Have a publicly listed telephone number and a dedicated
1017 phone number to send and receive faxes with a fax machine that
1018 shall be operational 24 hours per day.

1019 c. Have emergency lighting and communications.

1020 d. Have a reception and waiting area.

1021 e. Provide a restroom.

1022 f. Have an administrative area including room for storage
1023 of medical records, supplies and equipment.

1024 g. Have private patient examination rooms.

1025 h. Have treatment rooms, if treatment is being provided to
1026 the patient.

1027 i. Display a printed sign located in a conspicuous place
1028 in the waiting room viewable by the public with the name and
1029 contact information of the clinic-designated physician and the
1030 names of all physicians practicing in the clinic.

1031 j. If the clinic stores and dispenses prescription drug,
1032 comply with ss. 499.0121 and 893.07.

1033 2. This section does not excuse an osteopathic physician
1034 from providing any treatment or performing any medical duty
1035 without the proper equipment and materials as required by the
1036 standard of care. This section does not supersede the level of

1037 care, skill, and treatment recognized in general law related to
1038 healthcare licensure.

1039 (g) Each osteopathic physician practicing in a pain
1040 management clinic is responsible for ensuring compliance with
1041 the following infection control requirements.

1042 1. The clinic shall maintain equipment and supplies to
1043 support infection prevention and control activities.

1044 2. The clinic shall identify infection risks based on the
1045 following:

1046 a. Geographic location, community, and population served.

1047 b. The care, treatment and services it provides.

1048 c. An analysis of its infection surveillance and control
1049 data.

1050 3. The clinic shall maintain written infection prevention
1051 policies and procedures that address the following:

1052 a. Prioritized risks.

1053 b. Limiting unprotected exposure to pathogen.

1054 c. Limiting the transmission of infections associated with
1055 procedures performed in the clinic.

1056 d. Limiting the transmission of infections associated with
1057 the clinic's use of medical equipment, devices, and supplies.

1058 (h) Each osteopathic physician practicing in a pain
1059 management clinic is responsible for ensuring compliance with
1060 the following health and safety requirements.

1061 1. The clinic, including its grounds, buildings,
1062 furniture, appliances, and equipment shall be structurally
1063 sound, in good repair, clean, and free from health and safety
1064 hazards.

1065 2. The clinic shall have evacuation procedures in the
1066 event of an emergency which shall include provisions for the
1067 evacuation of disabled patients and employees.

1068 3. The clinic shall have a written facility-specific
1069 disaster plan which sets forth actions that will be taken in the
1070 event of clinic closure due to unforeseen disasters and shall
1071 include provisions for the protection of medical records and any
1072 controlled substances.

1073 4. Each clinic shall have at least one employee on the
1074 premises during patient care hours who is certified in Basic
1075 Life Support and is trained in reacting to accidents and medical
1076 emergencies until emergency medical personnel arrive.

1077 (i) The designated physician is responsible for ensuring
1078 compliance with the following quality assurance requirements.
1079 Each pain management clinic shall have an ongoing quality
1080 assurance program that objectively and systematically monitors
1081 and evaluates the quality and appropriateness of patient care,
1082 evaluates methods to improve patient care, identifies and
1083 corrects deficiencies within the facility, alerts the designated
1084 physician to identify and resolve recurring problems, and
1085 provides for opportunities to improve the facility's performance
1086 and to enhance and improve the quality of care provided to the
1087 public. The designated physician shall establish a quality
1088 assurance program that includes the following components:

1089 1. The identification, investigation, and analysis of the
1090 frequency and causes of adverse incidents to patients.

1091 2. The identification of trends or patterns of incidents.

1092 3. The development of measures to correct, reduce,

1093 minimize, or eliminate the risk of adverse incidents to
1094 patients.

1095 4. The documentation of these functions and periodic
1096 review no less than quarterly of such information by the
1097 designated physician.

1098 (j) The designated physician is responsible for ensuring
1099 compliance with the following data collection and reporting
1100 requirements:

1101 1. The designated physician for each pain-management
1102 clinic shall report all adverse incidents to the department as
1103 set forth in s. 459.026.

1104 2. The designated physician shall also report to the Board
1105 of Osteopathic Medicine, in writing, on a quarterly basis, the
1106 following data:

1107 a. Number of new and repeat patients seen and treated at
1108 the clinic who are prescribed controlled substance medications
1109 for the treatment of chronic, nonmalignant pain.

1110 b. The number of patients discharged due to drug abuse.

1111 c. The number of patients discharged due to drug
1112 diversion.

1113 d. The number of patients treated at the pain clinic whose
1114 domicile is located somewhere other than in this state. A
1115 patient's domicile is the patient's fixed or permanent home to
1116 which he or she intends to return even though he or she may
1117 temporarily reside elsewhere.

1118 (3) INSPECTION.—

1119 (a) The department shall inspect the pain-management
1120 clinic annually, including a review of the patient records, to

CS/CS/HB 7095, Engrossed 1

2011

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

1126 (b) During an onsite inspection, the department shall make
1127 a reasonable attempt to discuss each violation with the owner or
1128 designated physician of the pain-management clinic before
1129 issuing a formal written notification.

1130 (c) Any action taken to correct a violation shall be
1131 documented in writing by the owner or designated physician of
1132 the pain-management clinic and verified by followup visits by
1133 departmental personnel.

1134 (4) RULEMAKING.—

1135 (a) The department shall adopt rules necessary to
1136 administer the registration and inspection of pain-management
1137 clinics which establish the specific requirements, procedures,
1138 forms, and fees.

1139 ~~(b) The department shall adopt a rule defining what~~
1140 ~~constitutes practice by a designated osteopathic physician at~~
1141 ~~the clinic location for which the physician has assumed~~
1142 ~~responsibility, as set forth in subsection (1). When adopting~~
1143 ~~the rule, the department shall consider the number of clinic~~
1144 ~~employees, the location of the pain-management clinic, the~~
1145 ~~clinic's hours of operation, and the amount of controlled~~
1146 ~~substances being prescribed, dispensed, or administered at the~~
1147 ~~pain-management clinic.~~

1148 ~~(c) The Board of Osteopathic Medicine shall adopt a rule~~

CS/CS/HB 7095, Engrossed 1

2011

~~establishing the maximum number of prescriptions for Schedule II or Schedule III controlled substances or the controlled substance Alprazolam which may be written at any one registered pain management clinic during any 24-hour period.~~

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

~~1. Facility operations;~~

~~2. Physical operations;~~

~~3. Infection control requirements;~~

~~4. Health and safety requirements;~~

~~5. Quality assurance requirements;~~

~~6. Patient records;~~

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

~~8. Inspections; and~~

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

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

CS/CS/HB 7095, Engrossed 1

2011

~~pain or more than 90 days after surgery.~~

(5) PENALTIES; ENFORCEMENT.—

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

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

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

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

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

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

CS/CS/HB 7095, Engrossed 1

2011

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

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

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

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

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

459.013 Penalty for violations.—

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

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

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

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

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

1233 (tt) Dispensing a controlled substance listed in Schedule
1234 II or Schedule III in violation of s. 465.0276.

1235 Section 10. Subsections (3) and (4) of section 465.015,
1236 Florida Statutes, are renumbered as subsections (4) and (5),
1237 respectively, a new subsection (3) is added to that section, and
1238 present subsection (4) of that section is amended, to read:

1239 465.015 Violations and penalties.—

1240 (3) It is unlawful for any pharmacist to fail to report to
1241 the sheriff of the county where the pharmacy is located within
1242 24 hours after learning of any instance in which a person
1243 obtained or attempted to obtain a controlled substance, as
1244 defined in s. 893.02, that the pharmacist knew or reasonably
1245 should have known was obtained or attempted to be obtained from
1246 the pharmacy through fraudulent methods or representations. Any
1247 pharmacist who fails to make such a report within 24 hours after
1248 learning of the fraud or attempted fraud commits a misdemeanor
1249 of the first degree, punishable as provided in s. 775.082 or s.
1250 775.083. A sufficient report of the fraudulent obtaining of
1251 controlled substances under this subsection shall contain, at a
1252 minimum, a copy of the prescription used or presented and a
1253 narrative, including all information available to the pharmacy
1254 concerning the transaction, such as the name and telephone
1255 number of the prescribing physician; the name, description, and
1256 any personal identification information pertaining to the person
1257 who presented the prescription; and all other material
1258 information, such as photographic or video surveillance of the
1259 transaction.

1260 (5)~~(4)~~ Any person who violates any provision of subsection

CS/CS/HB 7095, Engrossed 1

2011

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

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

465.016 Disciplinary actions.—

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

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

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

CS/CS/HB 7095, Engrossed 1

2011

1289 Section 12. Section 465.018, Florida Statutes, is amended
1290 to read:

1291 465.018 Community pharmacies; permits.—

1292 (1) Any person desiring a permit to operate a community
1293 pharmacy shall apply to the department.

1294 (2) If the board office certifies that the application
1295 complies with the laws of the state and the rules of the board
1296 governing pharmacies, the department shall issue the permit. No
1297 permit shall be issued unless a licensed pharmacist is
1298 designated as the prescription department manager ~~responsible~~
1299 ~~for maintaining all drug records, providing for the security of~~
1300 ~~the prescription department, and following such other rules as~~
1301 ~~relate to the practice of the profession of pharmacy. The~~
1302 ~~permittee and the newly designated prescription department~~
1303 ~~manager shall notify the department within 10 days of any change~~
1304 ~~in prescription department manager.~~

1305 (3) The board may suspend or revoke the permit of, or may
1306 refuse to issue a permit to:

1307 (a) Any person who has been disciplined or who has
1308 abandoned a permit or allowed a permit to become void after
1309 written notice that disciplinary proceedings had been or would
1310 be brought against the permit;

1311 (b) Any person who is an officer, director, or person
1312 interested directly or indirectly in a person or business entity
1313 that has had a permit disciplined or abandoned or become void
1314 after written notice that disciplinary proceedings had been or
1315 would be brought against the permit; or

1316 (c) Any person who is or has been an officer of a business

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

1322 (4) In addition to any other remedies provided by law, the
1323 board may deny the application or suspend or revoke the license,
1324 registration, or certificate of any entity regulated or licensed
1325 by it if the applicant, licensee, registrant, or licenseholder,
1326 or, in the case of a corporation, partnership, or other business
1327 entity, if any officer, director, agent, or managing employee of
1328 that business entity or any affiliated person, partner, or
1329 shareholder having an ownership interest equal to 5 percent or
1330 greater in that business entity, has failed to pay all
1331 outstanding fines, liens, or overpayments assessed by final
1332 order of the department, unless a repayment plan is approved by
1333 the department; or for failure to comply with any repayment
1334 plan.

1335 (5) In reviewing any application requesting a change of
1336 ownership or a change of licensee or registrant, the transferor
1337 shall, before board approval of the change, repay or make
1338 arrangements to repay any amounts owed to the department. If the
1339 transferor fails to repay or make arrangements to repay the
1340 amounts owed to the department, the license or registration may
1341 not be issued to the transferee until repayment or until
1342 arrangements for repayment are made.

1343 (6) Passing an onsite inspection is a prerequisite to the
1344 issuance of an initial permit or a permit for a change of

CS/CS/HB 7095, Engrossed 1

2011

1345 location. The department must make the inspection within 90 days
1346 before issuance of the permit.

1347 (7) Community pharmacies that dispense controlled
1348 substances must maintain a record of all controlled substance
1349 dispensing consistent with the requirements of s. 893.07 and
1350 must make the record available to the department and law
1351 enforcement agencies upon request.

1352 Section 13. In order to dispense controlled substances
1353 listed in Schedule II or Schedule III, as provided in s. 893.03,
1354 Florida Statutes, a community pharmacy must be permitted as a
1355 community pharmacy pursuant to chapter 465, Florida Statutes, as
1356 amended by this act and any rules adopted thereunder, by March
1357 1, 2012.

1358 Section 14. Section 465.022, Florida Statutes, is amended
1359 to read:

1360 465.022 Pharmacies; general requirements; fees.—

1361 (1) The board shall adopt rules pursuant to ss. 120.536(1)
1362 and 120.54 to implement the provisions of this chapter. Such
1363 rules shall include, but shall not be limited to, rules relating
1364 to:

1365 (a) General drug safety measures.

1366 (b) Minimum standards for the physical facilities of
1367 pharmacies.

1368 (c) Safe storage of floor-stock drugs.

1369 (d) Functions of a pharmacist in an institutional
1370 pharmacy, consistent with the size and scope of the pharmacy.

1371 (e) Procedures for the safe storage and handling of
1372 radioactive drugs.

1373 (f) Procedures for the distribution and disposition of
1374 medicinal drugs distributed pursuant to s. 499.028.

1375 (g) Procedures for transfer of prescription files and
1376 medicinal drugs upon the change of ownership or closing of a
1377 pharmacy.

1378 (h) Minimum equipment which a pharmacy shall at all times
1379 possess to fill prescriptions properly.

1380 (i) Procedures for the dispensing of controlled substances
1381 to minimize dispensing based on fraudulent representations or
1382 invalid practitioner-patient relationships.

1383 (2) A pharmacy permit may ~~shall~~ be issued only to a
1384 natural person who is at least 18 years of age, to a partnership
1385 comprised of at least one natural person and all of whose
1386 partners are ~~all~~ at least 18 years of age, to a government
1387 agency, or to a business entity that is properly registered with
1388 the Secretary of State, if required by law, and has been issued
1389 a federal employer tax identification number ~~corporation that is~~
1390 ~~registered pursuant to chapter 607 or chapter 617 whose~~
1391 ~~officers, directors, and shareholders are at least 18 years of~~
1392 ~~age.~~ Permits issued to business entities may be issued only to
1393 entities whose affiliated persons, members, partners, officers,
1394 directors, and agents, including persons required to be
1395 fingerprinted under subsection (3), are not less than 18 years
1396 of age.

1397 (3) Any person or business entity, ~~partnership, or~~
1398 ~~corporation~~ before engaging in the operation of a pharmacy,
1399 shall file with the board a sworn application on forms provided
1400 by the department. For purposes of this section, any person

1401 required to provide fingerprints under this subsection is an
1402 affiliated person within the meaning of s. 465.023(1).

1403 (a) An application for a pharmacy permit must include a
1404 set of fingerprints from each person having an ownership
1405 interest of 5 percent or greater and from any person who,
1406 directly or indirectly, manages, oversees, or controls the
1407 operation of the applicant, including officers and members of
1408 the board of directors of an applicant that is a corporation.
1409 The applicant must provide payment in the application for the
1410 cost of state and national criminal history records checks.

1411 1. For corporations having more than \$100 million of
1412 business taxable assets in this state, in lieu of these
1413 fingerprint requirements, the department shall require the
1414 prescription department manager or consultant pharmacist of
1415 record who will be directly involved in the management and
1416 operation of the pharmacy to submit a set of fingerprints.

1417 2. A representative of a corporation described in
1418 subparagraph 1. satisfies the requirement to submit a set of his
1419 or her fingerprints if the fingerprints are on file with the
1420 department or the Agency for Health Care Administration, meet
1421 the fingerprint specifications for submission by the Department
1422 of Law Enforcement, and are available to the department.

1423 (b) The department shall submit the fingerprints provided
1424 by the applicant to the Department of Law Enforcement for a
1425 state criminal history records check. The Department of Law
1426 Enforcement shall forward the fingerprints to the Federal Bureau
1427 of Investigation for a national criminal history records check.

1428 (c) In addition to those documents required by the

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

1439 (4) An application for a pharmacy permit must include the
1440 applicant's written policies and procedures for preventing
1441 controlled substance dispensing based on fraudulent
1442 representations or invalid practitioner-patient relationships.
1443 The board must review the policies and procedures and may deny a
1444 permit if the policies and procedures are insufficient to
1445 reasonably prevent such dispensing. The department may phase in
1446 the submission and review of policies and procedures over one
1447 18-month period beginning July 1, 2011.

1448 (5)(4) The department or board shall deny an application
1449 for a pharmacy permit if the applicant or an affiliated person,
1450 partner, officer, director, or prescription department manager
1451 or consultant pharmacist of record of the applicant has:

1452 (a) Has obtained a permit by misrepresentation or fraud.~~+~~

1453 (b) Has attempted to procure, or has procured, a permit
1454 for any other person by making, or causing to be made, any false
1455 representation.~~+~~

1456 (c) Has been convicted of, or entered a plea of guilty or

CS/CS/HB 7095, Engrossed 1

2011

1457 nolo contendere to, regardless of adjudication, a crime in any
1458 jurisdiction which relates to the practice of, or the ability to
1459 practice, the profession of pharmacy.~~†~~

1460 (d) Has been convicted of, or entered a plea of guilty or
1461 nolo contendere to, regardless of adjudication, a crime in any
1462 jurisdiction which relates to health care fraud.~~†~~

1463 (e) Has been convicted of, or entered a plea of guilty or
1464 nolo contendere to, regardless of adjudication, a felony under
1465 chapter 409, chapter 817, or chapter 893, or a similar felony
1466 offense committed in another state or jurisdiction, since July
1467 1, 2009. ~~Been terminated for cause, pursuant to the appeals~~
1468 ~~procedures established by the state or Federal Government, from~~
1469 ~~any state Medicaid program or the federal Medicare program,~~
1470 ~~unless the applicant has been in good standing with a state~~
1471 ~~Medicaid program or the federal Medicare program for the most~~
1472 ~~recent 5 years and the termination occurred at least 20 years~~
1473 ~~ago; or~~

1474 (f) Has been convicted of, or entered a plea of guilty or
1475 nolo contendere to, regardless of adjudication, a felony under
1476 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1,
1477 2009.

1478 (g) Has been terminated for cause from the Florida
1479 Medicaid program pursuant to s. 409.913, unless the applicant
1480 has been in good standing with the Florida Medicaid program for
1481 the most recent 5-year period.

1482 (h) Has been terminated for cause, pursuant to the appeals
1483 procedures established by the state, from any other state
1484 Medicaid program, unless the applicant has been in good standing

1485 with a state Medicaid program for the most recent 5-year period
1486 and the termination occurred at least 20 years before the date
1487 of the application.

1488 (i) Is currently listed on the United States Department of
1489 Health and Human Services Office of Inspector General's List of
1490 Excluded Individuals and Entities.

1491 (j)~~(f)~~ Has dispensed any medicinal drug based upon a
1492 communication that purports to be a prescription as defined by
1493 s. 465.003(14) or s. 893.02 when the pharmacist knows or has
1494 reason to believe that the purported prescription is not based
1495 upon a valid practitioner-patient relationship that includes a
1496 documented patient evaluation, including history and a physical
1497 examination adequate to establish the diagnosis for which any
1498 drug is prescribed and any other requirement established by
1499 board rule under chapter 458, chapter 459, chapter 461, chapter
1500 463, chapter 464, or chapter 466.

1501 (k) Has violated or failed to comply with any provision of
1502 this chapter; chapter 499, the Florida Drug and Cosmetic Act;
1503 chapter 893; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
1504 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
1505 Abuse Prevention and Control Act; or any rules or regulations
1506 promulgated thereunder.

1507
1508 For felonies in which the defendant entered a plea of guilty or
1509 nolo contendere in an agreement with the court to enter a
1510 pretrial intervention or drug diversion program, the department
1511 may not approve or deny the application for a renewal of a
1512 license, certificate, or registration until the final resolution

1513 of the case.

1514 (6)~~(5)~~ After the application has been filed with the board
1515 and the permit fee provided in this section has been received,
1516 the board shall cause the application to be fully investigated,
1517 both as to the qualifications of the applicant and the
1518 prescription department manager or consultant pharmacist
1519 designated to be in charge and as to the premises and location
1520 described in the application.

1521 (7)~~(6)~~ The Board of Pharmacy shall have the authority to
1522 determine whether a bona fide transfer of ownership is present
1523 and that the sale of a pharmacy is not being accomplished for
1524 the purpose of avoiding an administrative prosecution.

1525 (8)~~(7)~~ Upon the completion of the investigation of an
1526 application, the board shall approve or deny ~~disapprove~~ the
1527 application. If approved, the permit shall be issued by the
1528 department.

1529 (9)~~(8)~~ A permittee must notify the department, on a form
1530 approved by the board, within 10 days after any change in
1531 prescription department manager or consultant pharmacist of
1532 record. ~~Permits issued by the department are not transferable.~~

1533 (10) A permittee must notify the department of the
1534 identity of the prescription department manager within 10 days
1535 after employment. The prescription department manager must
1536 comply with the following requirements:

1537 (a) The prescription department manager of a permittee
1538 must obtain and maintain all drug records required by any state
1539 or federal law to be obtained by a pharmacy, including, but not
1540 limited to, records required by or under this chapter, chapter

CS/CS/HB 7095, Engrossed 1

2011

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

1545 (b) The prescription department manager must ensure the
1546 security of the prescription department. The prescription
1547 department manager must notify the board of any theft or
1548 significant loss of any controlled substances within 1 business
1549 day after discovery of the theft or loss.

1550 (c) A registered pharmacist may not serve as the
1551 prescription department manager in more than one location unless
1552 approved by the board.

1553 (11) The board shall adopt rules that require the keeping
1554 of such records of prescription drugs as are necessary for the
1555 protection of public health, safety, and welfare.

1556 (a) All required records documenting prescription drug
1557 distributions shall be readily available or immediately
1558 retrievable during an inspection by the department.

1559 (b) The records must be maintained for 4 years after the
1560 creation or receipt of the record, whichever is later.

1561 (12) Permits issued by the department are not
1562 transferable.

1563 (13)-(9)- The board shall set the fees for the following:

1564 (a) Initial permit fee not to exceed \$250.

1565 (b) Biennial permit renewal not to exceed \$250.

1566 (c) Delinquent fee not to exceed \$100.

1567 (d) Change of location fee not to exceed \$250 ~~\$100~~.

1568 Section 15. Paragraph (b) of subsection (1) of section

CS/CS/HB 7095, Engrossed 1

2011

465.0276, Florida Statutes, is amended to read:

465.0276 Dispensing practitioner.—

(1)

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

This paragraph does not apply to:

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

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

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

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

3. Controlled substances dispensed within 7 days after surgery for which general anesthesia was used.

CS/CS/HB 7095, Engrossed 1

2011

1597 Section 16. Subsections (16) and (17) are added to section
1598 499.0051, Florida Statutes, to read:

1599 499.0051 Criminal acts.—

1600 (16) FALSE REPORT.—Any person who submits a report
1601 required by s. 499.0121(14) knowing that such report contains a
1602 false statement commits a felony of the third degree, punishable
1603 as provided in s. 775.082, s. 775.083, or s. 775.084.

1604 (17) CONTROLLED SUBSTANCE DISTRIBUTION.—Any wholesale
1605 distributor who distributes controlled substances in violation
1606 of s. 499.0121(14) commits a felony of the third degree,
1607 punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
1608 In addition to any other fine that may be imposed, a wholesale
1609 distributor convicted of such a violation may be sentenced to
1610 pay a fine that does not exceed three times the gross monetary
1611 value gained from such violation, plus court costs and the
1612 reasonable costs of investigation and prosecution.

1613 Section 17. Paragraph (o) is added to subsection (8) of
1614 section 499.012, Florida Statutes, to read:

1615 499.012 Permit application requirements.—

1616 (8) An application for a permit or to renew a permit for a
1617 prescription drug wholesale distributor or an out-of-state
1618 prescription drug wholesale distributor submitted to the
1619 department must include:

1620 (o) Documentation of the credentialing policies and
1621 procedures required by s. 499.0121(14).

1622 Section 18. Subsections (14) and (15) are added to section
1623 499.0121, Florida Statutes, to read:

1624 499.0121 Storage and handling of prescription drugs;

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

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

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

CS/CS/HB 7095, Engrossed 1

2011

1653 (b) The federal Drug Enforcement Administration
1654 registration number of the entity to which the drugs are
1655 distributed or from which the drugs are received.

1656 (c) The transaction code that indicates the type of
1657 transaction.

1658 (d) The National Drug Code identifier of the product and
1659 the quantity distributed or received.

1660 (e) The Drug Enforcement Administration Form 222 number or
1661 Controlled Substance Ordering System Identifier on all schedule
1662 II transactions.

1663 (f) The date of the transaction.

1664
1665 The department must share the reported data with the Department
1666 of Law Enforcement and local law enforcement agencies upon
1667 request and must monitor purchasing to identify purchasing
1668 levels that are inconsistent with the purchasing entity's
1669 clinical needs. The Department of Law Enforcement shall
1670 investigate purchases at levels that are inconsistent with the
1671 purchasing entity's clinical needs to determine whether
1672 violations of chapter 893 have occurred.

1673 (15) DUE DILIGENCE OF PURCHASERS.—

1674 (a) Each wholesale distributor must establish and maintain
1675 policies and procedures to credential physicians licensed under
1676 chapter 458, chapter 459, chapter 459, chapter 461, or chapter
1677 466 and pharmacies that would purchase or otherwise receive from
1678 the wholesale distributor controlled substances listed in
1679 Schedule II or Schedule III as provided in s. 893.03. The
1680 wholesale distributor shall maintain records of such

CS/CS/HB 7095, Engrossed 1

2011

1681 credentialing and make the records available to the department
1682 upon request. Such credentialing must, at a minimum, include:

1683 1. A determination of the clinical nature of the receiving
1684 entity, including any specialty practice area.

1685 2. A review of the receiving entity's history of Schedule
1686 II and Schedule III controlled substance purchasing from the
1687 wholesale distributor.

1688 3. A determination that the receiving entity's Schedule II
1689 and Schedule III controlled substance purchasing history, if
1690 any, is consistent with and reasonable for that entity's
1691 clinical business needs.

1692 4. Conduct of a level 2 background screening pursuant to
1693 chapter 435 through the department on any person who owns a
1694 controlling interest in or, directly or indirectly, manages,
1695 oversees, or controls the operation of the entity, including
1696 officers and members of the board of directors of an entity that
1697 is a corporation. This requirement does not apply to publicly
1698 traded entities or entities having more than \$100 million of
1699 business taxable assets in this state. For such entities,
1700 wholesale distributors must require current documentation of all
1701 state and federal licenses and permits.

1702 (b) A wholesale distributor must take reasonable measures
1703 to identify its customers, understand the normal and expected
1704 transactions conducted by those customers, and identify those
1705 transactions that are suspicious in nature. A wholesale
1706 distributor must establish internal policies and procedures for
1707 identifying suspicious orders and preventing suspicious
1708 transactions. A wholesale distributor must assess orders for

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

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

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

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

1749 Section 19. Paragraphs (o) and (p) are added to subsection
1750 (1) of section 499.05, Florida Statutes, to read:

1751 499.05 Rules.—

1752 (1) The department shall adopt rules to implement and
1753 enforce this part with respect to:

1754 (o) Wholesale distributor reporting requirements of s.
1755 499.0121(14).

1756 (p) Wholesale distributor credentialing and distribution
1757 requirements of s. 499.0121(15).

1758 Section 20. Subsections (8) and (9) are added to section
1759 499.067, Florida Statutes, to read:

1760 499.067 Denial, suspension, or revocation of permit,
1761 certification, or registration.—

1762 (8) The department may deny, suspend, or revoke a permit
1763 if it finds the permittee has not complied with the
1764 credentialing requirements of s. 499.0121(15).

CS/CS/HB 7095, Engrossed 1

2011

1765 (9) The department may deny, suspend, or revoke a permit
1766 if it finds the permittee has not complied with the reporting
1767 requirements of, or knowingly made a false statement in a report
1768 required by, s. 499.0121(14).

1769 Section 21. Paragraph (f) is added to subsection (3) of
1770 section 810.02, Florida Statutes, to read:

1771 810.02 Burglary.—

1772 (3) Burglary is a felony of the second degree, punishable
1773 as provided in s. 775.082, s. 775.083, or s. 775.084, if, in the
1774 course of committing the offense, the offender does not make an
1775 assault or battery and is not and does not become armed with a
1776 dangerous weapon or explosive, and the offender enters or
1777 remains in a:

1778 (f) Structure or conveyance when the offense intended to
1779 be committed therein is theft of a controlled substance as
1780 defined in s. 893.02. Notwithstanding any other law, separate
1781 judgments and sentences for burglary with the intent to commit
1782 theft of a controlled substance under this paragraph and for any
1783 applicable possession of controlled substance offense under s.
1784 893.13 or trafficking in controlled substance offense under s.
1785 893.135 may be imposed when all such offenses involve the same
1786 amount or amounts of a controlled substance.

1787
1788 However, if the burglary is committed within a county that is
1789 subject to a state of emergency declared by the Governor under
1790 chapter 252 after the declaration of emergency is made and the
1791 perpetration of the burglary is facilitated by conditions
1792 arising from the emergency, the burglary is a felony of the

CS/CS/HB 7095, Engrossed 1

2011

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

1806 Section 22. Paragraph (c) of subsection (2) of section
1807 812.014, Florida Statutes, is amended to read:

1808 812.014 Theft.—

1809 (2)

1810 (c) It is grand theft of the third degree and a felony of
1811 the third degree, punishable as provided in s. 775.082, s.
1812 775.083, or s. 775.084, if the property stolen is:

- 1813 1. Valued at \$300 or more, but less than \$5,000.
- 1814 2. Valued at \$5,000 or more, but less than \$10,000.
- 1815 3. Valued at \$10,000 or more, but less than \$20,000.
- 1816 4. A will, codicil, or other testamentary instrument.
- 1817 5. A firearm.
- 1818 6. A motor vehicle, except as provided in paragraph (a).
- 1819 7. Any commercially farmed animal, including any animal of
1820 the equine, bovine, or swine class, or other grazing animal, and

CS/CS/HB 7095, Engrossed 1

2011

1821 including aquaculture species raised at a certified aquaculture
1822 facility. If the property stolen is aquaculture species raised
1823 at a certified aquaculture facility, then a \$10,000 fine shall
1824 be imposed.

1825 8. Any fire extinguisher.

1826 9. Any amount of citrus fruit consisting of 2,000 or more
1827 individual pieces of fruit.

1828 10. Taken from a designated construction site identified
1829 by the posting of a sign as provided for in s. 810.09(2)(d).

1830 11. Any stop sign.

1831 12. Anhydrous ammonia.

1832 13. Any amount of a controlled substance as defined in s.
1833 893.02. Notwithstanding any other law, separate judgments and
1834 sentences for theft of a controlled substance under this
1835 subparagraph and for any applicable possession of controlled
1836 substance offense under s. 893.13 or trafficking in controlled
1837 substance offense under s. 893.135 may be imposed when all such
1838 offenses involve the same amount or amounts of a controlled
1839 substance.

1840
1841 However, if the property is stolen within a county that is
1842 subject to a state of emergency declared by the Governor under
1843 chapter 252, the property is stolen after the declaration of
1844 emergency is made, and the perpetration of the theft is
1845 facilitated by conditions arising from the emergency, the
1846 offender commits a felony of the second degree, punishable as
1847 provided in s. 775.082, s. 775.083, or s. 775.084, if the
1848 property is valued at \$5,000 or more, but less than \$10,000, as

CS/CS/HB 7095, Engrossed 1

2011

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

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

893.055 Prescription drug monitoring program.—

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

(a) "Patient advisory report" or "advisory report" means information provided by the department in writing, or as determined by the department, to a prescriber, dispenser, pharmacy, or patient concerning the dispensing of controlled substances. All advisory reports are for informational purposes only and impose no obligations of any nature or any legal duty on a prescriber, dispenser, pharmacy, or patient. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)8. The advisory reports issued by the department are not subject to discovery or introduction into evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient arising out of matters that are the subject of the report; and a person who participates in preparing, reviewing, issuing, or any other activity related to an advisory

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

1881 (b) "Controlled substance" means a controlled substance
1882 listed in Schedule II, Schedule III, or Schedule IV in s.
1883 893.03.

1884 (c) "Dispenser" means a pharmacy, dispensing pharmacist,
1885 or dispensing health care practitioner.

1886 (d) "Health care practitioner" or "practitioner" means any
1887 practitioner who is subject to licensure or regulation by the
1888 department under chapter 458, chapter 459, chapter 461, chapter
1889 462, chapter 464, chapter 465, or chapter 466.

1890 (e) "Health care regulatory board" means any board for a
1891 practitioner or health care practitioner who is licensed or
1892 regulated by the department.

1893 (f) "Pharmacy" means any pharmacy that is subject to
1894 licensure or regulation by the department under chapter 465 and
1895 that dispenses or delivers a controlled substance to an
1896 individual or address in this state.

1897 (g) "Prescriber" means a prescribing physician,
1898 prescribing practitioner, or other prescribing health care
1899 practitioner.

1900 (h) "Active investigation" means an investigation that is
1901 being conducted with a reasonable, good faith belief that it
1902 could lead to the filing of administrative, civil, or criminal
1903 proceedings, or that is ongoing and continuing and for which
1904 there is a reasonable, good faith anticipation of securing an

1905 arrest or prosecution in the foreseeable future.

1906 (i) "Law enforcement agency" means the Department of Law
1907 Enforcement, a Florida sheriff's department, a Florida police
1908 department, or a law enforcement agency of the Federal
1909 Government which enforces the laws of this state or the United
1910 States relating to controlled substances, and which its agents
1911 and officers are empowered by law to conduct criminal
1912 investigations and make arrests.

1913 (j) "Program manager" means an employee of or a person
1914 contracted by the Department of Health who is designated to
1915 ensure the integrity of the prescription drug monitoring program
1916 in accordance with the requirements established in paragraphs
1917 (2) (a) and (b) .

1918 (2) (a) ~~By December 1, 2010,~~ The department shall design
1919 and establish a comprehensive electronic database system that
1920 has controlled substance prescriptions provided to it and that
1921 provides prescription information to a patient's health care
1922 practitioner and pharmacist who inform the department that they
1923 wish the patient advisory report provided to them. Otherwise,
1924 the patient advisory report will not be sent to the
1925 practitioner, pharmacy, or pharmacist. The system shall be
1926 designed to provide information regarding dispensed
1927 prescriptions of controlled substances and shall not infringe
1928 upon the legitimate prescribing or dispensing of a controlled
1929 substance by a prescriber or dispenser acting in good faith and
1930 in the course of professional practice. The system shall be
1931 consistent with standards of the American Society for Automation
1932 in Pharmacy (ASAP). The electronic system shall also comply with

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

(b) The department, when the direct support organization receives at least \$20,000 in nonstate moneys or the state receives at least \$20,000 in federal grants for the prescription drug monitoring program, ~~and in consultation with the Office of Drug Control,~~ shall adopt rules as necessary concerning the reporting, accessing the database, evaluation, management, development, implementation, operation, security, and storage of information within the system, including rules for when patient advisory reports are provided to pharmacies and prescribers. The

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

1973 (c) All dispensers and prescribers subject to these
1974 reporting requirements shall be notified by the department of
1975 the implementation date for such reporting requirements.

1976 (d) The program manager shall work with professional
1977 health care licensure boards and the stakeholders listed in
1978 paragraph (b) to develop rules appropriate for identifying
1979 indicators of controlled substance abuse.

1980 (3) The pharmacy dispensing the controlled substance and
1981 each prescriber who directly dispenses a controlled substance
1982 shall submit to the electronic system, by a procedure and in a
1983 format established by the department and consistent with an
1984 ASAP-approved format, the following information for inclusion in
1985 the database:

1986 (a) The name of the prescribing practitioner, the
1987 practitioner's federal Drug Enforcement Administration
1988 registration number, the practitioner's National Provider

1989 Identification (NPI) or other appropriate identifier, and the
1990 date of the prescription.

1991 (b) The date the prescription was filled and the method of
1992 payment, such as cash by an individual, insurance coverage
1993 through a third party, or Medicaid payment. This paragraph does
1994 not authorize the department to include individual credit card
1995 numbers or other account numbers in the database.

1996 (c) The full name, address, and date of birth of the
1997 person for whom the prescription was written.

1998 (d) The name, national drug code, quantity, and strength
1999 of the controlled substance dispensed.

2000 (e) The full name, federal Drug Enforcement Administration
2001 registration number, and address of the pharmacy or other
2002 location from which the controlled substance was dispensed. If
2003 the controlled substance was dispensed by a practitioner other
2004 than a pharmacist, the practitioner's full name, federal Drug
2005 Enforcement Administration registration number, and address.

2006 (f) The name of the pharmacy or practitioner, other than a
2007 pharmacist, dispensing the controlled substance and the
2008 practitioner's National Provider Identification (NPI).

2009 (g) Other appropriate identifying information as
2010 determined by department rule.

2011 (4) Each time a controlled substance is dispensed to an
2012 individual, the controlled substance shall be reported to the
2013 department through the system as soon thereafter as possible,
2014 but not more than 7 ~~15~~ days after the date the controlled
2015 substance is dispensed unless an extension is approved by the
2016 department for cause as determined by rule. A dispenser must

CS/CS/HB 7095, Engrossed 1

2011

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

2023 (5) When the following acts of dispensing or administering
2024 occur, the following are exempt from reporting under this
2025 section for that specific act of dispensing or administration:

2026 (a) A health care practitioner when administering a
2027 controlled substance directly to a patient if the amount of the
2028 controlled substance is adequate to treat the patient during
2029 that particular treatment session.

2030 (b) A pharmacist or health care practitioner when
2031 administering a controlled substance to a patient or resident
2032 receiving care as a patient at a hospital, nursing home,
2033 ambulatory surgical center, hospice, or intermediate care
2034 facility for the developmentally disabled which is licensed in
2035 this state.

2036 (c) A practitioner when administering or dispensing a
2037 controlled substance in the health care system of the Department
2038 of Corrections.

2039 (d) A practitioner when administering a controlled
2040 substance in the emergency room of a licensed hospital.

2041 (e) A health care practitioner when administering or
2042 dispensing a controlled substance to a person under the age of
2043 16.

2044 (f) A pharmacist or a dispensing practitioner when

2045 dispensing a one-time, 72-hour emergency resupply of a
2046 controlled substance to a patient.

2047 (6) The department may establish when to suspend and when
2048 to resume reporting information during a state-declared or
2049 nationally declared disaster.

2050 (7)(a) A practitioner or pharmacist who dispenses a
2051 controlled substance must submit the information required by
2052 this section in an electronic or other method in an ASAP format
2053 approved by rule of the department unless otherwise provided in
2054 this section. The cost to the dispenser in submitting the
2055 information required by this section may not be material or
2056 extraordinary. Costs not considered to be material or
2057 extraordinary include, but are not limited to, regular postage,
2058 electronic media, regular electronic mail, and facsimile
2059 charges.

2060 (b) A pharmacy, prescriber, or dispenser shall have access
2061 to information in the prescription drug monitoring program's
2062 database which relates to a patient of that pharmacy,
2063 prescriber, or dispenser in a manner established by the
2064 department as needed for the purpose of reviewing the patient's
2065 controlled substance prescription history. Other access to the
2066 program's database shall be limited to the program's manager and
2067 to the designated program and support staff, who may act only at
2068 the direction of the program manager or, in the absence of the
2069 program manager, as authorized. Access by the program manager or
2070 such designated staff is for prescription drug program
2071 management only or for management of the program's database and
2072 its system in support of the requirements of this section and in

CS/CS/HB 7095, Engrossed 1

2011

2073 furtherance of the prescription drug monitoring program.

2074 Confidential and exempt information in the database shall be
2075 released only as provided in paragraph (c) and s. 893.0551.

2076 (c) The following entities shall not be allowed direct
2077 access to information in the prescription drug monitoring
2078 program database but may request from the program manager and,
2079 when authorized by the program manager, the program manager's
2080 program and support staff, information that is confidential and
2081 exempt under s. 893.0551. Prior to release, the request shall be
2082 verified as authentic and authorized with the requesting
2083 organization by the program manager, the program manager's
2084 program and support staff, or as determined in rules by the
2085 department as being authentic and as having been authorized by
2086 the requesting entity:

2087 1. The department or its relevant health care regulatory
2088 boards responsible for the licensure, regulation, or discipline
2089 of practitioners, pharmacists, or other persons who are
2090 authorized to prescribe, administer, or dispense controlled
2091 substances and who are involved in a specific controlled
2092 substance investigation involving a designated person for one or
2093 more prescribed controlled substances.

2094 2. The Attorney General for Medicaid fraud cases involving
2095 prescribed controlled substances.

2096 3. A law enforcement agency during active investigations
2097 regarding potential criminal activity, fraud, or theft regarding
2098 prescribed controlled substances.

2099 4. A patient or the legal guardian or designated health
2100 care surrogate of an incapacitated patient as described in s.

CS/CS/HB 7095, Engrossed 1

2011

893.0551 who, for the purpose of verifying the accuracy of the database information, submits a written and notarized request that includes the patient's full name, address, and date of birth, and includes the same information if the legal guardian or health care surrogate submits the request. The request shall be validated by the department to verify the identity of the patient and the legal guardian or health care surrogate, if the patient's legal guardian or health care surrogate is the requestor. Such verification is also required for any request to change a patient's prescription history or other information related to his or her information in the electronic database.

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

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

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

~~2. The Program Implementation and Oversight Task Force for~~

CS/CS/HB 7095, Engrossed 1

2011

~~its reporting to the Governor, the President of the Senate, and the Speaker of the House of Representatives regarding the prescription drug monitoring program. This subparagraph expires July 1, 2012.~~

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

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

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

the following outcomes:

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

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

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

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

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

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

CS/CS/HB 7095, Engrossed 1

2011

costs for this purpose include, but are not limited to, the costs of mailing and personnel assigned to research or apply for a grant. Notwithstanding the exemptions to competitive-solicitation requirements under s. 287.057(3)(f), the department shall comply with the competitive-solicitation requirements under s. 287.057 for the procurement of any goods or services required by this section. Funds provided, directly or indirectly, by prescription drug manufacturers may not be used to implement the program.

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

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

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

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

(b) The direct-support organization is not considered a

2213 lobbying firm within the meaning of s. 11.045.

2214 (c) The State Surgeon General ~~director of the Office of~~
2215 ~~Drug Control~~ shall appoint a board of directors for the direct-
2216 support organization. ~~The director may designate employees of~~
2217 ~~the Office of Drug Control, state employees other than state~~
2218 ~~employees from the department, and any other nonstate employees~~
2219 ~~as appropriate, to serve on the board.~~ Members of the board
2220 shall serve at the pleasure of ~~the director of the~~ State Surgeon
2221 General ~~Office of Drug Control~~. The State Surgeon General
2222 ~~director~~ shall provide guidance to members of the board to
2223 ensure that moneys received by the direct-support organization
2224 are not received from inappropriate sources. Inappropriate
2225 sources include, but are not limited to, donors, grantors,
2226 persons, or organizations that may monetarily or substantively
2227 benefit from the purchase of goods or services by the department
2228 in furtherance of the prescription drug monitoring program.

2229 (d) The direct-support organization shall operate under
2230 written contract with the department ~~Office of Drug Control~~. The
2231 contract must, at a minimum, provide for:

2232 1. Approval of the articles of incorporation and bylaws of
2233 the direct-support organization by the department ~~Office of Drug~~
2234 ~~Control~~.

2235 2. Submission of an annual budget for the approval of the
2236 department ~~Office of Drug Control~~.

2237 3. Certification by the department ~~Office of Drug Control~~
2238 in consultation with the department that the direct-support
2239 organization is complying with the terms of the contract in a
2240 manner consistent with and in furtherance of the goals and

CS/CS/HB 7095, Engrossed 1

2011

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

2245 4. The reversion, without penalty, to ~~the Office of Drug~~
2246 ~~Control, or to the state if the Office of Drug Control ceases to~~
2247 ~~exist~~, of all moneys and property held in trust by the direct-
2248 support organization for the benefit of the prescription drug
2249 monitoring program if the direct-support organization ceases to
2250 exist or if the contract is terminated.

2251 5. The fiscal year of the direct-support organization,
2252 which must begin July 1 of each year and end June 30 of the
2253 following year.

2254 6. The disclosure of the material provisions of the
2255 contract to donors of gifts, contributions, or bequests,
2256 including such disclosure on all promotional and fundraising
2257 publications, and an explanation to such donors of the
2258 distinction between the department ~~Office of Drug Control~~ and
2259 the direct-support organization.

2260 7. The direct-support organization's collecting,
2261 expending, and providing of funds to the department for the
2262 development, implementation, and operation of the prescription
2263 drug monitoring program as described in this section and s. 2,
2264 chapter 2009-198, Laws of Florida, as long as the task force is
2265 authorized. The direct-support organization may collect and
2266 expend funds to be used for the functions of the direct-support
2267 organization's board of directors, as necessary and approved by
2268 the department ~~director of the Office of Drug Control~~. In

CS/CS/HB 7095, Engrossed 1

2011

addition, the direct-support organization may collect and provide funding to the department in furtherance of the prescription drug monitoring program by:

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

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

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

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

e. Providing funds for travel expenses.

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

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

(e) The activities of the direct-support organization must be consistent with the goals and mission of the department ~~Office of Drug Control~~, as determined by the ~~office in~~ ~~consultation with the~~ department, and in the best interests of the state. The direct-support organization must obtain a written approval from the department ~~director of the Office of Drug Control~~ for any activities in support of the prescription drug

CS/CS/HB 7095, Engrossed 1

2011

2297 monitoring program before undertaking those activities.

2298 (f) ~~The Office of Drug Control, in consultation with the~~
2299 ~~department,~~ may permit, without charge, appropriate use of
2300 administrative services, property, and facilities of ~~the Office~~
2301 ~~of Drug Control and~~ the department by the direct-support
2302 organization, subject to this section. The use must be directly
2303 in keeping with the approved purposes of the direct-support
2304 organization and may not be made at times or places that would
2305 unreasonably interfere with opportunities for the public to use
2306 such facilities for established purposes. Any moneys received
2307 from rentals of facilities and properties managed by the ~~Office~~
2308 ~~of Drug Control and the department~~ may be held ~~by the Office of~~
2309 ~~Drug Control or~~ in a separate depository account in the name of
2310 the direct-support organization and subject to the provisions of
2311 the letter of agreement with the department ~~Office of Drug~~
2312 ~~Control~~. The letter of agreement must provide that any funds
2313 held in the separate depository account in the name of the
2314 direct-support organization must revert to the department ~~Office~~
2315 ~~of Drug Control~~ if the direct-support organization is no longer
2316 approved by the department ~~Office of Drug Control~~ to operate in
2317 the best interests of the state.

2318 (g) ~~The Office of Drug Control, in consultation with the~~
2319 ~~department,~~ may adopt rules under s. 120.54 to govern the use of
2320 administrative services, property, or facilities of the
2321 department or office by the direct-support organization.

2322 (h) The department ~~Office of Drug Control~~ may not permit
2323 the use of any administrative services, property, or facilities
2324 of the state by a direct-support organization if that

CS/CS/HB 7095, Engrossed 1

2011

organization does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, gender, age, or national origin.

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

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

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

(13) To the extent that funding is provided for such purpose through federal or private grants or gifts and other types of available moneys, the department, ~~in collaboration with the Office of Drug Control,~~ shall study the feasibility of enhancing the prescription drug monitoring program for the purposes of public health initiatives and statistical reporting

CS/CS/HB 7095, Engrossed 1

2011

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

2367 (14) A pharmacist, pharmacy, or dispensing health care
2368 practitioner or his or her agent, before releasing a controlled
2369 substance to any person not known to such dispenser, shall
2370 require the person purchasing, receiving, or otherwise acquiring
2371 the controlled substance to present valid photographic
2372 identification or other verification of his or her identity to
2373 the dispenser. If the person does not have proper
2374 identification, the dispenser may verify the validity of the
2375 prescription and the identity of the patient with the prescriber
2376 or his or her authorized agent. Verification of health plan
2377 eligibility through a real-time inquiry or adjudication system
2378 will be considered to be proper identification. This subsection
2379 does not apply in an institutional setting or to a long-term
2380 care facility, including, but not limited to, an assisted living

CS/CS/HB 7095, Engrossed 1

2011

2381 facility or a hospital to which patients are admitted. As used
2382 in this subsection, the term "proper identification" means an
2383 identification that is issued by a state or the Federal
2384 Government containing the person's photograph, printed name, and
2385 signature or a document considered acceptable under 8 C.F.R. s.
2386 274a.2(b)(1)(v)(A) and (B).

2387 (15) The Agency for Health Care Administration shall
2388 continue the promotion of electronic prescribing by health care
2389 practitioners, health care facilities, and pharmacies under s.
2390 408.0611.

2391 (16) ~~By October 1, 2010,~~ The department shall adopt rules
2392 pursuant to ss. 120.536(1) and 120.54 to administer the
2393 provisions of this section, which shall include as necessary the
2394 reporting, accessing, evaluation, management, development,
2395 implementation, operation, and storage of information within the
2396 monitoring program's system.

2397 Section 24. Section 893.065, Florida Statutes, is amended
2398 to read:

2399 893.065 Counterfeit-resistant prescription blanks for
2400 controlled substances listed in Schedule II, Schedule III, or
2401 Schedule IV.—The Department of Health shall develop and adopt by
2402 rule the form and content for a counterfeit-resistant
2403 prescription blank which must ~~may~~ be used by practitioners for
2404 the purpose of prescribing a controlled substance listed in
2405 Schedule II, Schedule III, ~~or~~ Schedule IV, or Schedule V
2406 pursuant to s. 456.42. The Department of Health may require the
2407 prescription blanks to be printed on distinctive, watermarked
2408 paper and to bear the preprinted name, address, and category of

CS/CS/HB 7095, Engrossed 1

2011

professional licensure of the practitioner and that practitioner's federal registry number for controlled substances. The prescription blanks may not be transferred.

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

893.07 Records.—

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

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

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

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

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

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

(b) In the event of the discovery of the theft or loss of

CS/CS/HB 7095, Engrossed 1

2011

controlled substances, report such theft or loss to the sheriff of that county within 24 hours after its discovery. A person who fails to report a theft or loss of a substance listed in s. 893.03(3), (4), or (5) within 24 hours after discovery as required in this paragraph commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. A person who fails to report a theft or loss of a substance listed in s. 893.03(2) within 24 hours after discovery as required in this paragraph commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

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

Section 27. (1) BUY-BACK PROGRAM.—

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

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

distributor; and identifying the corresponding sales invoice number and date of sale from that wholesale distributor; or

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

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

1. The name and address of the returning entity.

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

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

4. The date of return.

(2) PUBLIC HEALTH EMERGENCY.—

(a) The Legislature finds that:

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

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

2493 3. Physicians in this state purchased over 85 percent of
2494 the oxycodone purchased by all practitioners in the United
2495 States in 2006.

2496 4. Physicians in this state purchased over 93 percent of
2497 the methadone purchased by all practitioners in the United
2498 States in 2006.

2499 5. Some physicians in this state dispense medically
2500 unjustifiable amounts of controlled substances to addicts and
2501 people who intend to illegally sell the drugs.

2502 6. Physicians in this state who have purchased large
2503 quantities of controlled substances may have significant
2504 inventory on the effective date of this act.

2505 7. On the effective date of this act, the only legal
2506 method for a dispensing practitioner to sell or otherwise
2507 transfer controlled substances listed in Schedule II or Schedule
2508 III as provided in s. 893.03, Florida Statutes, purchased for
2509 dispensing is through the buy-back procedure or abandonment
2510 procedures of subsection (1).

2511 8. It is likely that the same physicians who purchase and
2512 dispense medically unjustifiable amounts of drugs will not
2513 legally dispose of remaining inventory.

2514 9. The actions of such dispensing practitioners may result
2515 in substantial injury to the public health.

2516 (b) Immediately on the effective date of this act, the
2517 State Health Officer shall declare a public health emergency
2518 pursuant to s. 381.00315, Florida Statutes. Pursuant to that
2519 declaration, the Department of Health, the Attorney General, the
2520 Department of Law Enforcement, and local law enforcement

agencies shall take the following actions:

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

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

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

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

3. The Department of Law Enforcement or local law enforcement agencies shall ensure the security of such inventory 24 hours a day through the 10th day after the effective date of

CS/CS/HB 7095, Engrossed 1

2011

2549 this act or until the inventory is validly transferred pursuant
2550 to subsection (1), whichever is earlier.

2551 4. On the 11th day after the effective date of this act,
2552 any remaining inventory of controlled substances listed in
2553 Schedule II or Schedule III as provided in s. 893.03, Florida
2554 Statutes, purchased for dispensing by practitioners is deemed
2555 contraband under s. 893.12, Florida Statutes. The Department of
2556 Law Enforcement or local law enforcement agencies shall seize
2557 the inventory and comply with the provisions of s. 893.12,
2558 Florida Statutes, to destroy it.

2559 (c) In order to implement the provisions of this
2560 subsection, the sum of \$3 million of nonrecurring funds from the
2561 General Revenue Fund is appropriated to the Department of Law
2562 Enforcement for the 2010-2011 fiscal year. The Department of Law
2563 Enforcement shall expend the appropriation by reimbursing local
2564 law enforcement agencies for the overtime-hour costs associated
2565 with securing the quarantined controlled substance inventory as
2566 provided in paragraph (b) and activities related to
2567 investigation and prosecution of crimes related to prescribed
2568 controlled substances. If requests for reimbursement exceed the
2569 amount appropriated, the reimbursements shall be prorated by the
2570 hours of overtime per requesting agency at a maximum of one law
2571 enforcement officer per quarantine site.

2572 (3) REPEAL.—This section is repealed January 1, 2013.

2573 Section 28. This act shall take effect July 1, 2011.