

By the Committee on Health Regulation; and Senator Bogdanoff

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1 A bill to be entitled
2 An act relating to controlled substances; amending s.
3 400.9905, F.S.; redefining the terms "clinic" and
4 "portable equipment provider" for purposes of the
5 Health Care Clinic Act; amending s. 456.037, F.S.;
6 conforming provisions to changes made by the act;
7 amending s. 456.057, F.S.; authorizing the Department
8 of Health to obtain patient records pursuant to a
9 subpoena and without notification to the patient from
10 a controlled-substance medical clinic under certain
11 circumstances; amending s. 458.3265, F.S.; renaming
12 pain-management clinics as "controlled-substance
13 medical clinics"; prohibiting controlled-substance
14 medical clinics from advertising services related to
15 the dispensing of medication; revising the criteria
16 requiring registration with the department as a
17 controlled-substance medical clinic; conforming
18 provisions to changes made by the act; revising the
19 circumstances in which the department may revoke the
20 certificate of registration for a controlled-substance
21 medical clinic; providing an exception for revoking
22 and suspending a certificate of registration for a
23 controlled-substance medical clinic; revising the
24 responsibilities of a physician who provides
25 professional services in a controlled-substance
26 medical clinic; deleting the requirement that the
27 Board of Medicine adopt a rule establishing the
28 maximum number of prescriptions that can be written
29 for certain controlled substances within a specified

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30 time; revising the rules setting forth the standards
31 of practice that the board is required to adopt;
32 deleting the provision that describes when a physician
33 is primarily engaged in the treatment of pain;
34 amending s. 458.327, F.S.; conforming provisions to
35 changes made by the act; amending s. 458.331, F.S.;
36 conforming provisions to changes made by the act;
37 revising the acts that constitute grounds for
38 disciplinary action for a licensee who serves as a
39 designated physician of a controlled-substance medical
40 clinic; amending s. 459.0137, F.S.; renaming pain-
41 management clinics as "controlled-substance medical
42 clinics"; prohibiting controlled-substance medical
43 clinics from advertising services related to the
44 dispensing of medication; revising the criteria
45 requiring registration with the department as a
46 controlled-substance medical clinic; conforming
47 provisions to changes made by the act; revising the
48 circumstances in which the department may revoke the
49 certificate of registration for a controlled-substance
50 medical clinic; providing an exception for revoking
51 and suspending a certificate of registration for a
52 controlled-substance medical clinic; revising the
53 responsibilities of an osteopathic physician who
54 provides professional services in a controlled-
55 substance medical clinic; deleting the requirement
56 that the Board of Osteopathic Medicine adopt a rule
57 establishing the maximum number of prescriptions that
58 can be written for certain controlled substances

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59 within a specified time; revising the rules setting
60 forth the standards of practice that the board is
61 required to adopt; deleting the provision that
62 describes when an osteopathic physician is primarily
63 engaged in the treatment of pain; amending s. 459.015,
64 F.S.; conforming provisions to changes made by the
65 act; revising the acts that constitute grounds for
66 disciplinary action for a licensee who serves as a
67 designated osteopathic physician of a controlled-
68 substance medical clinic; amending s. 465.0276, F.S.;
69 deleting the provision that prohibits a dispensing
70 practitioner from dispensing a specified amount of a
71 controlled substance under certain circumstances;
72 amending s. 893.055, F.S.; redefining the term
73 "patient advisory report" as it relates to the
74 prescription drug monitoring program; revising the
75 date by which the department is required to establish
76 a comprehensive electronic database system; revising
77 the responsibilities of the dispenser and the
78 prescriber with regard to the electronic database
79 system; revising the circumstances in which the
80 department is required to adopt rules regarding
81 reporting, accessing the database, evaluation,
82 management, development, implementation, operation,
83 security, and storage of information within the
84 electronic database system; deleting the Office of
85 Drug Control as one of the organizations that the
86 department is required to work with in developing
87 rules for the prescription drug monitoring program;

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88 requiring that a dispensed controlled substance be
89 reported to the department within a specified number
90 of hours; authorizing law enforcement agencies to
91 request certain confidential and exempt information
92 from the electronic database system upon determination
93 that probable cause exists that a crime is being
94 committed and issuance of a search warrant; providing
95 that all costs incurred by the department in
96 administering the prescription drug monitoring program
97 be funded through federal grants, dispensing
98 registration fees, or private funding applied for or
99 received by the state; requiring the department rather
100 than the Office of Drug Control to establish a direct-
101 support organization; requiring the State Surgeon
102 General to appoint the board of directors for the
103 direct-support organization; requiring the direct-
104 support organization to operate under written contract
105 with the department; revising requirements for the
106 contract; requiring the activities of the direct-
107 support organization to be consistent with the goals
108 and mission of the department; authorizing the
109 department to permit use of certain services,
110 property, and facilities of the department by the
111 direct-support organization; prohibiting the
112 department from permitting the use of any
113 administrative services, property, or facilities of
114 the state by the direct-support organization under
115 certain conditions; requiring the department rather
116 than the Office of Drug Control to study the

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117 feasibility of enhancing the prescription drug
118 monitoring program for specified purposes; requiring
119 the direct-support organization to provide funding for
120 the department rather than the Office of Drug Control
121 to conduct training in using the prescription drug
122 monitoring program; revising the date in which the
123 department must adopt rules; amending s. 893.0551,
124 F.S.; authorizing a law enforcement agency to disclose
125 certain confidential and exempt information received
126 from the department to a criminal justice agency
127 pursuant to a search warrant; providing an effective
128 date.

129
130 Be It Enacted by the Legislature of the State of Florida:

131
132 Section 1. Subsections (4) and (7) of section 400.9905,
133 Florida Statutes, are amended to read:

134 400.9905 Definitions.—

135 (4) "Clinic" means an entity at which health care services
136 are provided to individuals and which tenders charges for
137 reimbursement or payment for such services, including a mobile
138 clinic and a portable equipment provider. For purposes of this
139 part, the term does not include and the licensure requirements
140 of this part do not apply to:

141 (a) Entities licensed or registered by the state under
142 chapter 395; or entities licensed or registered by the state and
143 providing only health care services within the scope of services
144 authorized under their respective licenses granted under ss.
145 383.30-383.335, chapter 390, chapter 394, chapter 397, this

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146 chapter except part X, chapter 429, chapter 463, chapter 465,
147 chapter 466, chapter 478, part I of chapter 483, chapter 484, or
148 chapter 651; end-stage renal disease providers authorized under
149 42 C.F.R. part 405, subpart U; or providers certified under 42
150 C.F.R. part 485, subpart B or subpart H; or any entity that
151 provides neonatal or pediatric hospital-based health care
152 services or other health care services by licensed practitioners
153 solely within a hospital licensed under chapter 395.

154 (b) Entities that own, directly or indirectly, entities
155 licensed or registered by the state pursuant to chapter 395; or
156 entities that own, directly or indirectly, entities licensed or
157 registered by the state and providing only health care services
158 within the scope of services authorized pursuant to their
159 respective licenses granted under ss. 383.30-383.335, chapter
160 390, chapter 394, chapter 397, this chapter except part X,
161 chapter 429, chapter 463, chapter 465, chapter 466, chapter 478,
162 part I of chapter 483, chapter 484, chapter 651; end-stage renal
163 disease providers authorized under 42 C.F.R. part 405, subpart
164 U; or providers certified under 42 C.F.R. part 485, subpart B or
165 subpart H; or any entity that provides neonatal or pediatric
166 hospital-based health care services by licensed practitioners
167 solely within a hospital licensed under chapter 395.

168 (c) Entities that are owned, directly or indirectly, by an
169 entity licensed or registered by the state pursuant to chapter
170 395; or entities that are owned, directly or indirectly, by an
171 entity licensed or registered by the state and providing only
172 health care services within the scope of services authorized
173 pursuant to their respective licenses granted under ss. 383.30-
174 383.335, chapter 390, chapter 394, chapter 397, this chapter

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175 except part X, chapter 429, chapter 463, chapter 465, chapter
176 466, chapter 478, part I of chapter 483, chapter 484, or chapter
177 651; end-stage renal disease providers authorized under 42
178 C.F.R. part 405, subpart U; or providers certified under 42
179 C.F.R. part 485, subpart B or subpart H; or any entity that
180 provides neonatal or pediatric hospital-based health care
181 services by licensed practitioners solely within a hospital
182 under chapter 395.

183 (d) Entities that are under common ownership, directly or
184 indirectly, with an entity licensed or registered by the state
185 pursuant to chapter 395; or entities that are under common
186 ownership, directly or indirectly, with an entity licensed or
187 registered by the state and providing only health care services
188 within the scope of services authorized pursuant to their
189 respective licenses granted under ss. 383.30-383.335, chapter
190 390, chapter 394, chapter 397, this chapter except part X,
191 chapter 429, chapter 463, chapter 465, chapter 466, chapter 478,
192 part I of chapter 483, chapter 484, or chapter 651; end-stage
193 renal disease providers authorized under 42 C.F.R. part 405,
194 subpart U; or providers certified under 42 C.F.R. part 485,
195 subpart B or subpart H; or any entity that provides neonatal or
196 pediatric hospital-based health care services by licensed
197 practitioners solely within a hospital licensed under chapter
198 395.

199 (e) An entity that is exempt from federal taxation under 26
200 U.S.C. s. 501(c)(3) or (4), an employee stock ownership plan
201 under 26 U.S.C. s. 409 that has a board of trustees not less
202 than two-thirds of which are Florida-licensed health care
203 practitioners and provides only physical therapy services under

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204 physician orders, any community college or university clinic,
205 and any entity owned or operated by the federal or state
206 government, including agencies, subdivisions, or municipalities
207 thereof.

208 (f) A sole proprietorship, group practice, partnership, or
209 corporation that provides health care services by physicians
210 covered by s. 627.419, that is directly supervised by one or
211 more of such physicians, and that is wholly owned by one or more
212 of those physicians or by a physician and the spouse, parent,
213 child, or sibling of that physician.

214 (g) A sole proprietorship, group practice, partnership, or
215 corporation that provides health care services by licensed
216 health care practitioners under chapter 457, chapter 458,
217 chapter 459, chapter 460, chapter 461, chapter 462, chapter 463,
218 chapter 466, chapter 467, chapter 480, chapter 484, chapter 486,
219 chapter 490, chapter 491, or part I, part III, part X, part
220 XIII, or part XIV of chapter 468, or s. 464.012, which are
221 wholly owned by one or more licensed health care practitioners,
222 or the licensed health care practitioners set forth in this
223 paragraph and the spouse, parent, child, or sibling of a
224 licensed health care practitioner, so long as one of the owners
225 who is a licensed health care practitioner is supervising the
226 business activities and is legally responsible for the entity's
227 compliance with all federal and state laws. However, a health
228 care practitioner may not supervise services beyond the scope of
229 the practitioner's license, except that, for the purposes of
230 this part, a clinic owned by a licensee in s. 456.053(3)(b) that
231 provides only services authorized pursuant to s. 456.053(3)(b)
232 may be supervised by a licensee specified in s. 456.053(3)(b).

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233 (h) Clinical facilities affiliated with an accredited
234 medical school at which training is provided for medical
235 students, residents, or fellows.

236 (i) Entities that provide only oncology or radiation
237 therapy services by physicians licensed under chapter 458 or
238 chapter 459 or entities that provide oncology or radiation
239 therapy services by physicians licensed under chapter 458 or
240 chapter 459 which are owned by a corporation whose shares are
241 publicly traded on a recognized stock exchange.

242 (j) Clinical facilities affiliated with a college of
243 chiropractic accredited by the Council on Chiropractic Education
244 at which training is provided for chiropractic students.

245 (k) Entities that provide licensed practitioners to staff
246 emergency departments or to deliver anesthesia services in
247 facilities licensed under chapter 395 and that derive at least
248 90 percent of their gross annual revenues from the provision of
249 such services. Entities claiming an exemption from licensure
250 under this paragraph must provide documentation demonstrating
251 compliance.

252 (l) Orthotic or prosthetic clinical facilities that are a
253 publicly traded corporation or that are wholly owned, directly
254 or indirectly, by a publicly traded corporation. As used in this
255 paragraph, a publicly traded corporation is a corporation that
256 issues securities traded on an exchange registered with the
257 United States Securities and Exchange Commission as a national
258 securities exchange.

259 (7) "Portable equipment provider" means an entity that
260 contracts with or employs persons to provide portable equipment
261 to multiple locations performing treatment or diagnostic testing

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262 of individuals, ~~that bills third-party payors for those~~
263 ~~services,~~ and that otherwise meets the definition of a clinic in
264 subsection (4).

265 Section 2. Subsection (5) of section 456.037, Florida
266 Statutes, is amended to read:

267 456.037 Business establishments; requirements for active
268 status licenses; delinquency; discipline; applicability.—

269 (5) This section applies to any business establishment
270 registered, permitted, or licensed by the department to do
271 business. Business establishments include, but are not limited
272 to, dental laboratories, electrology facilities, massage
273 establishments, pharmacies, and controlled-substance medical
274 ~~pain-management~~ clinics required to be registered under s.
275 458.3265 or s. 459.0137.

276 Section 3. Paragraph (a) of subsection (9) of section
277 456.057, Florida Statutes, is amended to read:

278 456.057 Ownership and control of patient records; report or
279 copies of records to be furnished.—

280 (9) (a) 1. The department may obtain patient records pursuant
281 to a subpoena without written authorization from the patient if
282 the department and the probable cause panel of the appropriate
283 board, if any, find reasonable cause to believe that a health
284 care practitioner has excessively or inappropriately prescribed
285 any controlled substance specified in chapter 893 in violation
286 of this chapter or any professional practice act or that a
287 health care practitioner has practiced his or her profession
288 below that level of care, skill, and treatment required as
289 defined by this chapter or any professional practice act and
290 also find that appropriate, reasonable attempts were made to

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291 obtain a patient release. Notwithstanding the foregoing, the
292 department need not attempt to obtain a patient release when
293 investigating an offense involving the inappropriate
294 prescribing, overprescribing, or diversion of controlled
295 substances and the offense involves a controlled-substance
296 medical pain-management clinic. The department may obtain
297 patient records pursuant to a subpoena and without patient
298 authorization or notification to the patient subpoena from any
299 controlled-substance medical pain-management clinic required to
300 be licensed if the department has probable cause to believe that
301 a violation of any provision of s. 458.3265 or s. 459.0137 is
302 occurring or has occurred and reasonably believes that obtaining
303 such patient authorization is not feasible due to the volume of
304 the dispensing and prescribing activity involving controlled
305 substances and that obtaining patient authorization ~~or the~~
306 ~~issuance of a subpoena~~ would jeopardize the investigation.

307 2. The department may obtain patient records and insurance
308 information pursuant to a subpoena without written authorization
309 from the patient if the department and the probable cause panel
310 of the appropriate board, if any, find reasonable cause to
311 believe that a health care practitioner has provided inadequate
312 medical care based on termination of insurance and also find
313 that appropriate, reasonable attempts were made to obtain a
314 patient release.

315 3. The department may obtain patient records, billing
316 records, insurance information, provider contracts, and all
317 attachments thereto pursuant to a subpoena without written
318 authorization from the patient if the department and probable
319 cause panel of the appropriate board, if any, find reasonable

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320 cause to believe that a health care practitioner has submitted a
321 claim, statement, or bill using a billing code that would result
322 in payment greater in amount than would be paid using a billing
323 code that accurately describes the services performed, requested
324 payment for services that were not performed by that health care
325 practitioner, used information derived from a written report of
326 an automobile accident generated pursuant to chapter 316 to
327 solicit or obtain patients personally or through an agent
328 regardless of whether the information is derived directly from
329 the report or a summary of that report or from another person,
330 solicited patients fraudulently, received a kickback as defined
331 in s. 456.054, violated the patient brokering provisions of s.
332 817.505, or presented or caused to be presented a false or
333 fraudulent insurance claim within the meaning of s.
334 817.234(1)(a), and also find that, within the meaning of s.
335 817.234(1)(a), patient authorization cannot be obtained because
336 the patient cannot be located or is deceased, incapacitated, or
337 suspected of being a participant in the fraud or scheme, and if
338 the subpoena is issued for specific and relevant records.

339 4. Notwithstanding subparagraphs 1.-3., when the department
340 investigates a professional liability claim or undertakes action
341 pursuant to s. 456.049 or s. 627.912, the department may obtain
342 patient records pursuant to a subpoena without written
343 authorization from the patient if the patient refuses to
344 cooperate or if the department attempts to obtain a patient
345 release and the failure to obtain the patient records would be
346 detrimental to the investigation.

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

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349 458.3265 Controlled-substance medical ~~pain-management~~
350 clinics.-

351 (1) REGISTRATION.-

352 (a) A ~~All~~ privately owned controlled-substance medical
353 clinic, facility, or office ~~pain-management clinics, facilities,~~
354 ~~or offices,~~ hereinafter referred to as a "clinic," "clinics,"
355 may not advertise services related to the dispensing of
356 medication. A controlled-substance medical clinic is a facility
357 that employs a physician who prescribes on any given day more
358 than 25 prescriptions of Schedule II or Schedule III controlled
359 substance medications, or a combination thereof, ~~which advertise~~
360 ~~in any medium for any type of pain-management services,~~ or
361 employs ~~employ~~ a physician who is primarily engaged in the
362 ~~treatment of pain by prescribing or~~ dispensing controlled
363 substance medications. Such a clinic, must register with the
364 department unless:

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

367 2. The majority of the physicians who provide services in
368 the clinic primarily provide interventional pain-management
369 procedures or other surgical services;

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

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

377 ~~5. The clinic does not prescribe or dispense controlled~~

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378 ~~substances for the treatment of pain; or~~

379 ~~5.6.~~ The clinic is owned by a corporate entity exempt from
380 federal taxation under 26 U.S.C. s. 501(c)(3).

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

384 (c) As a part of registration, a clinic must designate a
385 physician who is responsible for complying with all requirements
386 related to registration and operation of the clinic in
387 compliance with this section. Within 10 days after termination
388 of a designated physician, the clinic must notify the department
389 of the identity of another designated physician for that clinic.
390 The designated physician shall have a full, active, and
391 unencumbered license under this chapter or chapter 459 and shall
392 practice at the clinic location for which the physician has
393 assumed responsibility. Failing to have a licensed designated
394 physician practicing at the location of the registered clinic
395 may be the basis for a summary suspension of the clinic
396 registration certificate as described in s. 456.073(8) for a
397 license or s. 120.60(6).

398 (d) The department shall deny registration to any clinic
399 that is not fully owned by a physician licensed under this
400 chapter or chapter 459 or a group of physicians, each of whom is
401 licensed under this chapter or chapter 459; or that is not a
402 health care clinic licensed under part X of chapter 400.

403 (e) The department shall deny registration to any
404 controlled-substance medical ~~pain-management~~ clinic owned by or
405 with any contractual or employment relationship with a
406 physician:

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

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

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

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

430 (g) The department may revoke the clinic's certificate of
431 registration and prohibit all physicians associated with that
432 controlled-substance medical ~~pain-management~~ clinic from
433 practicing at that clinic location based upon an annual
434 inspection and evaluation of the factors described in subsection
435 (3) and upon a final determination by the probable cause panel

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436 of the appropriate board that any physician associated with that
437 controlled-substance medical clinic knew or should have known of
438 any violations of the factors described in subsection (3).

439 (h) 1. If the registration of a controlled-substance medical
440 ~~pain-management~~ clinic is revoked or suspended, the designated
441 physician of the controlled-substance medical ~~pain-management~~
442 clinic, the owner or lessor of the controlled-substance medical
443 ~~pain-management~~ clinic property, the manager, and the proprietor
444 shall cease to operate the facility as a controlled-substance
445 medical ~~pain-management~~ clinic as of the effective date of the
446 suspension or revocation.

447 2. Notwithstanding subparagraph 1., the clinic's
448 registration shall not be revoked or suspended if the clinic,
449 within 24 hours after notification of suspension or revocation,
450 appoints another designated physician who has a full, active,
451 and unencumbered license under this chapter or chapter 459 to
452 operate a controlled-substance medical clinic.

453 (i) If a controlled-substance medical ~~pain-management~~
454 clinic registration is revoked or suspended, the designated
455 physician of the controlled-substance medical ~~pain-management~~
456 clinic, the owner or lessor of the clinic property, the manager,
457 or the proprietor is responsible for removing all signs and
458 symbols identifying the premises as a controlled-substance
459 medical ~~pain-management~~ clinic.

460 (j) Upon the effective date of the suspension or
461 revocation, the designated physician of the controlled-substance
462 medical ~~pain-management~~ clinic shall advise the department of
463 the disposition of the medicinal drugs located on the premises.
464 The disposition is subject to the supervision and approval of

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465 the department. Medicinal drugs that are purchased or held by a
466 controlled-substance medical ~~pain-management~~ clinic that is not
467 registered may be deemed adulterated pursuant to s. 499.006.

468 (k) If the clinic's registration is revoked, any person
469 named in the registration documents of the controlled-substance
470 medical ~~pain-management~~ clinic, including persons owning or
471 operating the controlled-substance medical ~~pain-management~~
472 clinic, may not, as an individual or as a part of a group, apply
473 to operate a controlled-substance medical ~~pain-management~~ clinic
474 for 5 years after the date the registration is revoked upon a
475 finding of probable cause, and an opportunity to be heard, that
476 the persons operating such clinic knew or should have known of
477 the violations causing such revocation.

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

481 (m) A change of ownership of a registered controlled-
482 substance medical ~~pain-management~~ clinic requires submission of
483 a new registration application.

484 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
485 apply to any physician who provides professional services in a
486 controlled-substance medical ~~pain-management~~ clinic that is
487 required to be registered in subsection (1).

488 (a) A physician may not practice medicine in a controlled-
489 substance medical ~~pain-management~~ clinic, as described in
490 subsection (4), if:

491 ~~1.~~ the controlled-substance medical ~~pain-management~~ clinic
492 is not registered with the department as required by this
493 section. ~~;~~ ~~or~~

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

501
502 ~~Any physician who qualifies to practice medicine in a pain-~~
503 ~~management clinic pursuant to rules adopted by the Board of~~
504 ~~Medicine as of July 1, 2012, may continue to practice medicine~~
505 ~~in a pain management clinic as long as the physician continues~~
506 ~~to meet the qualifications set forth in the board rules. A~~
507 ~~physician who violates this paragraph is subject to disciplinary~~
508 ~~action by his or her appropriate medical regulatory board.~~

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

513 (c) A physician, advanced registered nurse practitioner, or
514 a physician assistant must perform an appropriate medical ~~a~~
515 ~~physical~~ examination of a patient on the same day that the
516 physician ~~he or she~~ dispenses or prescribes a controlled
517 substance to a patient at a controlled-substance medical ~~pain-~~
518 ~~management~~ clinic. A ~~If the physician may not dispense~~
519 ~~prescribes or dispenses~~ more than a 30-day supply ~~72-hour dose~~
520 of controlled substances to any patient ~~for the treatment of~~
521 ~~chronic nonmalignant pain, the physician must document in the~~
522 ~~patient's record the reason for prescribing or dispensing that~~

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523 quantity.

524 (d) A physician authorized to prescribe controlled
525 substances who practices at a controlled-substance medical ~~pain-~~
526 ~~management~~ clinic is responsible for maintaining the control and
527 security of his or her prescription blanks and any other method
528 used for prescribing controlled substance pain medication. The
529 physician shall comply with the requirements for counterfeit-
530 resistant prescription blanks in s. 893.065 and the rules
531 adopted pursuant to that section. The physician shall notify, in
532 writing, the department within 24 hours after discovering
533 ~~following~~ any theft or loss of a prescription blank or breach of
534 any other method for prescribing controlled substances ~~pain~~
535 ~~medication~~.

536 (e) The designated physician of a controlled-substance
537 medical ~~pain-management~~ clinic shall notify the applicable board
538 in writing of the date of termination of employment within 10
539 days after terminating his or her employment with a controlled-
540 substance medical ~~pain-management~~ clinic that is required to be
541 registered under subsection (1).

542 (3) INSPECTION.—

543 (a) The department shall inspect the controlled-substance
544 medical ~~pain-management~~ clinic annually, including a review of
545 the patient records, to ensure that it complies with this
546 section and the rules of the Board of Medicine adopted pursuant
547 to subsection (4) unless the clinic is accredited by a
548 nationally recognized accrediting agency approved by the Board
549 of Medicine.

550 (b) During an onsite inspection, the department shall make
551 a reasonable attempt to discuss each violation with the owner or

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552 designated physician of the controlled-substance medical ~~pain-~~
553 ~~management~~ clinic before issuing a formal written notification.

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

558 (4) RULEMAKING.—

559 (a) The department shall adopt rules necessary to
560 administer the registration and inspection of controlled-
561 substance medical ~~pain-management~~ clinics which establish the
562 specific requirements, procedures, forms, and fees.

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

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

578 (c) ~~(d)~~ The Board of Medicine shall adopt rules setting
579 forth standards of practice for physicians practicing in
580 privately owned controlled-substance medical ~~pain-management~~

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581 clinics that primarily engage in the treatment of pain by
582 prescribing or dispensing controlled substance medications. Such
583 rules shall address, but need not be limited to:

- 584 1. Facility operations;
- 585 2. Physical operations;
- 586 3. Infection control requirements;
- 587 4. Health and safety requirements;
- 588 5. Quality assurance requirements;
- 589 6. Patient records;

590 ~~7. Training requirements for all facility health care~~
591 ~~practitioners who are not regulated by another board;~~

592 7.8. Inspections; and

593 8.9. Data collection and reporting requirements.

594
595 ~~A physician is primarily engaged in the treatment of pain by~~
596 ~~prescribing or dispensing controlled substance medications when~~
597 ~~the majority of the patients seen are prescribed or dispensed~~
598 ~~controlled substance medications for the treatment of chronic~~
599 ~~nonmalignant pain. Chronic nonmalignant pain is pain unrelated~~
600 ~~to cancer which persists beyond the usual course of the disease~~
601 ~~or the injury that is the cause of the pain or more than 90 days~~
602 ~~after surgery.~~

603 (5) PENALTIES; ENFORCEMENT.—

604 (a) The department may impose an administrative fine on the
605 clinic of up to \$5,000 per violation for violating the
606 requirements of this section; chapter 499, the Florida Drug and
607 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
608 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
609 Abuse Prevention and Control Act; chapter 893, the Florida

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610 Comprehensive Drug Abuse Prevention and Control Act; or the
611 rules of the department. In determining whether a penalty is to
612 be imposed, and in fixing the amount of the fine, the department
613 shall consider the following factors:

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

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

623 3. Whether there were any previous violations at the
624 controlled-substance medical ~~pain-management~~ clinic.

625 4. The financial benefits that the controlled-substance
626 medical ~~pain-management~~ clinic derived from committing or
627 continuing to commit the violation.

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

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

637 (d) An owner or designated physician of a controlled-
638 substance medical ~~pain-management~~ clinic who concurrently

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639 operates an unregistered controlled-substance medical ~~pain-~~
640 ~~management~~ clinic is subject to an administrative fine of \$5,000
641 per day.

642 (e) If the owner of a controlled-substance medical ~~pain-~~
643 ~~management~~ clinic that requires registration fails to apply to
644 register the clinic upon a change of ownership and operates the
645 clinic under the new ownership, the owner is subject to a fine
646 of \$5,000.

647 Section 5. Paragraphs (a) and (e) of subsection (1) and
648 paragraph (f) of subsection (2) of section 458.327, Florida
649 Statutes, are amended to read:

650 458.327 Penalty for violations.—

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

654 (a) The practice of medicine or an attempt to practice
655 medicine without a license to practice in this state ~~Florida~~.

656 (e) Knowingly operating, owning, or managing a
657 nonregistered controlled-substance medical ~~pain-management~~
658 clinic that is required to be registered with the Department of
659 Health pursuant to s. 458.3265(1).

660 (2) Each of the following acts constitutes a misdemeanor of
661 the first degree, punishable as provided in s. 775.082 or s.
662 775.083:

663 (f) Knowingly prescribing or dispensing, or causing to be
664 prescribed or dispensed, controlled substances in a
665 nonregistered controlled-substance medical ~~pain-management~~
666 clinic that is required to be registered with the Department of
667 Health pursuant to s. 458.3265(1).

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668 Section 6. Paragraphs (oo) and (pp) of subsection (1) of
669 section 458.331, Florida Statutes, are amended to read:

670 458.331 Grounds for disciplinary action; action by the
671 board and department.—

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

674 (oo) Applicable to a licensee who serves as the designated
675 physician of a controlled-substance medical ~~pain-management~~
676 clinic as defined in s. 458.3265 or s. 459.0137:

677 1. Registering a controlled-substance medical ~~pain-~~
678 ~~management~~ clinic through misrepresentation or fraud;

679 2. Procuring, or attempting to procure, the registration of
680 a controlled-substance medical ~~pain-management~~ clinic for any
681 other person by making or causing to be made, any false
682 representation;

683 3. Failing to comply with any requirement of chapter 499,
684 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
685 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
686 the Drug Abuse Prevention and Control Act; or chapter 893, the
687 Florida Comprehensive Drug Abuse Prevention and Control Act;

688 4. Being convicted or found guilty of, regardless of
689 adjudication to, a felony or any other crime involving moral
690 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
691 the courts of this state, of any other state, or of the United
692 States;

693 ~~5. Being convicted of, or disciplined by a regulatory~~
694 ~~agency of the Federal Government or a regulatory agency of~~
695 ~~another state for, any offense that would constitute a violation~~
696 ~~of this chapter;~~

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697 ~~5.6.~~ Being convicted of, or entering a plea of guilty or
 698 nolo contendere to, regardless of adjudication, a crime in any
 699 jurisdiction of the courts of this state, of any other state, or
 700 of the United States which relates to the practice of, or the
 701 ability to practice, a licensed health care profession;

702 ~~6.7.~~ Being convicted of, or entering a plea of guilty or
 703 nolo contendere to, regardless of adjudication, a crime in any
 704 jurisdiction of the courts of this state, of any other state, or
 705 of the United States which relates to health care fraud;

706 ~~7.8.~~ Dispensing any medicinal drug based upon a
 707 communication that purports to be a prescription as defined in
 708 s. 465.003(14) or s. 893.02 if the dispensing practitioner knows
 709 or has reason to believe that the purported prescription is not
 710 based upon a valid practitioner-patient relationship; or

711 ~~8.9.~~ Failing to timely notify the board of the date of his
 712 or her termination from a controlled-substance medical ~~pain-~~
 713 ~~management~~ clinic as required by s. 458.3265(2).

714 (pp) Failing to timely notify the department of the theft
 715 of prescription blanks from a controlled-substance medical ~~pain-~~
 716 ~~management~~ clinic or a breach of other methods for prescribing
 717 within 24 hours as required by s. 458.3265(2).

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

720 459.0137 Controlled-substance medical ~~pain-management~~
 721 clinics.-

722 (1) REGISTRATION.-

723 (a) A ~~All~~ privately owned controlled-substance medical
 724 clinic, facility, or office ~~pain-management clinics, facilities,~~
 725 ~~or offices,~~ hereinafter referred to as a "clinic," "clinics,"

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726 may not advertise services related to the dispensing of
727 medication. A controlled-substance medical clinic is a facility
728 that employs an osteopathic physician who prescribes on any
729 given day more than 25 prescriptions of Schedule II or Schedule
730 III controlled substance medications, or a combination thereof,
731 ~~which advertise in any medium for any type of pain-management~~
732 ~~services, or employs employ an osteopathic physician who is~~
733 ~~primarily engaged in the treatment of pain by prescribing or~~
734 ~~dispensing controlled substance medications.~~ Such clinic must
735 register with the department unless:

- 736 1. That clinic is licensed as a facility pursuant to
737 chapter 395;
- 738 2. The majority of the physicians who provide services in
739 the clinic primarily provide surgical services;
- 740 3. The clinic is owned by a publicly held corporation whose
741 shares are traded on a national exchange or on the over-the-
742 counter market and whose total assets at the end of the
743 corporation's most recent fiscal quarter exceeded \$50 million;
- 744 4. The clinic is affiliated with an accredited medical
745 school at which training is provided for medical students,
746 residents, or fellows; or
- 747 ~~5. The clinic does not prescribe or dispense controlled~~
748 ~~substances for the treatment of pain; or~~
- 749 ~~5.6.~~ The clinic is owned by a corporate entity exempt from
750 federal taxation under 26 U.S.C. s. 501(c)(3).

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

754 (c) As a part of registration, a clinic must designate an

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755 osteopathic, dispensing physician who is responsible for
756 complying with all requirements related to registration and
757 operation of the clinic in compliance with this section. Within
758 10 days after termination of a designated osteopathic physician,
759 the clinic must notify the department of the identity of another
760 designated physician for that clinic. The designated physician
761 shall have a full, active, and unencumbered license under
762 chapter 458 or this chapter and shall practice at the clinic
763 location for which the physician has assumed responsibility.
764 Failing to have a licensed designated osteopathic physician
765 practicing at the location of the registered clinic may be the
766 basis for a summary suspension of the clinic registration
767 certificate as described in s. 456.073(8) for a license or s.
768 120.60(6).

769 (d) The department shall deny registration to any clinic
770 that is not fully owned by a physician licensed under chapter
771 458 or this chapter or a group of physicians, each of whom is
772 licensed under chapter 458 or this chapter; or that is not a
773 health care clinic licensed under part X of chapter 400.

774 (e) The department shall deny registration to any
775 controlled-substance medical ~~pain-management~~ clinic owned by or
776 with any contractual or employment relationship with a
777 physician:

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

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

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

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

789 (f) If the department finds upon a hearing by the probable
790 cause panel of the appropriate medical board that a controlled-
791 substance medical ~~pain-management~~ clinic does not meet the
792 requirement of paragraph (d) or is owned, directly or
793 indirectly, by a person meeting any criteria listed in paragraph
794 (e), the department shall revoke the certificate of registration
795 previously issued by the department. As determined by rule, the
796 department may grant an exemption to denying a registration or
797 revoking a previously issued registration if more than 10 years
798 have elapsed since adjudication. As used in this subsection, the
799 term "convicted" includes an adjudication of guilt following a
800 plea of guilty or nolo contendere or the forfeiture of a bond
801 when charged with a crime.

802 (g) The department may revoke the clinic's certificate of
803 registration and prohibit all physicians associated with that
804 controlled-substance medical ~~pain-management~~ clinic from
805 practicing at that clinic location based upon an annual
806 inspection and evaluation of the factors described in subsection
807 (3) and upon a final determination by the probable cause panel
808 of the appropriate medical board that any physician associated
809 with that controlled-substance medical clinic knew or should
810 have known of any violations of the factors described in
811 subsection (3).

812 (h) 1. If the registration of a controlled-substance medical

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813 ~~pain-management~~ clinic is revoked or suspended, the designated
814 physician of the controlled-substance medical ~~pain-management~~
815 clinic, the owner or lessor of the controlled-substance medical
816 ~~pain-management~~ clinic property, the manager, and the proprietor
817 shall cease to operate the facility as a controlled-substance
818 medical ~~pain-management~~ clinic as of the effective date of the
819 suspension or revocation.

820 2. Notwithstanding subparagraph 1., the clinic's
821 registration shall not be revoked or suspended if the clinic,
822 within 24 hours after notification of suspension or revocation,
823 appoints another designated physician who has a full, active,
824 and unencumbered license under this chapter or chapter 458 to
825 operate a controlled-substance medical clinic.

826 (i) If a controlled-substance medical ~~pain-management~~
827 clinic registration is revoked or suspended, the designated
828 physician of the controlled-substance medical ~~pain-management~~
829 clinic, the owner or lessor of the clinic property, the manager,
830 or the proprietor is responsible for removing all signs and
831 symbols identifying the premises as a controlled-substance
832 medical ~~pain-management~~ clinic.

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

841 (k) If the clinic's registration is revoked, any person

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842 named in the registration documents of the controlled-substance
843 medical ~~pain-management~~ clinic, including persons owning or
844 operating the controlled-substance medical ~~pain-management~~
845 clinic, may not, as an individual or as a part of a group, make
846 application for a permit to operate a controlled-substance
847 medical ~~pain-management~~ clinic for 5 years after the date the
848 registration is revoked upon a finding by the probable cause
849 panel, and an opportunity to be heard, the persons operating
850 such clinic knew or should have known of violations causing such
851 revocation.

852 (1) The period of suspension for the registration of a
853 controlled-substance medical ~~pain-management~~ clinic shall be
854 prescribed by the department, but may not exceed 1 year.

855 (m) A change of ownership of a registered controlled-
856 substance medical ~~pain-management~~ clinic requires submission of
857 a new registration application.

858 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
859 apply to any osteopathic physician who provides professional
860 services in a controlled-substance medical ~~pain-management~~
861 clinic that is required to be registered in subsection (1).

862 (a) An osteopathic physician may not practice medicine in a
863 controlled-substance medical ~~pain-management~~ clinic, as
864 described in subsection (4), if:

865 ~~1. the controlled-substance medical ~~pain-management~~ clinic~~
866 ~~is not registered with the department as required by this~~
867 ~~section.;~~ ~~or~~

868 ~~2. Effective July 1, 2012, the physician has not~~
869 ~~successfully completed a ~~pain-medicine~~ fellowship that is~~
870 ~~accredited by the Accreditation Council for Graduate Medical~~

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

876

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

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

889 (c) An osteopathic physician, an advanced registered nurse
890 practitioner, or a physician assistant must perform an
891 appropriate medical ~~a physical~~ examination of a patient on the
892 same day that the osteopathic physician ~~he or she~~ dispenses or
893 prescribes a controlled substance to a patient at a controlled-
894 substance medical pain-management clinic. An ~~If the~~ osteopathic
895 physician may not dispense ~~prescribes or dispenses~~ more than a
896 30-day supply ~~72-hour dose~~ of controlled substances to any
897 patient ~~for the treatment of chronic nonmalignant pain, the~~
898 ~~osteopathic physician must document in the patient's record the~~
899 ~~reason for prescribing or dispensing that quantity.~~

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900 (d) An osteopathic physician authorized to prescribe
901 controlled substances who practices at a controlled-substance
902 medical ~~pain-management~~ clinic is responsible for maintaining
903 the control and security of his or her prescription blanks and
904 any other method used for prescribing controlled substance pain
905 medication. The osteopathic physician shall comply with the
906 requirements for counterfeit-resistant prescription blanks in s.
907 893.065 and the rules adopted pursuant to that section. The
908 osteopathic physician shall notify, in writing, the department
909 within 24 hours after discovering ~~following~~ any theft or loss of
910 a prescription blank or breach of any other method for
911 prescribing controlled substances ~~pain medication~~.

912 (e) The designated osteopathic physician of a controlled-
913 substance medical ~~pain-management~~ clinic shall notify the
914 applicable board in writing of the date of termination of
915 employment within 10 days after terminating his or her
916 employment with a controlled-substance medical ~~pain-management~~
917 clinic that is required to be registered under subsection (1).

918 (3) INSPECTION.—

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

926 (b) During an onsite inspection, the department shall make
927 a reasonable attempt to discuss each violation with the owner or
928 designated physician of the controlled-substance medical ~~pain-~~

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929 ~~management~~ clinic before issuing a formal written notification.

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

934 (4) RULEMAKING.—

935 (a) The department shall adopt rules necessary to
936 administer the registration and inspection of controlled-
937 substance medical ~~pain-management~~ clinics which establish the
938 specific requirements, procedures, forms, and fees.

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

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

954 ~~(c)-(d)~~ (c) The Board of Osteopathic Medicine shall adopt rules
955 setting forth standards of practice for osteopathic physicians
956 practicing in privately owned controlled-substance medical ~~pain-~~
957 ~~management~~ clinics that primarily engage in the treatment of

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958 pain by prescribing or dispensing controlled substance
959 medications. Such rules shall address, but need not be limited
960 to:

- 961 1. Facility operations;
- 962 2. Physical operations;
- 963 3. Infection control requirements;
- 964 4. Health and safety requirements;
- 965 5. Quality assurance requirements;
- 966 6. Patient records;
- 967 ~~7. Training requirements for all facility health care~~
968 ~~practitioners who are not regulated by another board;~~
- 969 7.8. Inspections; and
- 970 8.9. Data collection and reporting requirements.

971
972 ~~An osteopathic physician is primarily engaged in the treatment~~
973 ~~of pain by prescribing or dispensing controlled substance~~
974 ~~medications when the majority of the patients seen are~~
975 ~~prescribed or dispensed controlled substance medications for the~~
976 ~~treatment of chronic nonmalignant pain. Chronic nonmalignant~~
977 ~~pain is pain unrelated to cancer which persists beyond the usual~~
978 ~~course of the disease or the injury that is the cause of the~~
979 ~~pain or more than 90 days after surgery.~~

980 (5) PENALTIES; ENFORCEMENT.—

981 (a) The department may impose an administrative fine on the
982 clinic of up to \$5,000 per violation for violating the
983 requirements of this section; chapter 499, the Florida Drug and
984 Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and
985 Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug
986 Abuse Prevention and Control Act; chapter 893, the Florida

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987 Comprehensive Drug Abuse Prevention and Control Act; or the
988 rules of the department. In determining whether a penalty is to
989 be imposed, and in fixing the amount of the fine, the department
990 shall consider the following factors:

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

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

1000 3. Whether there were any previous violations at the
1001 controlled-substance medical ~~pain-management~~ clinic.

1002 4. The financial benefits that the controlled-substance
1003 medical ~~pain-management~~ clinic derived from committing or
1004 continuing to commit the violation.

1005 (b) Each day a violation continues after the date fixed for
1006 termination of the violation as ordered by the department
1007 constitutes an additional, separate, and distinct violation.

1008 (c) The department may impose a fine and, in the case of an
1009 owner-operated controlled-substance medical ~~pain-management~~
1010 clinic, revoke or deny a controlled-substance medical ~~pain-~~
1011 management clinic's registration, if the clinic's designated
1012 osteopathic physician knowingly and intentionally misrepresents
1013 actions taken to correct a violation.

1014 (d) An owner or designated osteopathic physician of a
1015 controlled-substance medical ~~pain-management~~ clinic who

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1016 concurrently operates an unregistered controlled-substance
1017 medical pain-management clinic is subject to an administrative
1018 fine of \$5,000 per day.

1019 (e) If the owner of a controlled-substance medical pain-
1020 management clinic that requires registration fails to apply to
1021 register the clinic upon a change of ownership and operates the
1022 clinic under the new ownership, the owner is subject to a fine
1023 of \$5,000.

1024 Section 8. Paragraphs (qq) and (rr) of subsection (1) of
1025 section 459.015, Florida Statutes, are amended to read:

1026 459.015 Grounds for disciplinary action; action by the
1027 board and department.—

1028 (1) The following acts constitute grounds for denial of a
1029 license or disciplinary action, as specified in s. 456.072(2):

1030 (qq) Applicable to a licensee who serves as the designated
1031 physician of a controlled-substance medical pain-management
1032 clinic as defined in s. 458.3265 or s. 459.0137:

1033 1. Registering a controlled-substance medical pain-
1034 management clinic through misrepresentation or fraud;

1035 2. Procuring, or attempting to procure, the registration of
1036 a pain-management clinic for any other person by making or
1037 causing to be made, any false representation;

1038 3. Failing to comply with any requirement of chapter 499,
1039 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
1040 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
1041 the Drug Abuse Prevention and Control Act; or chapter 893, the
1042 Florida Comprehensive Drug Abuse Prevention and Control Act;

1043 4. Being convicted or found guilty of, regardless of
1044 adjudication to, a felony or any other crime involving ~~moral~~

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1045 ~~turpitude~~, fraud, dishonesty, or deceit in any jurisdiction of
1046 the courts of this state, of any other state, or of the United
1047 States;

1048 ~~5. Being convicted of, or disciplined by a regulatory~~
1049 ~~agency of the Federal Government or a regulatory agency of~~
1050 ~~another state for, any offense that would constitute a violation~~
1051 ~~of this chapter;~~

1052 5.6. Being convicted of, or entering a plea of guilty or
1053 nolo contendere to, regardless of adjudication, a crime in any
1054 jurisdiction of the courts of this state, of any other state, or
1055 of the United States which relates to the practice of, or the
1056 ability to practice, a licensed health care profession;

1057 6.7. Being convicted of, or entering a plea of guilty or
1058 nolo contendere to, regardless of adjudication, a crime in any
1059 jurisdiction of the courts of this state, of any other state, or
1060 of the United States which relates to health care fraud;

1061 7.8. Dispensing any medicinal drug based upon a
1062 communication that purports to be a prescription as defined in
1063 s. 465.003(14) or s. 893.02 if the dispensing practitioner knows
1064 or has reason to believe that the purported prescription is not
1065 based upon a valid practitioner-patient relationship; or

1066 8.9. Failing to timely notify the board of the date of his
1067 or her termination from a controlled-substance medical pain-
1068 ~~management~~ clinic as required by s. 459.0137(2).

1069 (rr) Failing to timely notify the department of the theft
1070 of prescription blanks from a controlled-substance medical pain-
1071 ~~management~~ clinic or a breach of other methods for prescribing
1072 within 24 hours as required by s. 459.0137(2).

1073 Section 9. Subsection (1) of section 465.0276, Florida

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1074 Statutes, is amended to read:

1075 465.0276 Dispensing practitioner.—

1076 ~~(1)(a)~~ A person may not dispense medicinal drugs unless
1077 licensed as a pharmacist or otherwise authorized under this
1078 chapter to do so, except that a practitioner authorized by law
1079 to prescribe drugs may dispense such drugs to her or his
1080 patients in the regular course of her or his practice in
1081 compliance with this section.

1082 ~~(b) A practitioner registered under this section may not~~
1083 ~~dispense more than a 72-hour supply of a controlled substance~~
1084 ~~listed in Schedule II, Schedule III, Schedule IV, or Schedule V~~
1085 ~~of s. 893.03 for any patient who pays for the medication by~~
1086 ~~cash, check, or credit card in a clinic registered under s.~~
1087 ~~458.3265 or s. 459.0137. A practitioner who violates this~~
1088 ~~paragraph commits a felony of the third degree, punishable as~~
1089 ~~provided in s. 775.082, s. 775.083, or s. 775.084. This~~
1090 ~~paragraph does not apply to:~~

1091 1. ~~A practitioner who dispenses medication to a workers'~~
1092 ~~compensation patient pursuant to chapter 440.~~

1093 2. ~~A practitioner who dispenses medication to an insured~~
1094 ~~patient who pays by cash, check, or credit card to cover any~~
1095 ~~applicable copayment or deductible.~~

1096 3. ~~The dispensing of complimentary packages of medicinal~~
1097 ~~drugs to the practitioner's own patients in the regular course~~
1098 ~~of her or his practice without the payment of a fee or~~
1099 ~~remuneration of any kind, whether direct or indirect, as~~
1100 ~~provided in subsection (5).~~

1101 Section 10. Section 893.055, Florida Statutes, is amended
1102 to read:

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1103 893.055 Prescription drug monitoring program.—

1104 (1) As used in this section, the term:

1105 (a) "Patient advisory report" or "advisory report" means

1106 information provided by the department in writing, via

1107 electronic delivery, or as determined by the department, to a

1108 controlled-substance medical clinic and its employed physicians,

1109 an advanced registered nurse practitioner, a physician

1110 assistant, a prescriber, dispenser, pharmacy, or a patient

1111 concerning the dispensing of controlled substances. A

1112 controlled-substance medical clinic and its employed physicians,

1113 an advanced registered nurse practitioner, a physician

1114 assistant, or a pharmacy shall review each patient advisory

1115 report before any controlled substance is dispensed to a

1116 patient. All advisory reports are for informational purposes

1117 only and impose no obligations of any nature or any legal duty

1118 on a prescriber, dispenser, pharmacy, or patient. The patient

1119 advisory report shall be provided in accordance with s.

1120 893.13(7)(a)8. The advisory reports issued by the department are

1121 not subject to discovery or introduction into evidence in any

1122 civil or administrative action against a prescriber, dispenser,

1123 pharmacy, or patient arising out of matters that are the subject

1124 of the report; and a person who participates in preparing,

1125 reviewing, issuing, or any other activity related to an advisory

1126 report may not be permitted or required to testify in any such

1127 civil action as to any findings, recommendations, evaluations,

1128 opinions, or other actions taken in connection with preparing,

1129 reviewing, or issuing such a report.

1130 (b) "Controlled substance" means a controlled substance

1131 listed in Schedule II, Schedule III, or Schedule IV in s.

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1132 893.03.

1133 (c) "Controlled-substance medical clinic" means a facility
1134 that employs a physician or osteopathic physician who prescribes
1135 on any given day more than 25 prescriptions of Schedule II or
1136 Schedule III controlled substance medications, or a combination
1137 thereof, or employs a physician or an osteopathic physician who
1138 is engaged in dispensing controlled substance medications.

1139 (d)~~(e)~~ "Dispenser" means a pharmacy, dispensing pharmacist,
1140 or dispensing health care practitioner.

1141 (e)~~(d)~~ "Health care practitioner" or "practitioner" means
1142 any practitioner who is subject to licensure or regulation by
1143 the department under chapter 458, chapter 459, chapter 461,
1144 chapter 462, chapter 464, chapter 465, or chapter 466.

1145 (f)~~(e)~~ "Health care regulatory board" means any board for a
1146 practitioner or health care practitioner who is licensed or
1147 regulated by the department.

1148 (g)~~(f)~~ "Pharmacy" means any pharmacy that is subject to
1149 licensure or regulation by the department under chapter 465 and
1150 that dispenses or delivers a controlled substance to an
1151 individual or address in this state.

1152 (h)~~(g)~~ "Prescriber" means a prescribing physician,
1153 prescribing practitioner, or other prescribing health care
1154 practitioner.

1155 (i)~~(h)~~ "Active investigation" means an investigation that
1156 is being conducted with a reasonable, good faith belief that it
1157 could lead to the filing of administrative, civil, or criminal
1158 proceedings, or that is ongoing and continuing and for which
1159 there is a reasonable, good faith anticipation of securing an
1160 arrest or prosecution in the foreseeable future.

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1161 (j)~~(i)~~ "Law enforcement agency" means the Department of Law
1162 Enforcement, a Florida sheriff's department, a Florida police
1163 department, or a law enforcement agency of the Federal
1164 Government which enforces the laws of this state or the United
1165 States relating to controlled substances, and which its agents
1166 and officers are empowered by law to conduct criminal
1167 investigations and make arrests.

1168 (k)~~(j)~~ "Program manager" means an employee of or a person
1169 contracted by the Department of Health who is designated to
1170 ensure the integrity of the prescription drug monitoring program
1171 in accordance with the requirements established in paragraphs
1172 (2) (a) and (b).

1173 (2) (a) By December 1, 2012 ~~2010~~, the department shall
1174 design and establish a comprehensive electronic database system
1175 that has controlled substance prescriptions provided to it and
1176 that provides prescription information to a patient's health
1177 care practitioner and pharmacist who inform the department that
1178 they wish the patient advisory report provided to them.
1179 Otherwise, the patient advisory report will not be sent to the
1180 practitioner, pharmacy, or pharmacist. The system shall be
1181 designed to provide information regarding dispensed
1182 prescriptions of controlled substances and shall not infringe
1183 upon the legitimate prescribing or dispensing of a controlled
1184 substance by a prescriber or dispenser acting in good faith and
1185 in the course of professional practice. The dispenser and the
1186 practitioners employed at or practicing at a controlled-
1187 substance medical clinic shall review the comprehensive
1188 electronic database system before prescribing or dispensing any
1189 controlled substances to a patient. If the dispenser identifies

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1190 or has any issues or concerns regarding the dispensing of the
1191 controlled substance medications, the dispenser shall
1192 immediately contact the prescriber before dispensing the
1193 controlled substance medication. The system shall be consistent
1194 with standards of the American Society for Automation in
1195 Pharmacy (ASAP). The electronic system shall also comply with
1196 the Health Insurance Portability and Accountability Act (HIPAA)
1197 as it pertains to protected health information (PHI), electronic
1198 protected health information (EPHI), and all other relevant
1199 state and federal privacy and security laws and regulations. The
1200 department shall establish policies and procedures as
1201 appropriate regarding the reporting, accessing the database,
1202 evaluation, management, development, implementation, operation,
1203 storage, and security of information within the system. The
1204 reporting of prescribed controlled substances shall include a
1205 dispensing transaction with a dispenser pursuant to chapter 465
1206 or through a dispensing transaction to an individual or address
1207 in this state with a pharmacy that is not located in this state
1208 but that is otherwise subject to the jurisdiction of this state
1209 as to that dispensing transaction. The reporting of patient
1210 advisory reports refers only to reports to patients, pharmacies,
1211 and practitioners. Separate reports that contain patient
1212 prescription history information and that are not patient
1213 advisory reports are provided to persons and entities as
1214 authorized in paragraphs (7) (b) and (c) and s. 893.0551.

1215 (b) The department, ~~when the direct support organization~~
1216 ~~receives at least \$20,000 in nonstate moneys or the state~~
1217 ~~receives at least \$20,000 in federal grants for the prescription~~
1218 ~~drug monitoring program, and in consultation with the Office of~~

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1219 ~~Drug Control~~, shall adopt rules as necessary concerning the
1220 reporting, accessing the database, evaluation, management,
1221 development, implementation, operation, security, and storage of
1222 information within the system, including rules for when patient
1223 advisory reports are provided to pharmacies and prescribers, if:

1224 1. The direct-support organization receives at least
1225 \$20,000 in nonstate moneys for the prescription drug monitoring
1226 program;

1227 2. The state receives at least \$20,000 in federal grants
1228 for the prescription drug monitoring program; or

1229 3. The department collects at least \$20,000 through
1230 registration fees required by the state to dispense controlled
1231 substances.

1232
1233 The patient advisory report shall be provided in accordance with
1234 s. 893.13(7)(a)8. The department shall work with the
1235 professional health care licensure boards, such as the Board of
1236 Medicine, the Board of Osteopathic Medicine, and the Board of
1237 Pharmacy; other appropriate organizations, such as the Florida
1238 Pharmacy Association, ~~the Office of Drug Control~~, the Florida
1239 Medical Association, the Florida Retail Federation, and the
1240 Florida Osteopathic Medical Association, including those
1241 relating to pain management; and the Attorney General, the
1242 Department of Law Enforcement, and the Agency for Health Care
1243 Administration to develop rules appropriate for the prescription
1244 drug monitoring program.

1245 (c) All dispensers and prescribers subject to these
1246 reporting requirements shall be notified by the department of
1247 the implementation date for such reporting requirements.

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1248 (d) The program manager shall work with professional health
1249 care licensure boards and the stakeholders listed in paragraph
1250 (b) to develop rules appropriate for identifying indicators of
1251 controlled substance abuse and diversion.

1252 (3) The pharmacy dispensing the controlled substance and
1253 each prescriber who directly dispenses a controlled substance
1254 shall submit to the electronic system, by a procedure and in a
1255 format established by the department and consistent with an
1256 ASAP-approved format, the following information for inclusion in
1257 the database:

1258 (a) The name of the prescribing practitioner, the
1259 practitioner's federal Drug Enforcement Administration
1260 registration number, the practitioner's National Provider
1261 Identification (NPI) or other appropriate identifier, and the
1262 date of the prescription.

1263 (b) The date the prescription was filled and the method of
1264 payment, such as cash by an individual, insurance coverage
1265 through a third party, or Medicaid payment. This paragraph does
1266 not authorize the department to include individual credit card
1267 numbers or other account numbers in the database.

1268 (c) The full name, address, and date of birth of the person
1269 for whom the prescription was written.

1270 (d) The name, national drug code, quantity, and strength of
1271 the controlled substance dispensed.

1272 (e) The full name, federal Drug Enforcement Administration
1273 registration number, and address of the pharmacy or other
1274 location from which the controlled substance was dispensed. If
1275 the controlled substance was dispensed by a practitioner other
1276 than a pharmacist, the practitioner's full name, federal Drug

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1277 Enforcement Administration registration number, and address.

1278 (f) The name of the pharmacy or practitioner, other than a
1279 pharmacist, dispensing the controlled substance and the
1280 practitioner's National Provider Identification (NPI).

1281 (g) Other appropriate identifying information as determined
1282 by department rule.

1283 (4) Each time a controlled substance is dispensed to an
1284 individual, the controlled substance shall be reported to the
1285 department through the system ~~as soon thereafter as possible,~~
1286 but not more than 24 hours ~~15 days~~ after ~~the date~~ the controlled
1287 substance is dispensed ~~unless an extension is approved by the~~
1288 ~~department for cause as determined by rule.~~ A dispenser must
1289 meet the reporting requirements of this section by providing the
1290 required information concerning each controlled substance that
1291 it dispensed in a department-approved, secure methodology and
1292 format. Such approved formats may include, but are not limited
1293 to, submission via the Internet, on a disc, or by use of regular
1294 mail.

1295 (5) When the following acts of dispensing or administering
1296 occur, the following are exempt from reporting under this
1297 section for that specific act of dispensing or administration:

1298 (a) A health care practitioner when administering a
1299 controlled substance directly to a patient if the amount of the
1300 controlled substance is adequate to treat the patient during
1301 that particular treatment session.

1302 (b) A pharmacist or health care practitioner when
1303 administering a controlled substance to a patient or resident
1304 receiving care as a patient at a hospital, nursing home,
1305 ambulatory surgical center, hospice, or intermediate care

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1306 facility for the developmentally disabled which is licensed in
1307 this state.

1308 (c) A practitioner when administering or dispensing a
1309 controlled substance in the health care system of the Department
1310 of Corrections.

1311 (d) A practitioner when administering a controlled
1312 substance in the emergency room of a licensed hospital.

1313 (e) A health care practitioner when administering or
1314 dispensing a controlled substance to a person under the age of
1315 16.

1316 (f) A pharmacist or a dispensing practitioner when
1317 dispensing a one-time, 72-hour emergency resupply of a
1318 controlled substance to a patient.

1319 (6) The department may establish when to suspend and when
1320 to resume reporting information during a state-declared or
1321 nationally declared disaster.

1322 (7) (a) A practitioner or pharmacist who dispenses a
1323 controlled substance must submit the information required by
1324 this section in an electronic or other method in an ASAP format
1325 approved by rule of the department unless otherwise provided in
1326 this section. The cost to the dispenser in submitting the
1327 information required by this section may not be material or
1328 extraordinary. Costs not considered to be material or
1329 extraordinary include, but are not limited to, regular postage,
1330 electronic media, regular electronic mail, and facsimile
1331 charges.

1332 (b) A pharmacy, prescriber, or dispenser shall have access
1333 to information in the prescription drug monitoring program's
1334 database which relates to a patient of that pharmacy,

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1335 prescriber, or dispenser in a manner established by the
1336 department as needed for the purpose of reviewing the patient's
1337 controlled substance prescription history. Other access to the
1338 program's database shall be limited to the program's manager and
1339 to the designated program and support staff, who may act only at
1340 the direction of the program manager or, in the absence of the
1341 program manager, as authorized. Access by the program manager or
1342 such designated staff is for prescription drug program
1343 management only or for management of the program's database and
1344 its system in support of the requirements of this section and in
1345 furtherance of the prescription drug monitoring program.
1346 Confidential and exempt information in the database shall be
1347 released only as provided in paragraph (c) and s. 893.0551.

1348 (c) The following entities shall not be allowed direct
1349 access to information in the prescription drug monitoring
1350 program database but may request from the program manager and,
1351 when authorized by the program manager, the program manager's
1352 program and support staff, information that is confidential and
1353 exempt under s. 893.0551. Prior to release, the request shall be
1354 verified as authentic and authorized with the requesting
1355 organization by the program manager, the program manager's
1356 program and support staff, or as determined in rules by the
1357 department as being authentic and as having been authorized by
1358 the requesting entity:

1359 1. The department or its relevant health care regulatory
1360 boards responsible for the licensure, regulation, or discipline
1361 of practitioners, pharmacists, or other persons who are
1362 authorized to prescribe, administer, or dispense controlled
1363 substances and who are involved in a specific controlled

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1364 substance investigation involving a designated person for one or
1365 more prescribed controlled substances.

1366 2. The Attorney General for Medicaid fraud cases involving
1367 prescribed controlled substances.

1368 3. A law enforcement agency upon determination that
1369 probable cause exists that a crime is being committed and
1370 issuance of a search warrant regarding the ~~during active~~
1371 ~~investigations regarding~~ potential criminal activity, fraud, or
1372 theft regarding prescribed controlled substances.

1373 4. A patient or the legal guardian or designated health
1374 care surrogate of an incapacitated patient as described in s.
1375 893.0551 who, for the purpose of verifying the accuracy of the
1376 database information, submits a written and notarized request
1377 that includes the patient's full name, address, and date of
1378 birth, and includes the same information if the legal guardian
1379 or health care surrogate submits the request. The request shall
1380 be validated by the department to verify the identity of the
1381 patient and the legal guardian or health care surrogate, if the
1382 patient's legal guardian or health care surrogate is the
1383 requestor. Such verification is also required for any request to
1384 change a patient's prescription history or other information
1385 related to his or her information in the electronic database.

1386
1387 Information in the database for the electronic prescription drug
1388 monitoring system is not discoverable or admissible in any civil
1389 or administrative action, except in an investigation and
1390 disciplinary proceeding by the department or the appropriate
1391 regulatory board.

1392 (d) The following entities shall not be allowed direct

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1393 access to information in the prescription drug monitoring
1394 program database but may request from the program manager and,
1395 when authorized by the program manager, the program manager's
1396 program and support staff, information that contains no
1397 identifying information of any patient, physician, health care
1398 practitioner, prescriber, or dispenser and that is not
1399 confidential and exempt:

1400 1. Department staff for the purpose of calculating
1401 performance measures pursuant to subsection (8).

1402 2. The Program Implementation and Oversight Task Force for
1403 its reporting to the Governor, the President of the Senate, and
1404 the Speaker of the House of Representatives regarding the
1405 prescription drug monitoring program. This subparagraph expires
1406 July 1, 2012.

1407 (e) All transmissions of data required by this section must
1408 comply with relevant state and federal privacy and security laws
1409 and regulations. However, any authorized agency or person under
1410 s. 893.0551 receiving such information as allowed by s. 893.0551
1411 may maintain the information received for up to 24 months before
1412 purging it from his or her records or maintain it for longer
1413 than 24 months if the information is pertinent to ongoing health
1414 care or an active law enforcement investigation or prosecution.

1415 (f) The program manager, upon determining a pattern
1416 consistent with the rules established under paragraph (2)(d) and
1417 having cause to believe a violation of s. 893.13(7)(a)8.,
1418 (8)(a), or (8)(b) has occurred, may provide relevant information
1419 to the applicable law enforcement agency.

1420 (8) To assist in fulfilling program responsibilities,
1421 performance measures shall be reported annually to the Governor,

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1422 the President of the Senate, and the Speaker of the House of
1423 Representatives by the department each December 1, beginning in
1424 2011. Data that does not contain patient, physician, health care
1425 practitioner, prescriber, or dispenser identifying information
1426 may be requested during the year by department employees so that
1427 the department may undertake public health care and safety
1428 initiatives that take advantage of observed trends. Performance
1429 measures may include, but are not limited to, efforts to achieve
1430 the following outcomes:

1431 (a) Reduction of the rate of inappropriate use of
1432 prescription drugs through department education and safety
1433 efforts.

1434 (b) Reduction of the quantity of pharmaceutical controlled
1435 substances obtained by individuals attempting to engage in fraud
1436 and deceit.

1437 (c) Increased coordination among partners participating in
1438 the prescription drug monitoring program.

1439 (d) Involvement of stakeholders in achieving improved
1440 patient health care and safety and reduction of prescription
1441 drug abuse and prescription drug diversion.

1442 (9) Any person who willfully and knowingly fails to report
1443 the dispensing of a controlled substance as required by this
1444 section commits a misdemeanor of the first degree, punishable as
1445 provided in s. 775.082 or s. 775.083.

1446 (10) All costs incurred by the department in administering
1447 the prescription drug monitoring program shall be funded through
1448 federal grants, registration fees for controlled-substance
1449 medical clinics, or private funding applied for or received by
1450 the state. The department may not commit funds for the

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1451 monitoring program without ensuring funding is available. The
1452 prescription drug monitoring program and the implementation
1453 thereof are contingent upon receipt of the ~~nonstate~~ funding
1454 provided in this subsection. The department and state government
1455 shall cooperate with the direct-support organization established
1456 pursuant to subsection (11) in seeking federal grant funds,
1457 other nonstate grant funds, gifts, donations, or other private
1458 moneys for the department so long as the costs of doing so are
1459 not considered material. Nonmaterial costs for this purpose
1460 include, but are not limited to, the costs of mailing and
1461 personnel assigned to research or apply for a grant.
1462 Notwithstanding the exemptions to competitive-solicitation
1463 requirements under s. 287.057(3)(f), the department shall comply
1464 with the competitive-solicitation requirements under s. 287.057
1465 for the procurement of any goods or services required by this
1466 section.

1467 (11) ~~The Office of Drug Control, in coordination with the~~
1468 ~~department,~~ may establish a direct-support organization that has
1469 a board consisting of at least five members to provide
1470 assistance, funding, and promotional support for the activities
1471 authorized for the prescription drug monitoring program.

1472 (a) As used in this subsection, the term "direct-support
1473 organization" means an organization that is:

1474 1. A Florida corporation not for profit incorporated under
1475 chapter 617, exempted from filing fees, and approved by the
1476 Department of State.

1477 2. Organized and operated to conduct programs and
1478 activities; raise funds; request and receive grants, gifts, and
1479 bequests of money; acquire, receive, hold, and invest, in its

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1480 own name, securities, funds, objects of value, or other
1481 property, either real or personal; and make expenditures or
1482 provide funding to or for the direct or indirect benefit of the
1483 department in the furtherance of the prescription drug
1484 monitoring program.

1485 (b) The direct-support organization is not considered a
1486 lobbying firm within the meaning of s. 11.045.

1487 (c) The State Surgeon General ~~director of the Office of~~
1488 ~~Drug Control~~ shall appoint a board of directors for the direct-
1489 support organization. The State Surgeon General ~~director~~ may
1490 designate ~~employees of the Office of Drug Control~~, state
1491 employees other than state employees from the department, and
1492 any other nonstate employees as appropriate, to serve on the
1493 board. ~~Members of the board shall serve at the pleasure of the~~
1494 ~~director of the Office of Drug Control~~. The State Surgeon
1495 General ~~director~~ shall provide guidance to members of the board
1496 to ensure that moneys received by the direct-support
1497 organization are not received from inappropriate sources.
1498 Inappropriate sources include, but are not limited to, donors,
1499 grantors, persons, or organizations that may monetarily or
1500 substantively benefit from the purchase of goods or services by
1501 the department in furtherance of the prescription drug
1502 monitoring program.

1503 (d) The direct-support organization shall operate under
1504 written contract with the department ~~Office of Drug Control~~. The
1505 contract must, at a minimum, provide for:

1506 1. Approval of the articles of incorporation and bylaws of
1507 the direct-support organization by the department ~~Office of Drug~~
1508 ~~Control~~.

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1509 2. Submission of an annual budget for the approval of the
1510 department ~~Office of Drug Control~~.

1511 3. Certification by the Office of Drug Control in
1512 consultation with the department that the direct-support
1513 organization is complying with the terms of the contract in a
1514 manner consistent with and in furtherance of the goals and
1515 purposes of the prescription drug monitoring program and in the
1516 best interests of the state. Such certification must be made
1517 annually and reported in the official minutes of a meeting of
1518 the direct-support organization.

1519 4. The reversion, without penalty, ~~to the Office of Drug~~
1520 ~~Control, or to the state if the Office of Drug Control ceases to~~
1521 ~~exist,~~ of all moneys and property held in trust by the direct-
1522 support organization for the benefit of the prescription drug
1523 monitoring program if the direct-support organization ceases to
1524 exist or if the contract is terminated.

1525 5. The fiscal year of the direct-support organization,
1526 which must begin July 1 of each year and end June 30 of the
1527 following year.

1528 6. The disclosure of the material provisions of the
1529 contract to donors of gifts, contributions, or bequests,
1530 including such disclosure on all promotional and fundraising
1531 publications, and an explanation to such donors of the
1532 distinction between the department ~~Office of Drug Control~~ and
1533 the direct-support organization.

1534 7. The direct-support organization's collecting, expending,
1535 and providing of funds to the department for the development,
1536 implementation, and operation of the prescription drug
1537 monitoring program as described in this section and s. 2,

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1538 chapter 2009-198, Laws of Florida, as long as the task force is
1539 authorized. The direct-support organization may collect and
1540 expend funds to be used for the functions of the direct-support
1541 organization's board of directors, as necessary and approved by
1542 the State Surgeon General ~~director of the Office of Drug~~
1543 ~~Control~~. In addition, the direct-support organization may
1544 collect and provide funding to the department in furtherance of
1545 the prescription drug monitoring program by:

1546 a. Establishing and administering the prescription drug
1547 monitoring program's electronic database, including hardware and
1548 software.

1549 b. Conducting studies on the efficiency and effectiveness
1550 of the program to include feasibility studies as described in
1551 subsection (13).

1552 c. Providing funds for future enhancements of the program
1553 within the intent of this section.

1554 d. Providing user training of the prescription drug
1555 monitoring program, including distribution of materials to
1556 promote public awareness and education and conducting workshops
1557 or other meetings, for health care practitioners, pharmacists,
1558 and others as appropriate.

1559 e. Providing funds for travel expenses.

1560 f. Providing funds for administrative costs, including
1561 personnel, audits, facilities, and equipment.

1562 g. Fulfilling all other requirements necessary to implement
1563 and operate the program as outlined in this section.

1564 (e) The activities of the direct-support organization must
1565 be consistent with the goals and mission of the department
1566 ~~Office of Drug Control, as determined by the office in~~

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1567 ~~consultation with the department,~~ and in the best interests of
1568 the state. The direct-support organization must obtain a written
1569 approval from the director of the Office of Drug Control for any
1570 activities in support of the prescription drug monitoring
1571 program before undertaking those activities.

1572 (f) ~~The Office of Drug Control, in consultation with the~~
1573 ~~department,~~ may permit, without charge, appropriate use of
1574 administrative services, property, and facilities of the ~~Office~~
1575 ~~of Drug Control and the~~ department by the direct-support
1576 organization, subject to this section. The use must be directly
1577 in keeping with the approved purposes of the direct-support
1578 organization and may not be made at times or places that would
1579 unreasonably interfere with opportunities for the public to use
1580 such facilities for established purposes. Any moneys received
1581 from rentals of facilities and properties managed by the ~~Office~~
1582 ~~of Drug Control and the~~ department may be held ~~by the Office of~~
1583 ~~Drug Control or~~ in a separate depository account in the name of
1584 the direct-support organization ~~and subject to the provisions of~~
1585 ~~the letter of agreement with the Office of Drug Control. The~~
1586 ~~letter of agreement must provide that any funds held in the~~
1587 ~~separate depository account in the name of the direct support~~
1588 ~~organization must revert to the Office of Drug Control if the~~
1589 ~~direct support organization is no longer approved by the Office~~
1590 ~~of Drug Control to operate in the best interests of the state.~~

1591 (g) ~~The Office of Drug Control, in consultation with the~~
1592 ~~department,~~ may adopt rules under s. 120.54 to govern the use of
1593 administrative services, property, or facilities of the
1594 department or office by the direct-support organization.

1595 (g) ~~(h)~~ The department ~~Office of Drug Control~~ may not permit

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1596 the use of any administrative services, property, or facilities
1597 of the state by a direct-support organization if that
1598 organization does not provide equal membership and employment
1599 opportunities to all persons regardless of race, color,
1600 religion, gender, age, or national origin.

1601 (h) ~~(i)~~ The direct-support organization shall provide for an
1602 independent annual financial audit in accordance with s.
1603 215.981. Copies of the audit shall be provided to the Office of
1604 Drug Control and the Office of Policy and Budget in the
1605 Executive Office of the Governor.

1606 (i) ~~(j)~~ The direct-support organization may not exercise any
1607 power under s. 617.0302(12) or (16).

1608 (12) A prescriber or dispenser may have access to the
1609 information under this section which relates to a patient of
1610 that prescriber or dispenser as needed for the purpose of
1611 reviewing the patient's controlled drug prescription history. A
1612 prescriber or dispenser acting in good faith is immune from any
1613 civil, criminal, or administrative liability that might
1614 otherwise be incurred or imposed for receiving or using
1615 information from the prescription drug monitoring program. This
1616 subsection does not create a private cause of action, and a
1617 person may not recover damages against a prescriber or dispenser
1618 authorized to access information under this subsection for
1619 accessing or failing to access such information.

1620 (13) To the extent that funding is provided for such
1621 purpose through federal or private grants or gifts and other
1622 types of available moneys, the department, ~~in collaboration with~~
1623 ~~the Office of Drug Control,~~ shall study the feasibility of
1624 enhancing the prescription drug monitoring program for the

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1625 purposes of public health initiatives and statistical reporting
1626 that respects the privacy of the patient, the prescriber, and
1627 the dispenser. Such a study shall be conducted in order to
1628 further improve the quality of health care services and safety
1629 by improving the prescribing and dispensing practices for
1630 prescription drugs, taking advantage of advances in technology,
1631 reducing duplicative prescriptions and the overprescribing of
1632 prescription drugs, and reducing drug abuse. The requirements of
1633 the National All Schedules Prescription Electronic Reporting
1634 (NASPER) Act are authorized in order to apply for federal NASPER
1635 funding. In addition, the direct-support organization shall
1636 provide funding for the department, ~~in collaboration with the~~
1637 ~~Office of Drug Control,~~ to conduct training for health care
1638 practitioners and other appropriate persons in using the
1639 monitoring program to support the program enhancements.

1640 (14) A pharmacist, pharmacy, or dispensing health care
1641 practitioner or his or her agent, before releasing a controlled
1642 substance to any person not known to such dispenser, shall
1643 require the person purchasing, receiving, or otherwise acquiring
1644 the controlled substance to present valid photographic
1645 identification or other verification of his or her identity to
1646 the dispenser. If the person does not have proper
1647 identification, the dispenser may verify the validity of the
1648 prescription and the identity of the patient with the prescriber
1649 or his or her authorized agent. Verification of health plan
1650 eligibility through a real-time inquiry or adjudication system
1651 will be considered to be proper identification. This subsection
1652 does not apply in an institutional setting or to a long-term
1653 care facility, including, but not limited to, an assisted living

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1654 facility or a hospital to which patients are admitted. As used
1655 in this subsection, the term "proper identification" means an
1656 identification that is issued by a state or the Federal
1657 Government containing the person's photograph, printed name, and
1658 signature or a document considered acceptable under 8 C.F.R. s.
1659 274a.2(b)(1)(v)(A) and (B).

1660 (15) The Agency for Health Care Administration shall
1661 continue the promotion of electronic prescribing by health care
1662 practitioners, health care facilities, and pharmacies under s.
1663 408.0611.

1664 (16) By December 1, 2011 ~~October 1, 2010~~, the department
1665 shall adopt rules pursuant to ss. 120.536(1) and 120.54 to
1666 administer the provisions of this section, which shall include
1667 as necessary the reporting, accessing, evaluation, management,
1668 development, implementation, operation, and storage of
1669 information within the monitoring program's system.

1670 Section 11. Subsection (4) of section 893.0551, Florida
1671 Statutes, is amended to read:

1672 893.0551 Public records exemption for the prescription drug
1673 monitoring program.—

1674 (4) The department shall disclose such confidential and
1675 exempt information to the applicable law enforcement agency in
1676 accordance with s. 893.055(7)(f). The law enforcement agency may
1677 disclose the confidential and exempt information received from
1678 the department to a criminal justice agency as defined in s.
1679 119.011 pursuant to a search warrant ~~as part of an active~~
1680 ~~investigation~~ that is specific to a violation of s.
1681 893.13(7)(a)8., s. 893.13(8)(a), or s. 893.13(8)(b).

1682 Section 12. This act shall take effect July 1, 2011.